



Stumped at the Supermarket

Making Sense of Nutrition Rating Systems

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Introduction

The Nutrition, Labeling and Education Act of 1990¹ (NLEA) requires U.S. food manufacturers to disclose certain nutritional information about their products via standardized package labels. Despite the efforts of Congress and the Food and Drug Administration (FDA) in enacting and implementing the NLEA, many American consumers are still stumped at the supermarket. Studies suggest that nutrition labels are confusing to many consumers and have not necessarily helped them to make healthier dietary choices.² While consumers often report that they use nutrition labels to guide their food purchasing decisions and dietary choices, research shows that actual use is less than reported and nutrition labels frequently leave consumers feeling confused.³ One fairly recent report found that Americans' use of nutrition labels is declining, particularly among those under age thirty.⁴ Moreover, since the enactment of the NLEA, obesity rates in the United States have risen to unprecedented highs.⁵ It seems apparent that the current nutrition labeling scheme, standing alone, does not provide sufficient guidance to encourage healthy dietary choices.6

Partly in response to the escalating obesity epidemic, food manufacturers and retailers have developed a number of nutrition rating systems in recent years. Aimed at simplifying consumers' food purchasing decisions, these rating systems assign a given food product a "better for you" symbol (e.g., a "healthy check") or a numerical score or graphic rating (e.g., a score of one to 100 or a number of stars). Nutrition rating systems were first developed by food manufacturers and placed directly on the front of product packages. More recently, food retailers have also developed their own graphic icons and symbolic rating systems, which are typically placed on grocery store shelves and display cases, near a product's price tag. Food manufacturers and retailers assert that these nutrition rating systems can help consumers to make healthier food selections by providing them with a convenient, point-of-purchase "snapshot" of the nutrition profile of a particular food product.

While their efficacy in promoting healthier dietary choices is unproven at this point due to their recent origins, there is no disputing the increasing popularity of nutrition rating systems among food manufacturers and retailers. There are presently more than a dozen different front-of-package labeling and grocery shelf rating systems in use in U.S. markets. From 2008 to 2009 alone, the number of nutrition rating systems in American grocery stores nearly doubled.

Nutrition rating systems present opportunities for educating consumers about nutrition and promoting changes in dietary practices, but their varied formats and differing underlying criteria also pose potential problems. Some critics argue that nutrition rating systems, which were intended to simplify consumers' purchasing decisions and make nutritional information easier to comprehend, have instead led to a confusing maze of competing nutrition claims. Where once consumers had to consult only the Nutrition Facts panel and the ingredients list, they are now faced with a cacophony of different labels, symbols, ratings, on-package health claims, in-store signs, and food advertisements. It is no wonder that consumers report feeling conflicted, even bewildered, by the variety of different nutrition messages they encounter at the grocery store. One cannot help but wonder, are these nutrition rating systems informing food purchasing

decisions for the better and promoting healthier diets, or are they only confusing consumers more about what foods to eat? Are they helping us shop smarter, or causing information overload?

This paper analyzes the future of nutrition rating systems by considering the following issues. First, the paper briefly outlines some of the major front-ofpackage labeling and grocery shelf rating systems that have been used or are presently in use in the American marketplace, as well as the nutrition labeling and rating systems considered or implemented in other countries. Then it examines in detail the approach of and criticisms raised against one domestic example: the Smart Choices Program, a self-regulatory front-of-package labeling system introduced and suspended in 2009. The demise of the Smart Choices Program is considered in light of some critics' claims that nutrition rating systems and point-of-purchase food labeling must be regulated by the federal government in order to prevent conflicts of interest. Second, the paper discusses the role of the FDA in overseeing food labeling and explores the agency's responsibilities for ensuring that the claims made by nutrition rating systems are not misleading and are compliant with federal statutes and regulations. Third, the paper considers whether the variety of different front-of-package labeling and grocery rating approaches poses the potential to confuse American consumers, rather than inform their food purchasing decisions. Are varied nutrition rating approaches beneficial because they promote industry innovation, encourage product reformulation, and expand the research base about what labeling approaches work best? Or should the FDA promulgate regulations to require a more consistent, standardized approach to rating the nutritional quality of foods? Fourth and finally, this paper concludes by making recommendations about additional research that is needed to gauge the efficacy of nutrition rating systems and their potential to improve Americans' diets.

Emergence of Nutrition Rating Systems in the United States (1995–2009)

The rationale underlying the development of nutrition rating systems, aside from their marketing potential, is the idea that most consumers have difficulty deciphering the information on nutrition labels. Several studies suggest that the majority of consumers find the information listed on the back or side panels of packaged foods (e.g., the Nutrition Facts panel) to be confusing.8 In particular, consumers have difficulty performing calculations, interpreting serving size information, and placing nutrition information about a given food product in the context of overall daily dietary intake. Further, studies have shown that food label use is negatively linked to time pressure. ¹⁰ The average American is grocery shopping in a hurry, and few consumers are able or inclined to take the time to compare nutrition labels and perform mathematical calculations in the supermarket aisle. Front-of-package labeling was developed to supplement the Nutrition Facts panel by creating simple graphic or symbolic icons that consumers could quickly consult to compare foods within product categories. Of course, nutrition rating systems were also developed as an industry marketing strategy to respond to growing consumer interest in healthful foods and to increase the visibility of FDA-permitted nutrient content and health claims in the packaging and overall marketing of their products.11

Health Organization Labels

American Heart Association - Heart Check

The first nutrition rating system unveiled in American supermarkets was not an industry-developed system, but rather, the American Heart Association's (AHA) Heart Check label, which debuted in 1995. The AHA's Heart Check label is given to foods that meet the FDA's criteria for nutrient content claims like "low fat" or "low sodium." AHA allows its checkmark to be used if a single serving of a product has up to three grams of total fat, one gram of saturated fat, half a gram of trans fat, 20 milligrams of cholesterol, or 480 milligrams of sodium. The Heart Check label does not take carbohydrates into account.

Although praised for being trendsetting, some critics have questioned the objectivity of the Heart Check label, noting that companies pay a fee to get their products endorsed and the revenue generated is used to fund the program's operating costs.¹³ Further, some nutritionists asserted that the AHA's rating system focused too narrowly on limiting fat and cholesterol, while permitting certification of products containing significant amounts of added sugar. 14 The Heart Check label, however, was originally aimed at reducing the risk of cardiovascular disease and identifying foods low in fat, saturated fat, cholesterol, and sodium, and not necessarily at preventing overweight and obesity and identifying low-calorie foods.¹⁵ Further, at the time of its development, there was not a firm scientific consensus on how much to limit added sugars. In August 2009, the AHA issued recommendations urging Americans to limit their intake of added sugars, in recognition of scientific studies demonstrating a link between excess sugar consumption and obesity, high blood pressure, high cholesterol, and other risk factors for heart disease and stroke. ¹⁶ These questions aside, some studies suggest the Heart Check label has been influential because consumers are more likely to trust front-of-package claims that are endorsed by third parties and health organizations, as opposed to food manufacturers.¹⁷





Beginning in roughly 2004, food manufacturers became invested in the practice of nutrition profiling. Before long, several new icon-based ratings began appearing on the front labels of packaged foods. PepsiCo, General Mills, Kraft, Unilever and Kellogg's emerged as the early leaders in the front-of-package labeling and nutrition ratings race.

PepsiCo - Smart Spot

PepsiCo became one of the first big food manufacturers to launch a front-ofpackage rating system with the release of its Smart Spot label in 2004. The Smart Spot label, bearing the slogan, "Smart Choices Made Easy," was placed on the front packages of over 250 products in PepsiCo's "better for you" product lines, including juices, breakfast cereals, granola bars, chips, pretzels, and other snack foods. 18 According to PepsiCo, Smart Spot-qualifying food and beverage products must meet certain nutrition criteria "based on authoritative statements from the Food and Drug Administration (FDA) and the National Academies of Sciences (NAS)."19 Specifically, the Smart Spot label can be placed on PepsiCo products that: (1) contain at least 10% of the recommended daily value of a "targeted nutrient" (i.e., protein, fiber, calcium, iron, vitamin A, vitamin C) while staying within certain limits for fat, saturated fat, trans fat, cholesterol, sodium, and added sugar; (2) are reduced in calories, fat, saturated fat, sodium, or sugar, or (3) "are formulated to have specific health or wellness benefits." 20 One criticism of the Smart Spot approach is that it permits labeling of a product based on select positive attributes achieved through fortification, while leaving problematic nutrition information to be ferreted out by consumers through a close review of the Nutrition Facts panel.

PepsiCo began replacing its proprietary Smart Spot label with the Smart Choices logo in August 2009. PepsiCo initially endorsed the Smart Choices Program, a pan-industry effort aimed at developing a standardized voluntary approach to front-of-package labeling. However, as explained later in this paper, the Smart Choices Program was abandoned by its participating food manufacturers in late fall 2009 in the wake of considerable negative publicity and calls for investigation into its nutritional criteria and funding mechanism. It now appears that PepsiCo will be proceeding cautiously in the area of front-of-package labeling, and perhaps deferring further investment until the Food and Drug Administration signals its intentions with respect to developing regulations to guide point-of-purchase food labeling.

General Mills - Goodness Corner & Nutrition Highlights

General Mills followed quickly behind PepsiCo with the launch of its Goodness Corner front-of-package logo in 2004. Described as an "easy-to-read icon-based system that communicates important product benefits on the package right up front," Goodness Corner icons were placed on a variety of General Mills' products, most notably, its breakfast cereals.²¹ The Goodness Corner system's criteria are based on FDA regulations governing nutrition labeling and nutrient

content and health claims.²² Goodness Corner icons consist of colored circles with arrow indicators (e.g., low fat and low cholesterol are depicted with downward facing arrows) and other symbols, as well as numerical











quantities (e.g., "14 grams = excellent source of protein").²³ The system consists of twenty six different color-coded symbols that convey particular attributes in fifteen different nutrient categories, such as fat, vitamins and minerals, fiber, whole grain, grams of sugar, and net carbs, among others.²⁴ Some nutritionists and consumer advocates criticized the over two dozen different icons used by the Goodness Corner system, asserting that a single, clear-cut logo would be easier for consumers to understand.²⁵

In 2007, as part of its pledge to the Council of Better Business Bureau's Children's Food and Beverage Advertising Initiative (CFBAI), General Mills announced that it would add Nutrition Highlights labels on the front panels of its cereal packages.²⁶ The Nutrition Highlights system was designed to distill the information on the Nutrition Facts panel and provide consumers with at a glance information about key nutrients. It lists the number of calories, grams of fat and sugar, milligrams of sodium, calcium and other key nutrients per serving, and indicates the percent daily value of nutrients per serving.²⁷ The Nutrition Highlights label was described as an "evolution" of the Goodness Corner logos that had been appearing on General Mills' product packages for three years, 28 but it was likely also an attempt to move beyond and distance itself from the criticisms of Goodness Corner. As part of its CFBAI pledge, General Mills also agreed that it would no longer advertise products containing more than twelve grams of sugar per serving to children under the age of twelve.²⁹ At the time, this pledge was notable because General Mills is by far the biggest spender on advertising of packaged foods to children.³⁰ In particular, General Mills has been criticized for over-promoting the addition of whole grains to its cereal lines, while downplaying or ignoring the fact that many of its cereal products remain high in added sugar and are aggressively marketed to children.³¹

Kraft - Sensible Solution

Kraft Foods launched its Sensible Solution front-of-package label in 2005. Kraft applies the Sensible Solution symbol to its products if they meet one of two standards. A product must either: (1) provide beneficial nutrients (e.g., calcium or whole grains) at meaningful levels or deliver a functional or health benefit (e.g., heart health), while remaining within set limits on calories, fat, sodium, and sugar; or (2) meet certain specifications that vary by product type (e.g., cheese/dairy, crackers/snacks, salad dressings, etc.) for reduced calories, fat, sodium, or sugar. ³² As with PepsiCo's Smart Spot, one of the criticisms of Kraft's Sensible Solution label is that its underlying nutritional criteria are of questionable objectivity because it is fundamentally a proprietary marketing technique.

Kraft Foods Global began replacing its Sensible Solution label with the Smart Choices logo in late August 2009.³³ However, like several other major food manufacturers, Kraft discontinued using Smart Choices in late fall 2009 in the wake of sharp criticism levied against the program's nutritional criteria, funding mechanism, and potential conflicts of interest.³⁴ As of early 2010, it is unclear whether Kraft Foods will resume using Sensible Solution labels or wait until the FDA provides more guidance with respect to point-of-purchase labeling. Kraft Foods has merely said that until the Smart Choices Program resumes active operations, the company will be transitioning out of using the Smart Choices logo.³⁵







Unilever - Choices

In May 2006, Unilever launched the Choices Programme, a front-of-package logo designed to help consumers identify healthier foods and beverages within Unilever's portfolio. First implemented in the Netherlands, the original goal was to roll out the Choices Programme in all countries where Unilever markets its products over an eighteen-month period.³⁶ To guide the use of Choices labels, Unilever developed a Nutrition Enhancement Programme (NEP) that established nutritional benchmarks aimed at limiting sodium, sugars, trans fats, and saturated fats.³⁷

The Choices Programme was based on international dietary guidelines³⁸ and involved a pan-European effort. In the Netherlands, Unilever participated in a government-supported coalition comprised of food and beverage manufacturers and major retailers.³⁹ According to Unilever, it shared its NEP methodology and resulting benchmarks with various nutrition experts and expressed a willingness to share the Choices Programme with other parties with the goal of establishing more consistency in front-of-package labeling approaches.⁴⁰ In this way, Unilever may have set the stage for the collaborative development of Smart Choices in the U.S.

Unilever adopted the Smart Choices Program and began phasing out its proprietary Choices labeling system in 2009. However, like the other major food manufacturers behind Smart Choices, it withdrew its support for the program in late fall 2009. It now appears that Unilever may continue using Choices labels in European markets, but will await the FDA's direction with respect to front-of-package labeling of its products in the United States. ⁴²

Kellogg's - Nutrition at a Glance





In October 2007, Kellogg's followed the nutrition ratings trend when it launched its Nutrition at a Glance front-of-package label. Based on the European Guideline Daily Amounts (GDA) system, which is described in more detail later, Nutrition at a Glance labels are designed to distill the

information on the back of food packages into a simpler, more visual format. According to Kellogg's, its GDA approach is an easier way to convey the daily value percentages on the Nutrition Facts panel, which are reference amounts of nutrients based on the federal government's recommendations for a healthy diet. 43 Nutrition at a Glance labels display the total amount per serving of a key nutrient – calories, total fat, sodium, and sugar – along with a percentage indicating the extent to which consuming a serving of the product will satisfy the recommended daily value for the given nutrient.⁴⁴ The only nutrient for which a percentage is not displayed is sugar because there is no established daily value for sugar under the GDA system, although the Institute of Medicine suggests that an individual's added sugar intake should not exceed 25% of one's total calories to ensure adequate micronutrient intakes, and the World Health Organization suggests that added sugar intake should not exceed 10% of one's total calories.45 In addition, Nutrition at a Glance labels can highlight up to two additional nutrients – fiber, calcium, magnesium, potassium, and vitamins A, C, and E – that have been identified by the National Health and Nutrition Examination Survey (NHANES) as nutrients which are under-consumed by most Americans.46

Kellogg's endorsed the Smart Choices Program and announced that it would begin replacing Nutrition at a Glance labels with the Smart Choices logo in August 2009. By late October 2009, however, Kellogg's had announced that it would discontinue using Smart Choices labels. Kellogg's said that it would begin phasing out product packaging bearing the Smart Choices logo as its inventories ran out, although it would continue to be associated with the program and Celeste Clark, the company's senior vice president of global nutrition, would remain on the program's board.⁴⁷

Food Retailers' Nutrition Scoring and Rating Systems (2006–2009)

For consumers who are trying to eat better, but are confounded by the sheer number of "healthy" symbols, "better for you" logos, and nutrition claims that food manufacturers are placing on their product packages, help may be on the way from food retailers. In an effort to help consumers sort through the multiplicity of competing, and potentially misleading, front-of-package labels on food products, some American food retailers began rolling out their own nutrition rating systems beginning in 2006.

Unlike manufacturers' labeling systems, most food retailers' rating systems are placed on grocery store shelves or display cases, near the price tag, rather than on the front label of the product package. Further, most retailers' nutrition rating systems are applied to a number of products within a given food category, thereby allowing product comparison across different brands. A chart comparing the various grocery rating systems discussed herein may be found at Appendix A.⁴⁸

Hannaford Brothers supermarket chain led the way beginning in 2006, but food retailers' shelf rating systems gained widespread visibility just this past year. Five new grocery rating programs were announced or implemented in 2009 alone.

Guiding Stars

East Coast-based Hannaford Brothers supermarket chain developed the first store-wide, retailer rating system with its Guiding Stars program, introduced in 2006. Guiding Stars was developed by a team of nutrition and medical experts from Dartmouth Medical School, Tufts University's Human Nutrition Research Center on Aging (HNRCA) Research Laboratory, and the University of North Carolina's School of Public Health, among others. 49 Guiding Stars uses a three-star rating system based on a proprietary formula of algorithms designed to assess a food's nutrient content. One star is considered "good," two stars is considered "better," and three stars is considered "best." A product is credited for containing vitamins, minerals, and/or whole grains, and is docked for containing saturated fat, trans fat, cholesterol, added sugars, and/or added sodium.⁵⁰ Nutrient content is evaluated per 100-calorie portions. Nutritional criteria is customized by food group, recognizing that animal products like meat, poultry, seafood, and dairy are naturally higher in saturated fat and cholesterol and low in fiber, and that nuts, for example, contain key vitamins and minerals but are higher in fat.⁵¹ The system does not rate bottled water, coffee or tea, because these products are not a significant source of nutrients. Guiding Stars places a fresh or packaged food product's star rating on the unit price tags on grocery store shelves, produce signs, and meat, poultry, and seafood case signs.



Guiding Stars has been used to evaluate roughly 60,000 different fresh and packaged food products for sale in Hannaford stores.⁵² Approximately 28% of the products evaluated to date earn at least one star, which means that over two-thirds of the products evaluated (primarily packaged foods), do not earn any stars.⁵³ Under Guiding Stars' nutritional criteria, all fresh produce earns the maximum three stars, and 51% of cereals, 41% of seafood, 22% of dairy, 21% of meat, 7% of canned soups, and 7% of bakery products earn at least one star.⁵⁴ Interestingly, many packaged food products bearing nutrient content claims do not earn any stars (typically those containing high amounts of sodium or added sugar), which might suggest that FDA-approved claims such as "low fat" or "good source of ..." can be misleading if they divert attention from the overall nutritional quality of a food product to the presence or absence of one or more individual elements. For example, many food products that are branded "low fat" have significant amounts of added sugar and are high in calories.⁵⁵

Although the program's efficacy has not been rigorously evaluated,⁵⁶ Hannaford Brothers reports that Guiding Stars has impacted customers' food purchasing decisions for the better. Since the program's launch in 2006, sales of food products bearing stars have outpaced sales of those without, in some cases by wide margins.⁵⁷ After analyzing a year's worth of sales data, Hannaford Brothers reported that sales of ground beef with starred labels increased 7%, while sales of ground beef without stars dropped by 5%. 58 Sales of chicken with star ratings rose 5%, while sales of chicken without stars declined by 3%.⁵⁹ Similarly, sales of whole milk (no stars) dropped by 4%, while skim milk sales (three stars) increased by 1%.60 The same sales trends were observed with frozen and packaged foods. Sales of frozen dinners with starred labels increased at 4.5 times the rate of frozen entrees without stars, and sales of breakfast cereals labeled with stars increased 3.5 times over that of cereals without stars.⁶¹ Moreover, a survey of Hannaford customers found that 81% were aware of the Guiding Stars program, half of those surveyed said they used it "fairly often," and customers generally gave it positive reviews and said it informed or simplified their grocery shopping decisions.⁶²

By October of 2008, the Guiding Stars shelf rating system had expanded to more than 1,400 stores including Hannaford Supermarkets, Bloom Supermarkets, and Food Lion and Sweetbay stores. Because of the program's success, Guiding Stars Licensing Company was formed in mid-2008 to create opportunities for food manufacturers, restaurants, convenience stores, hospitals, and schools to purchase and implement Guiding Stars. As of January 2009, Guiding Stars had partnered with the Maine Public School System to implement the first school-based nutrition rating system. Hannaford Brothers reportedly hopes to expand Guiding Stars to a national packaged food labeling system. Despite Hannaford Brothers' participation in the Keystone Food and Nutrition Roundtable discussions leading to the development of the Smart Choices Program, discussed *infra*, they opted to continue using and promoting Guiding Stars.



NuVal

In 2007, NuVal became the second grocery store-wide nutrition rating system to hit American markets. NuVal rates foods with a numeric score from one to 100 using a proprietary algorithm, the Overall Nutritional Quality Index (ONQI), developed by a team of fifteen leading nutrition, medical, and public health experts and led by Dr. David L. Katz, Director of the Yale-Griffin Prevention Research Center.⁶⁷ ONQI is a complex mathematical formula that crunches more than thirty different nutritional variables to arrive at a single numeric rating for a given food item.⁶⁸

The ONQI formula uses the Institute of Medicine's Dietary Reference Intakes (DRIs) and the U.S. Department of Health and Human Services and Department of Agriculture's Dietary Guidelines for Americans (DGAs) to quantify the presence of more than thirty nutrients, including vitamins, minerals, antioxidants, fiber, sugar, salt, trans fat, saturated fat, and cholesterol.⁶⁹ The formula also incorporates measures for the quality of protein, fat, and carbohydrates, as well as calories and omega-3 fatty acids.⁷⁰ ONQI awards points for nutrients generally considered to be favorable to health – including all the traditional vitamins and minerals, plus fiber, omega-3s, cartenoids, bioflavonoids, protein quality, fat quality, glycemic load, and energy density – and subtracts points for saturated fat, trans fat, sodium, sugar, and cholesterol.⁷¹ Essentially, the ONQI system divides a food's positive score by its negative score, irrespective of portion size, to arrive at a composite score of between one and 100.⁷²

NuVal's developers assert that it is the most objective and useful grocery rating system because it is based on expert dietary guidelines and aims to stratify foods on the basis of overall nutritional quality, both across all food categories and within food categories. In this way, it differs from Guiding Stars, for example, under which products in the same category receiving the same number of stars cannot be compared against one another. According to Dr. Katz, another notable difference with NuVal is that if a grocery store agrees to use the system, all foods sold in the store must be scored. Therefore, NuVal provides specific guidance for every food item in the grocery store, whereas most of the other grocery rating systems only score a percentage of the products in the store. Finally, proponents of NuVal assert that it is the most bias-free of the food rating systems, having been developed by an independent team of nutrition experts who have no ties to the food industry, and thus no vested interest in how a particular product scores.

So how do foods rate under NuVal?⁷⁶ Not surprisingly, most fresh produce scores high. Raw spinach, strawberries and oranges earn perfect scores of 100, while even iceberg lettuce earns an 82.⁷⁷ Many frozen vegetables score as well as their fresh counterparts; Birds Eye frozen chopped spinach and broccoli cuts earn top scores of 100.⁷⁸ Atlantic salmon is one of the high-scoring fishes at 87.⁷⁹ Post Shredded Wheat beats most big-name cereals at 91.⁸⁰ Kellogg's All-Bran Complete Wheat Flakes receives a rather low score of 31, presumably because sugar and high fructose corn syrup are prominent ingredients.⁸¹ Notably, the median score for all breakfast cereals rated by NuVal is a modest 25.⁸²

NuVal aims to eventually score all of the 60,000-plus food products for sale in a typical American grocery store. ⁸³ The system is currently in place at three major grocery chains: Hy-Vee (launched in January 2009), Price Chopper (January 2009), and Meijer (May 2009). NuVal is expected to expand into more grocery chains and stores over the next two years.





nutrition iQ

Nutrition iQ was developed by Supervalu, Inc. and Harvard Medical School's Joslin Diabetes Center. He system uses color-coded shelf tags to identify products that meet specific nutrient thresholds. If a food product qualifies for a nutrient content claim, as specified by FDA regulations, it is identified with a color-coded shelf tag(s). The appearance of a nutrition iQ shelf tag denotes whether a food product is an "excellent" or "good" source of fiber, calcium, or protein. Nutrition iQ also considers whether a product is low in sodium, calories, or saturated fat, and whether a product contains whole grains. For example, a low-calorie, high-fiber product would bear a shelf tag with a purple (low-calorie) stripe and a tag with an orange (fiber) stripe. For simplicity purposes, no food product is allowed to bear more than two color-coded tags. Certain foods, including those generally regarded to be of low nutritional value (e.g., soft drinks, sugar-sweetened juices, candy, and cookies) are not rated. Ultimately, Supervalu expects that about 10% of its stores' 60,000 grocery items will receive a nutrition iQ shelf tag. He system is a shelf tag. Supervalue and tag.

Nutrition iQ debuted in early 2009 at Albertson's stores on the West Coast and arrived in mid-July 2009 at Cub Foods stores across the Midwest (in Minnesota, Iowa, Wisconsin, and Illinois). ⁸⁹ It is expected to expand into other Supervalu stores, such as Acme, bigg's, Jewel-Osco, Lucky, Shaw's/Star Market, and Shop'n Save, by early 2010. ⁹⁰



Healthy Ideas

Healthy Ideas is yet another grocery rating system that was unveiled in January 2009.91 The system was developed by an advisory panel of physicians and nutritionists affiliated with Harvard Medical School. 92 Thus far, it has been implemented in Giant Foods and Stop & Shop stores. The Healthy Ideas stamp appears on packaged foods' shelf tags, plus on the front-of-package labels of some store brands. To earn a Healthy Ideas stamp, foods must be low in cholesterol, sodium, total fat, and saturated fat. 93 Qualifying foods must also contain at least 10% of the federal nutrition guidelines for one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein, or fiber.⁹⁴ Qualifying food products must also be trans fat-free and, depending on the product category, either contain no added sugar (e.g., nuts) or contain less than 35% sugar, as measured by weight (e.g., breakfast cereals). 95 All fresh produce automatically qualifies for the Healthy Ideas stamp. 6 Items of low nutritional value, such as candy, ice cream, cookies, cakes, jellies, jams, dips and spreads, are not evaluated.⁹⁷ Snack foods, such as pretzels, popcorn, crackers, and granola bars, are rated because they are considered to be important sources of grains. 98 To date, approximately 4,000 packaged food products have qualified for the Healthy Ideas shelf tag.99

While all of these manufacturer- and retailer-developed nutrition rating systems are aimed at helping consumers make better dietary choices, some nutrition experts and food industry commentators fear that their multiplicity may be defeating the purpose. ¹⁰⁰ In just a few short years, an array of different nutrition labeling and scoring approaches have emerged in U.S. food markets, all of which are based on differing nutritional criteria. In certain circumstances, the systems' differing criteria may result in divergent results. For instance, the same name brand food product may receive dissimilar shelf ratings from different food retailers, leading to different interpretations of the product's nutritional quality



depending on where a consumer shops. Similarly, comparable or equivalent food products may receive different front-of-package ratings from their respective manufacturers. Finally, the manufacturer's front-of-package label on a food product could conflict with the retailer's shelf rating. These three scenarios demonstrate how varying nutrition rating approaches can result in conflicting nutritional messages, and may actually end up confusing consumers more about what foods they should eat as part of a balanced diet, instead of simplifying their grocery purchasing decisions.

Development and Suspension of Smart Choices (2007–2009)

Recognizing the need to create some standards around front-of-package food labeling and grocery scoring programs, in 2007 various stakeholders agreed to discuss the competing approaches and the future of nutrition rating systems. Leading food manufacturers, food retailers, industry trade groups, nutrition experts, health organizations, and government observers came together through meetings organized by the Keystone Center, a nonprofit organization that works to achieve mediated consensus solutions to public health, environmental, and other public policy issues. Known as the Keystone Food and Nutrition Roundtable, these meetings spanned from 2007 to 2009 and resulted in the development of Smart Choices, a self-regulatory front-of-package nutrition labeling and scoring program. ¹⁰³

Under the Smart Choices initiative, some of the world's largest food and beverage companies, including Con Agra Foods, General Mills, Kellogg's, Kraft Foods, PepsiCo and Unilever, pledged to accept common nutritional standards and use the same "better for you" logo on their products. ¹⁰⁴ Qualifying products bore the Smart Choices checkmark logo on their front labels, which also included the amount of calories per serving and the number of servings in the package. ¹⁰⁵ Smart Choices labels began appearing in grocery stores in August of 2009. Participating companies were expected to eventually replace their proprietary front-of-package symbols (such as Kraft's Sensible Solution, General Mill's Nutrition Highlights, PepsiCo's Smart Spot, and Unilever's Choices) with the Smart Choices logo. The program aimed to have 1,000 different products bear the Smart Choices logo by the end of 2009, and more than 2,000 products labeled by July 31, 2010. ¹⁰⁶

Smart Choices promised to "cut through the clutter" of competing front-of-package labels, and thereby provide some degree of consistency for consumers. ¹⁰⁷ The program's website indicates that it was created to address the need for "a single, trusted, and reliable front-of-pack nutrition labeling program" that could guide consumers' food and beverage choices and help improve health outcomes. ¹⁰⁸

Despite an auspicious start, the financial backing of many of the largest food manufacturers, and the endorsement of some leading nutrition professionals, the Smart Choices Program was suspended roughly two months after the appearance of its labels in stores. As this paper later explains, by late October 2009, Smart Choices had ceased active operations in the wake of scathing criticism from some nutritionists, consumer advocates, and the media. The final straw was the FDA's announcement that it will be investigating nutrition rating systems to determine if they violate federal nutrition labeling laws and developing regulatory standards to guide future point-of-purchase labeling schemes. 110

What lessons are to be learned from the rise and fall of the Smart Choices Program? Was the Smart Choices approach uniquely flawed? Or does the program's demise raise larger questions about the future of industry self-regulation of food marketing? Some critics might argue that the Smart Choices controversy illustrates that industry involvement is always a fatal and inherent conflict of interest in any self-regulatory system, whether it involves front-of-package nutrition labeling or otherwise. Evaluating the food industry's various self-regulatory efforts is beyond the scope of this paper, but the Smart Choices example may provide one lens through which to analyze the efficacy and value of the industry's voluntary efforts to address the obesity epidemic.

The Smart Choices Approach

Did Smart Choices differ materially from its predecessor front-of-package labeling systems? The program's stated objective of achieving food industry and health/nutrition expert collaboration in front-of-package labeling, with the aim of reducing consumer confusion and ultimately improving dietary choices, was certainly a laudable goal. Proponents claimed that the Smart Choices Program would achieve several previously-unachieved goals in front-of-package labeling, including consensus, congruence with accepted nutrition guidelines, superior format, and transparency. From the outside, the Smart Choices process appeared to be collaborative, with perspectives being offered by the food industry, leading nutrition and health experts, consumer advocates, and observers from the federal government's food regulatory agencies. But many Keystone Roundtable participants now seem to be saying that, despite the Roundtable's apparent collaborative structure, the decision-making process was dominated by the perspectives of the food industry and this impacted the resulting Smart Choices Program. As Michel Jacobson, Director of the Center for Science in the Public Interest (CSPI), has commented, "[a] disinterested funder and committee of experts free of conflicts of interest likely would have rated the healthfulness of foods differently from the 'better for you' Smart Choices Program."111

In the program's early stages, Smart Choices advocates frequently emphasized that it was based on "consensus science." The program's development was a collaborative effort bringing together a diverse group of influential stakeholders, including food industry representatives, nutritionists, academics, public health and consumer advocacy groups, and government observers. Because several leading food manufacturers agreed to replace their proprietary front-of-package logos with the Smart Choices label, the system promised to achieve some degree of consistency and reduce the dissonance created by competing front-of-package labeling approaches. Proponents also noted that Smart Choices' underlying nutritional criteria were based on federal dietary guidelines (the USDA's Dietary Guidelines for Americans) and Institute of Medicine recommendations (the IOM's Dietary Reference Intakes). 113 Further, they noted the program's flexibility, as the Smart Choices criteria were to be updated in 2010 to reflect changes in the revised Dietary Guidelines for Americans.¹¹⁴ Advocates also cited the more useful Smart Choices logo, which not only informs consumers that a product is a healthier choice, but also includes the product's calorie count per serving and the number of servings per package, so consumers need not scour the Nutrition Facts panel for this important information.¹¹⁵ Finally, Smart Choices promised transparency. Unlike many of the preceding front-of-package labeling and grocery rating systems on the market, which are based on proprietary algorithms, the

nutritional criteria underlying Smart Choices are readily available to the public via the program's website.¹¹⁶

Smart Choices' Nutritional Criteria

Because Smart Choices was sharply criticized for qualifying products like Froot Loops and Fudgesicles, 117 it seems useful to parse through the program's underlying nutritional criteria to determine if they indeed deviate from prevailing nutritional standards, or are notably different from the criteria employed by other nutrition rating systems. Smart Choices' nutritional criteria focus on three types of nutrients or food groups: nutrients to limit, nutrients to encourage, and food groups to encourage. 118 Under the "nutrients to limit" criterion, there are five nutrients to limit: (1) total fat, which cannot comprise more than 35% of calories or more than three grams per serving; (2) saturated fat, which cannot comprise more than 10% of calories or more than one gram per serving; (3) trans fat, which must be less than half a gram per serving; (4) cholesterol, which cannot be more than 60 milligrams per serving; and (5) sodium, which is limited at 480 milligrams or less per serving. 119 Under the "nutrients to encourage" criterion, a food must provide at least 10% of the Daily Value of one or more of the following nutrients to qualify: calcium, potassium, fiber, magnesium, or vitamins A, C, or E. 120 Finally, Smart Choices encourages entire food groups recommended by the Dietary Guidelines for Americans, such as fruits, vegetables, whole grains, and fat-free/low-fat dairy.¹²¹ A product must provide at least a half-serving of one of these food groups to qualify.

Smart Choices' three-pronged approach seems simple enough, until one considers that the criteria described above are applied differently to each of the food or product categories. The criteria are customized for nineteen food or product categories, such as dairy, meats, fish, grains, breakfast cereals, snack foods, and beverages. Therefore, a food product in the fish category is subject to different threshold nutrient levels than a food product in the meat category. The customized criteria help some products qualify for the Smart Choices label that otherwise would not. They also exclude some products that would otherwise appear to qualify.

For example, all fruits and vegetables free of added sugar, salt, or other additives automatically qualify as "Smart Choices," whether fresh, frozen, or canned. 124 Processed fruits and vegetables and juices, however, must meet the "nutrients to limit" criterion plus either the "nutrients to encourage" or "food groups to encourage" criterion.¹²⁵ Meats, fish, and poultry need only meet the "nutrients to limit" criterion to qualify. 126 In addition, fish may exceed the benchmark total fat limit under the "nutrients to limit" prong, because they are high in healthy omega-3 fatty acids.¹²⁷ Snack foods must meet the "nutrients to limit" criterion while also providing at least one nutrient or food group to encourage. 128 Several foods, including breads, pasta, processed fruits and vegetables, seeds and nuts, dressing and condiments, and snack foods are held to a stricter 240 milligrams or less of sodium per serving limit (as opposed to 480 milligrams, the default benchmark). 129 Calories, rather than grams of added sugar, are the limiting factor for sodas and other sugar-sweetened beverages. 130 While Smart Choices' proponents assert that these food or food product category-specific criteria are what makes the program's nutritional guidelines superior, because they are both nutritionally sound and flexible, the program's nutritional criteria have come under fire for being too lax, particularly where breakfast cereals are concerned.¹³¹

Did Smart Choices Fold Due to Fatal Conflicts of Interest?

1. Smart Choices: Questionable Nutrition Standards?

While Smart Choices promised to simplify front-of-package labeling, a review of its nutritional criteria reveals them to be rather complicated. Throughout the fall of 2009, nutritionists and other health experts debated whether Smart Choices' nutritional criteria were sound. For example, one might question whether Smart Choices' category-specific criteria are appropriate, or whether they allow for selective rating, particularly in categories like breakfast cereals and snack foods. Turther, some critics dispute the propriety of even having a distinct category for snack foods. On one hand, Americans consume snack foods in high quantities and arguably should be equipped with the information to make educated choices among competing snack products. On the other hand, should snack foods and sugary cereals be rated and labeled as "better for you"? 134

In particular, the category-specific variations in Smart Choices' nutritional criteria have been criticized. Consider the creation of separate categories for grains and cereals. Breakfast cereals are grain products, and consuming cereal can satisfy the "grain group" requirements of the USDA food pyramid. 135 But Smart Choices creates a distinct category for cereals apart from grains, one might argue because different criteria were necessary to allow breakfast cereals with up to twelve grams, or three teaspoons, of added sugar to qualify for the label. For example, Froot Loops contains the maximum twelve grams per serving of added sugar allowed under Smart Choices, which constitutes 41% of the product, measured by weight, and is more sugar than can be found in many brands of packaged cookies.¹³⁶ Some critics have argued that high-sugar cereals like Froot Loops should be called dessert, not breakfast. 137 Yet they qualify as "better for you" selections under Smart Choices, perhaps, as some have argued, because the industry participants in the Keystone Roundtable process lobbied for permissive standards on added sugars in order to allow some of their most profitable products to qualify for the label.

In addition, some critics question Smart Choices' allowance of heavily fortified foods. Although federal nutrition guidelines encourage the consumption of whole grains, ¹³⁸ the program's nutritional criteria allow breads made without whole grains to bear the Smart Choices logo if they have added nutrients. ¹³⁹ According to some nutrition experts, fortification only masks shortcomings in processed foods. One might argue that the Smart Choices approach allows virtually any food, no matter how nutritionally deficient, to make the cut if it contains the requisite amount of added nutrients. ¹⁴⁰ Michael Jacobson of CSPI has opined that "sawdust" with added calcium and vitamin A could meet the Smart Choices criteria. ¹⁴¹ In other words, fortification allows foods that are naturally low in nutrients to masquerade as foods of better nutritional value. As Marion Nestle, Professor of Nutrition, Food Studies and Public Health at New York University, has charged, "[t]he object of [Smart Choices] is to make highly processed foods appear as healthful as unprocessed foods, which they are not." ¹⁴²

2. Smart Choices: Skewed by Conflicts of Interest?

Opponents to Smart Choices essentially argue that the program failed to provide meaningful nutrition guidance to consumers and suffered from fatal conflicts of interest. Some critics suggest that the development of Smart Choices was simply an attempt by the food industry to band together and devise favorable front-of-package labeling standards that they could control, and thereby avoid more stringent federal regulation.¹⁴³ In this view, the food industry was primarily interested in circumventing uniform federal regulation and being able to exert more control over the emerging standards on front-of-package labeling. Thus, some would argue that the development of Smart Choices was little more than a preemptive strike, touted as corporate social responsibility.

Regardless of the catalyst for its development, critics have sharply questioned what appear to be inherent conflicts of interest in the funding, administration, and oversight of the Smart Choices Program. Smart Choices was a self-imposed and self-regulated system, leading many observers to question its objectivity. The program was to be jointly administered by the American Society for Nutrition (ASN) and NSF International, a nonprofit organization that certifies products and develops standards for food, water, and consumer goods. ASN was charged with ensuring the scientific integrity of the project. ASN and NSF were both charged with reviewing new applications to determine whether food products qualified for the Smart Choices logo. The program was overseen by a board of nine directors: four seats belonged to nutrition experts, four seats were held by food industry representatives, and the ninth seat was for a neutral party.¹⁴⁴

Some leading nutrition experts were appalled at ASN's involvement with Smart Choices, and openly questioned the organization's objectivity. Some nutritionists worried that ASN's affiliation would imply that the organization was only endorsing the select products that bear the Smart Choices logo, not ensuring that the program helps consumers to make better food choices, eat more balanced diets, and live healthier lives. Certain critics have suggested that endorsement of Smart Choices, or any industry-developed nutrition rating system, calls nutritionists' professional objectivity into question and puts them in a bind. As Marion Nestle queries, "If the most prestigious nutrition and health organizations have financial ties to food companies, how can you trust them to tell you what foods are the best to eat?" 147

The most pointed conflict of interest concerns were raised against Smart Choices' funding mechanisms. The program's operating costs were funded through sliding scale fees paid by the food manufacturers who pledged to put Smart Choices labels on their products. Because a sliding scale participation fee (ranging from \$5,000-\$100,000) was used, which depended on total sales of labeled products, the financial contributions of large food manufacturers dominated the Smart Choices' funding scheme. Marion Nestle noted: "The more products that qualify for the Smart Choices logo, the more money the program gets. I'd call that a clear conflict of interest." According to one source, between 2008 and 2009, the fourteen major participating food corporations paid a combined \$1.47 million to fund the development of Smart Choices. The Keystone Center reportedly received nearly \$700,000 from large food corporations to organize the Keystone Food and Nutrition Roundtable talks. Companies' individual contributions were not disclosed, reportedly due to a signed agreement indicating

that those figures would not be shared with other participants,¹⁵³ but the Keystone Center's 2008 annual report reveals that most of the large food manufacturers endorsing Smart Choices each contributed \$50,000 or more to the organization.¹⁵⁴ In sum, critics of Smart Choices say that the program was primarily developed by, and through its funding mechanism, would have continued to be controlled by, the food industry.¹⁵⁵

The Smart Choices Program described the fee per product as "negligible" and defended its funding mechanism in the press. ¹⁵⁶ Supporters of Smart Choices also stressed that it was administered by two independent organizations that would ensure its impartiality and overriding focus on health. For their part, participating food manufacturers asserted that their financial support of the development and ongoing administration of Smart Choices was a natural outgrowth of their consumer education efforts. ¹⁵⁷ In addition, the food manufacturers that initially funded the Smart Choices Program have asserted that they, like the grocery retailers engaged in the development of shelf rating systems, are innovators. ¹⁵⁸ In this view, "big food" should be credited, not demonized, because its resources and pioneering efforts are helping to build the research base for what works in point-of-purchase labeling.

Amidst all the controversy over the Smart Choices Program, the nutrition experts appointed to the Smart Choices board have consistently maintained that, on balance, Smart Choices would have been a positive development towards educating consumers and helping them make better dietary choices. 159 According to these nutrition professionals, Smart Choices was not a perfect system, but a definite step in the right direction, for several reasons. First, by achieving some degree of industry standardization in front-of-package labeling, Smart Choices would have reduced consumer confusion. Because the large food manufacturers who pledged to use the program planned to replace their proprietary, competing front-ofpackage logos with Smart Choices labels, there would have been more consistency in labeling approaches in the marketplace and, thus, less potential for consumer confusion. Second, if Smart Choices succeeded in becoming the industry standard for front-of-package labeling, then participating food manufacturers would have been compelled to reformulate their products in order to make more of them qualify for the Smart Choices logo. 160 Consumer demand for labeled products would have resulted in the greater availability of healthier packaged food choices in the American marketplace. Of course, the potential of Smart Choices to achieve these goals was never realized.

3. Smart Choices: Denouement?

Smart Choices-labeled products were greeted with a great deal of negative publicity when they began appearing in stores in mid-August 2009. As a result of the controversy, the American Dietetic Association, the American Diabetes Association, and Tufts University requested that their names be removed from the Smart Choices website and issued statements indicating that, while individuals affiliated with their organizations may be personally involved, the entities themselves neither participated in nor endorsed the program. Over the course of roughly ten weeks, the Smart Choices Program became the subject of scathing media criticism, petitions from consumer advocacy groups, and even calls for investigation from a U.S. congresswoman and a state attorney general. As explained in more detail later in this paper, the final blow came with an October

20, 2009 announcement by the FDA that it would be investigating whether front-of-package labeling systems violate federal nutrition labeling laws. 164

In response to the FDA's announcement, the Smart Choices Program halted active operations and pledged to await further direction from the agency.¹⁶⁵ On October 23, 2009, Smart Choices issued a press release indicating that the program "will voluntarily postpone active operations and not encourage wider use of the logo at this time by either new or currently enrolled companies."¹⁶⁶ Smart Choices' statement indicates that the program supports the FDA's goal of developing standardized criteria for front-of-package and shelf labeling, and in fact, Smart Choices was developed to respond to earlier governmental calls for industry to develop a more uniform, voluntary front-of-package labeling system.¹⁶⁷ The Smart Choices Program indicated that it "stands ready to work with and support the FDA, USDA and the Institute of Medicine in this effort."¹⁶⁸ In addition, Smart Choices stated that it would continue to work with others who have an interest in front-of-package labeling, and would cooperate with any investigations or requests for information from interested parties.¹⁶⁹

Within days after Smart Choices' announcement that it was postponing active operations, a number of its prominent participating food manufacturers, including Kraft, Kellogg's, General Mills, PepsiCo, and Unilever, announced that they would be phasing out their use of the Smart Choices label. The companies planned to exhaust their current inventory of product bearing Smart Choices labels, but discontinue putting the label on new product.

While the Smart Choices Program technically remains in existence and its website is still online, its funding stream appears to have dried up and its operations are on indefinite hold. It thus seems that Smart Choices has indeed folded in the wake of scalding media criticism and the FDA's announcement that the agency will be regulating the criteria that food manufacturers and retailers must follow if they use point-of-purchase labeling. The program's demise has cast serious doubts on the participating food companies' efforts, as well as the future of industry self-regulation of food labeling and marketing in general.¹⁷² As one commentator has noted:

The failure of Smart Choices removes a valuable marketing tool – an imprimatur of healthy eating – for the participating companies. But the uproar over the program has conveyed a definitive message to industry: Don't try to disguise a nutritional sin with a stamp of approval.¹⁷³

Some critics of the Smart Choices Program have noted that the companies who were involved in its development hoped that they could stave off federal regulation by developing an acceptable self-regulatory system on their own. Ironically, as Michael Jacobson has noted, "their device for preempting government involvement actually seems to have stimulated government involvement."

Nutrition Rating Systems:A Bad Idea, or Just Too Much of a Good Thing?

A Critique of Nutrition Rating Systems

The debate over the wisdom of the Smart Choices approach illustrates the basic positions of those in favor of, and those skeptical of, nutrition rating systems. On the plus side, nutrition rating systems promise to simplify consumers' food purchasing decisions and help them make more informed, healthier dietary choices. Simple, graphic logos and numeric ratings are arguably easier to interpret than the Nutrition Facts panel and they enable consumers to compare similar products and make decisions quickly. Because dietary calculations have already been made in labeling and scoring decisions, consumers no longer have to hurriedly "crunch the numbers" while grocery shopping. This may be beneficial because research suggests that consumers have difficulty using label information if the task requires math. 175 Icon-based food ratings make it easy for consumers to gauge, at a glance, which products within a given food category are healthier choices, which is useful because most grocery shoppers do not have the time to scrutinize nutrition labels. Early consumer perception research indicates that consumers like the idea of front-of-package labeling as a shopping aid, and most consumers surveyed state that they better understand the simplified information provided by such labels. 176

On the down side, however, many unanswered questions remain about the efficacy and objectivity of front-of-package labeling and nutrition scoring systems. First, most of the existing nutrition rating systems use their own proprietary methodology and have differing nutritional criteria. As described previously, the variance in underlying standards can result in divergent results, with the same product being rated a "healthy choice" by one system and not by another. The inconsistency in identifying healthier products across the different rating approaches is problematic and is likely to cause consumer confusion. How is a consumer supposed to reconcile competing claims if, for instance, a given food product qualifies for a Smart Choices label but also receives a modest NuVal score or fails to garner any Guiding Stars?

Second, the front-of-package food labeling and grocery scoring systems on the market are under-inclusive at best, and strategically selective at worse. Only a fraction of the items sold in participating stores are rated under existing grocery rating systems. Supervalu estimates that only about 10% of the items in its stores will eventually carry a nutrition iQ tag. 177 Similarly, a limitation of Guiding Stars is that only about a quarter of products sold in Hannaford stores warrant any stars. Under the program, roughly 27,000 products were evaluated, and only about 25% of products qualified for even one star. 178 Is the consumer to assume that products without shelf ratings were simply not scored, or that they failed to meet the program's criteria? The same limitations apply to front-of-package labeling systems like Smart Choices. Participating companies have some control over which products are evaluated and labeled, and they tend to score only the "better for you" choices. For example, Con Agra Foods pledged to feature the Smart Choices logo on qualifying products, such as Healthy Choice entrees and Egg Beaters. These brands are already marketed as the healthier products in Con Agra's portfolio, so is little meaningful information imparted by telling

consumers that they are "smart choices?" Further, a benchmark system like Smart Choices that focuses on "better for you" nutrition attributes may not flag products that contain potentially problematic levels of "worse for you" elements, like added sodium and sugar. Recent history has shown that if a food product bears a front-of-package label or a grocery shelf tag, it might be a heavily processed or fortified product. When strict nutritional standards are applied, most packaged foods do not make the cut.¹⁷⁹

On the other hand, one could argue that nutrition rating systems are not selective or exclusive enough, in the sense that entire categories of packaged foods ought not to be labeled or scored at all. Rating snack foods may arguably lead consumers into thinking that they are the most nutritious choices, when it would be better to encourage consumers to snack on fresh fruits and vegetables instead and eat more whole foods to improve their diets. According to Smart Choices, the logo is designed to "help[s] shoppers make smarter food and beverage choices within product categories in every supermarket aisle." In other words, "better for you" labeling is designed to help consumers identify smarter choices within all food product categories, including snack foods and sugary cereals, rather than advising consumers to steer clear of certain categories of foods that are more likely to get them into nutritional trouble.

One argument in favor of flagging healthier snack foods is that such products are ubiquitous in today's processed food-dominated marketplace, and consumers ought to be given easily accessible nutrition information about snack foods so they can more readily discern how to "spend" their discretionary calories. In 2005, the Dietary Guidelines for Americans introduced the concept of discretionary calories to assist people in meeting all of their nutrient requirements while avoiding excess total energy intake. 181 According to the Dietary Guidelines for Americans Advisory Committee, discretionary calories are "the balance of calories remaining in a person's 'energy allowance' after consuming sufficient nutrient-dense forms of foods to meet all nutrient needs for a day."182 A person's discretionary energy allowance can be determined by estimating the calories needed to meet one's nutrient requirements, and then subtracting this sum from the estimated energy intake required to maintain one's weight; the remainder is one's discretionary calorie allowance that can be "spent" on foods of one's choice, while still getting adequate nutrients and maintaining a healthy weight. Education about discretionary calories is a key factor in helping consumers decide whether and how snack foods can fit into a healthy diet. In today's food landscape, it is difficult for most sedentary individuals to consume a nutritionally adequate diet, avoid excessive calorie intake from snack foods and sugar-sweetened beverages, and maintain a healthy weight. National survey data indicate that excessive intake of added sugars is contributing to overconsumption of discretionary calories by Americans, and our waistlines are expanding as a result. 183 The American Heart Association recommends that discretionary calorie intake from added sugars not exceed 100 calories per day for most women and 150 calories per day for most men.¹⁸⁴ It is easy to exceed these discretionary calorie limits with the abundance of calorie-dense snack foods and sugar-sweetened beverages available in grocery stores and other retail outlets. Therefore, one might argue that flagging "better for you" snack foods and reduced-calorie soft drinks will help consumers to select healthier choices in these food categories, and such labeling may thereby reduce individual and population levels of overweight and obesity.

But the counterpoint to this position is that promoting "better for you" snack foods only benefits food manufacturers, not consumers, because it merely tricks consumers into thinking they can eat more "healthy" processed snack foods, rather than steering them towards the produce department and encouraging them to snack on fresh fruits and vegetables instead. 185 One might argue that promoting "healthy" snack foods sends the wrong message because it implicitly endorses the continued consumption of foods that can get people into dietary trouble in the first place. When snack products like Baked Lays potato chips receive "better for you" symbols, their sales tend to increase. 186 While baked chips may technically be better for you than fried chips, most nutritionists would probably agree that the best choice is to avoid chips all together. According to Marion Nestle, buying "healthier" potato chips "will delude you into thinking that you're doing something for your health when the best thing is to not eat them at all."187 Including reduced-calorie or reduced-fat products in the "better for you" category may be misleading; although such items may be relatively healthier than their more calorie-dense, full-fat counterparts, they may not be particularly healthy from an absolute perspective.¹⁸⁸ Perhaps "better for you" labels and rankings are just another way to market junk food, as Marion Nestle has argued. 189 As she queries: "is a 'better-for-you' junk food really a good choice?" 190

Third, while most critics tend to agree that the nutrition standards of industrydeveloped food rating systems are too permissive, some nutritionists and trade groups caution that their selective focus on certain "negative" nutrients can be overly simplistic.¹⁹¹ Most of the nutrition rating systems dock foods for containing "problematic" nutrients beyond certain threshold levels (e.g., a food containing saturated fat or sodium beyond a certain threshold will receive a lower NuVal score, or not qualify for a Smart Choices label or a Guiding Stars tag). However, an overriding emphasis on certain negative food attributes can arguably lead to curious and potentially misleading results, or at least elevate heavily processed products over natural foods. Consider that under Guiding Stars, whole milk receives no stars, due to its high saturated fat content. A fortified diet soda, however, receives one star. Whole milk is clearly a worse dietary choice than skim milk. But whole milk is arguably more nutrient dense than diet soda, containing eight grams of protein and 28% of the Daily Value for calcium per serving, and may be a permissible dietary choice for a healthy individual, if it is consumed in moderation. That conclusion might not be apparent to a consumer basing his/ her shopping choices on Guiding Stars ratings. Thus, some experts assert that nutrition rating systems' narrow focus on certain negative nutrients leads to binary classifications that draft all products into two categories – good and bad – and therefore these systems are unlikely to help consumers construct overall balanced diets in the real world, where food choices and nutrition tradeoffs are more complex.192

According to some nutrition experts, the problem with selectively emphasizing negative nutritional attributes and making them disqualifying, rather than balancing negative and positive nutritional elements, may be addressed by focusing on nutrient density. A nutrient density approach weighs the beneficial nutrients a food contains in relation to the calories it provides. It emphasizes enjoying nutrient-rich foods first within each food group identified in the USDA's *MyPyramid*, and selecting less nutrient-rich options as caloric recommendations allow. The Nutrient Rich Foods Coalition (NRFC), an organization consisting

of nutrition researchers, communications experts, and agricultural commodity groups representing all the major food groups, advocates a nutrient density approach for its scoring system, the Nutrient Rich Foods Index (NRFI).¹⁹⁷ The goal of the NRFC is to create a simple coding system to steer consumers towards the foods that pack the greatest nutritional punch for the number of calories they contain.¹⁹⁸ The NFRC asserts that a nutrient density approach is preferable because it gives equal weight to positive nutritional attributes of foods, takes a broader look at dietary patterns, and places scores for single food items within the context of overall dietary intake.¹⁹⁹ To date, the NRFI is one of the few nutrition profiling systems that has been peer-reviewed and has published its underlying criteria and methodology in an academic journal.²⁰⁰

Fourth, critics frequently cite the lack of transparency in most nutrition rating systems. Most of the private sector front-of-package labeling and grocery scoring systems are based on proprietary formulas involving complex algorithms, and the methodologies behind particular scoring approaches are not readily apparent nor publicly accessible. Due to this lack of transparency, most nutrition rating systems are difficult to evaluate. Some nutritionists have argued that food rating systems must be peer-reviewed and their methodologies must be made transparent and readily understandable to consumers.²⁰¹ As Eileen Kennedy, Dean of the Tufts University Friedman School of Nutrition Science and Policy and member of the Smart Choices Board of Directors, explained in a 2007 statement:

[M] any of the nutritional rating systems developed by the private sector have been difficult to evaluate since the processes and exact specifications for particular approaches are not transparent. Unless algorithms for nutritional profiling are available in the peer-reviewed, scientific literature, it will be impossible to critically evaluate the utility of one approach compared to another. Opinions or best guesses about what works most effectively are a poor metric for judging rigor. ²⁰²

Although its nutritional criteria came under fire for being too lenient, one defense of Smart Choices is that at least the program's criteria *could* be scrutinized, as they were published on the program's website even before Smart Choices-labeled products began appearing in stores.

Fifth, as discussed previously in reference to Smart Choices, critics of industry-developed nutrition rating systems point to conflicts of interest, noting that they are developed, administered, and funded by food manufacturers and retailers. Food manufacturers and food retailers are ultimately interested in getting consumers to purchase more products, not less. One might argue that the food industry is primarily motivated by increasing profits, and not necessarily concerned with encouraging healthier dietary choices and promoting better health. In this view, food industry involvement in the design and ongoing implementation of nutrition rating systems always poses a fatal and inherent conflict, because the industry will always self-regulate in a way that benefits its own self-interest.

As commentators opine about whether Smart Choices was doomed from the start due to fatal conflicts of interest, the nutrition community might question whether current research efforts might suffer from similar flaws, and whether steps should be taken to ensure the objectivity of future nutrition labeling research. The International Life Sciences Institute (ILSI) North American Conflict of Interest/Scientific Integrity Guiding Principles Working Group acknowledges that the food industry must disclose and manage financial conflicts of interest.²⁰³ The ILSI Working Group has developed guidelines to manage potential biases resulting from conflicts of interest between researchers and companies funding their work, which may be useful to safeguard future research on nutrition rating systems from undue influence by funders.²⁰⁴

Multiple Nutrition Rating Systems: Causing Consumer Confusion?

Critics seem to consistently say that the main problem with nutrition rating systems is the risk that their varying approaches are causing information overload.²⁰⁵ Are American consumers stymied by having too much nutritional information? Food packages are already crowded with a Nutrition Facts panel and an ingredients list, and sometimes also bear an endorsement from a health organization, like the American Heart Association's Heart Check symbol.²⁰⁶ Consumers frequently encounter questionable health-related claims on the front labels of food packages, such as manufacturers' claims that eating certain cereals may lower your cholesterol or boost your child's immune system.²⁰⁷ The new front-of-package labels and grocery shelf ratings are arguably only adding to these existing, sometimes contradictory, sources of information. Front-of-package labels and grocery ratings promise to help shoppers make better decisions in a hurry, but some critics say that these new tools are just confusing consumers more and making it even harder to select better food choices.²⁰⁸ Indeed, a recent survey conducted by Ipsos, a survey-based marketing research firm, found that 54% of Americans say they are overwhelmed by the information and advice they receive about what foods to eat.²⁰⁹ This confusion may be one of the reasons why food label use is reportedly on the decline in the United States.²¹⁰

The central problem with front-of-package labeling and grocery shelf rating systems seems to have been their rapid proliferation in the absence of any firm guiding standards. In just a few short years, roughly a dozen different labeling and scoring approaches have emerged in U.S. food markets, all of which are based on differing underlying nutritional criteria. This situation has led the Institute of Medicine to express caution about the likelihood of consumer confusion over various food rating approaches, particularly among young consumers, and to recommend that the Food and Drug Administration issue guidance on the future development and implementation of front-of-package food labeling and grocery shelf/signage scoring systems.²¹¹ As the IOM's 2006 report on food marketing to children explained:

While representing an important step to draw attention to more nutritious products, the array of categories, icons, and other graphics, as well as the different standards employed by these companies may introduce some confusion, especially for young consumers, thereby raising the need for developing and regulating standard and consistent approaches. The FDA has not yet fully explored its potential role for providing leadership and expertise to food companies in order to develop and enforce an industrywide rating system and graphic representation on food labels that is appealing to children and youth to convey the nutritional quality of foods and beverages.²¹²

The inconsistency created by varied nutrition rating systems has also led some public interest groups to call on the FDA to promulgate standards to ensure more uniformity across voluntary rating approaches, or to mandate the use of one universal nutrition rating system. For instance, as explained later in this paper, the Center for Science in the Public Interest (CSPI) has asserted that the only durable solution is for the federal government to step in and require one nutrition rating system as a national standard. And the system as a national standard.

If conflicting nutrition rating systems have proliferated too rapidly and consumers are becoming increasingly bewildered, what efforts have been made by the Food and Drug Administration to address the problem? According to some agency critics, the FDA has, until recently, paid insufficient attention and devoted inadequate resources to the problem of inconsistent front-of-package labeling and grocery shelf rating approaches. While such a criticism may have been warranted in the past, recent agency activity suggests that the FDA is now paying close attention to point-of-purchase nutrition rating systems and is carefully weighing its options for improving the nation's nutrition labeling scheme. The FDA may look to European countries' experiences with front-of-package labeling as it considers how to regulate point-of-purchase food labeling in the United States.

Nutrition Rating Systems Abroad: Lessons Learned from Foreign Examples

It is fair to say that European countries have outpaced the United States in developing and testing consumer responsiveness to front-of-package labeling schemes. Although the European Union does not mandate nutrition labeling for all packaged foods like the United States, it does requires labeling on products that bear nutrition or health claims.²¹⁵ In addition, several European countries, including the United Kingdom, Sweden, and the Netherlands, have implemented voluntary front-of-package labeling systems.²¹⁶ European frontof-package labeling systems, while purely voluntary, have received considerable support from government regulatory bodies, such as the United Kingdom's Food Standards Agency. Further, the European Commission has gone a step further and is presently considering a proposed regulation to make front-ofpackage labeling mandatory in all European Union (EU) member countries.²¹⁷ Lastly, several European studies have been conducted to assess consumer responsiveness to different front-of-package labeling formats and whether pointof-purchase labeling holds the potential to improve diets. ²¹⁸ While considerable research is still needed to assess the efficacy of front-of-package labeling systems and their potential to improve dietary choices, conclusions drawn from European research studies may be useful to the FDA as it considers how to best approach point-of-purchase food labeling in the United States.

FAT 7.78 per serving LOW SATURATES 2.0g per serving HIGH 42.2g per serving SALT 42.2g per serving

The United Kingdom

Two major variations of front-of-package labeling have been considered for use in the United Kingdom: (1) the Traffic Light (TL) system, developed by the UK's Food Standards Agency: and (2) the Guideline Daily Amount (GDA) system, supported by a coalition of the UK's largest food and beverage manufacturers, as well as major retailers such as Tesco, Somerfield, and Morrison.²¹⁹ (Other large retailers, such as Marks & Spencer and Sainsbury's, have adopted the TL system.)²²⁰ At present, both systems are used because front-of-package labeling is voluntary in the UK and the government does not mandate a uniform approach. Significant debate has emerged among nutrition experts and food manufacturers and retailers over which system should be utilized in the United Kingdom. ²²¹ The Food Standards Agency and the UK's National Heart Forum, an alliance of fifty cardiovascular health organizations, have promoted the TL system, 222 while food manufacturers have generally endorsed the GDA system.²²³ The debate over which system to use has prompted the UK government to consider making the Traffic Light system mandatory, 224 although no legislation has been introduced.

After a roughly two-year period of consultation and research, the UK Food Standards Agency (FSA) introduced the voluntary Traffic Light signpost system in March of 2006. The TL system focuses on nutrients deemed to be of greatest public health significance – total fat, saturated fat, sugar, and sodium – and color codes the amount of these nutrients in a food product as red (high), yellow (medium), or green (low). The system is based on benchmarks established by European Union Regulation No. 1904/2006, which governs nutrition and health claims, ²²⁵ and recommendations of the UK's own Committee on Medical Aspects of Food and Nutrition Policy (COMA) and

Scientific Advisory Committee on Nutrition (SACN).²²⁶ TL labels indicate the level of certain "problematic" nutrients in a food product with the colors red, yellow or green, in order to steer consumers away from "risky" (red) foods and towards healthier (green) foods.²²⁷ Other nutrition information (e.g., calcium or fiber) may be displayed on the front of packages, but must be separate from the traffic light signpost and comply with other applicable regulations.²²⁸ Research has suggested that the colors red, yellow and green have inherent significance to consumers, and thus TL labels will be processed automatically as consumers scan supermarket shelves, thereby impacting consumer purchasing behavior without conscious consideration.²²⁹

The Guideline Daily Amount (GDA) system was developed by the Confederation of Food and Drink Industries of the European Union (CIAA), ²³⁰ a food industry trade organization, in consultation with nutrition experts. According to CIAA, the GDA system's nutrition guidelines are based on recommendations from the Eurodiet project, a panel of scientific and policy experts established by the European Commission. ²³¹ The GDA system displays the percentage of daily requirements of energy (calories), total fat, saturated fat, sugar, and sodium that a serving of a food product provides. ²³² Information on fiber, vitamins, and minerals may also be provided. ²³³ Most European food manufacturers and their representative organizations have supported the GDA system over TL schemes, ²³⁴ perhaps in anticipation of the European Commission position on this issue, which has endorsed the GDA system and proposed making its use mandatory in all EU countries. ²³⁵

To date, UK studies have shown that consumers prefer the TL system over the GDA system. ²³⁶ Early consumer research suggests that TL labeling allows consumers to more easily and accurately select healthier food products, and to make product comparisons quickly at the point-of-purchase, whereas some consumers do not understand the percentages employed by the GDA system.²³⁷ A more recent Australian study, which compared consumers' ability to select healthier food products using variants of both the TL system and the GDA system, found that consumers are five times more likely to identify healthy food when they see color-coded traffic light labels than when labels present the information numerically by showing what percentage of the recommended daily nutrient intake each portion provides, as the GDA system does.²³⁸ Further, FSA officials and supportive food retailers report that UK sales data suggests that the TL system is influencing consumers' purchases towards healthier products.²³⁹ FSA officials also state that food manufacturers are reformulating less-healthy products so that they may move from the red into the yellow or green light categories.²⁴⁰ Research suggesting the efficacy of the TL system in helping consumers make healthier food selections has led some observers in the United States to suggest that the FDA should consider employing the TL model in promulgating federal standards to guide front-of-package labeling in American markets.241

Although early consumer research suggests that consumers prefer and better understand TL labeling, the system is not without its detractors. Some nutrition professionals reportedly find the information imparted by TL labeling to be oversimplistic and under-inclusive.²⁴² One notable criticism is that TL labeling only indicates the "bad" nutritional components of a food product, rather than also

highlighting the presence of "good" components.²⁴³ Further, the TL system could negatively impact the sales of certain "fat" products, such as olive oil, which may be high in fat but beneficial as part of an overall balanced diet.²⁴⁴

The FSA is currently reviewing its recommendations on front-of-package nutrition labeling, in light of the findings of an independent evaluation it commissioned to study the different front-of-package labeling schemes in use in the UK.²⁴⁵ This evaluation was conducted by a small independent panel known as the Project Management Panel (PMP).²⁴⁶ In May 2009, the PMP published its final report in the signpost evaluation project, the aim of which was to "evaluate the impact of the various front-of-package nutritional signposting schemes on consumer understanding and behavior."247 The main conclusions of the PMP's evaluation are: (1) a single front-of-package scheme would be most helpful for UK consumers, as the presence of multiple labeling systems in the marketplace can cause consumer confusion; (2) the strongest front-of-package label is one which combines elements of both the TL system and the GDA system; (3) consumers who use front-of-package labels value them and use them to compare products; and (4) there is generally a high level of awareness and understanding of front-of-package labels in the UK, which suggests that promoting a single front-of-package labeling scheme could result in increased use of front-of-package labels in making food purchasing decisions.²⁴⁸ It remains to be seen whether the UK government will use these findings to develop a single, mandatory approach to front-of-package labeling in the United Kingdom.



The Netherlands

The Netherlands launched its voluntary front-of-package "Healthy Choice" label in 2006. The Choices system was developed by food industry representatives (notably, Unilever) and endorsed by the national Ministry of Health. ²⁴⁹ The system is applicable to all foods with a few exceptions (alcoholic beverages, supplements, products for use under medical supervision, and infant food and formula). Generally, products may earn a Healthy Choice label if they have limited amounts of saturated fat, trans fat, sugar, and sodium, based on World Health Organization standards. ²⁵⁰ Distinct nutritional criteria were established for different food categories, since the criteria cannot be uniformly applied to all foods. ²⁵¹ For example, fiber is included in the qualifying criteria for bread products, but not meat products.

An independent foundation, the Choices International Foundation, was developed to introduce the Healthy Choice label to other countries. ²⁵² The system's nutritional criteria will be revaluated every two years by an independent scientific committee. ²⁵³ Studies conducted on the Healthy Choice system have shown that the label assists consumers in making healthier choices and encourages them to replace less healthy foods with healthier products. ²⁵⁴ However, there are relatively few consumer research studies assessing the efficacy of the Dutch labeling system, as compared with the number of studies analyzing the systems used in the United Kingdom.





Sweden

In 1989, the National Food Administration of Sweden introduced the voluntary "keyhole" front-of-package food labeling system to help consumers identify healthier products within particular food categories.²⁵⁵ For a food product to earn the keyhole symbol, it must be lower in fats (including saturated fat and trans fat), sugar, and sodium, and/or higher in fiber, than other foods within the same category.²⁵⁶ According to Swedish agency officials, the keyhole system has resulted in the development of healthier products and the reformulation of existing products.²⁵⁷ One Swedish retailer, ICA, reported that in 2003 and 2004 sales of keyhole-labeled products rose by over 15%.²⁵⁸ However, there do not appear to have been many studies directed at assessing the efficacy of the keyhole system.

The Swedish keyhole system has also been adopted in Denmark and Norway.²⁵⁹ While useful, one criticism of the keyhole system is that it only identifies healthier choices within particular food categories, as opposed to being applicable to all foods. It also does not identify food products that are less healthy, like the Traffic Light system does with its red light labels.

The European Union

In 2008, the European Commission proposed legislation that would mandate the use of a unified front-of-package labeling system in EU member countries in order to provide more consistency in labeling formats for European consumers.²⁶⁰ The proposed regulation would require packaged foods to display information on calories, fat, saturated fat, carbohydrates, sugars, and salt on their frontof-package labels. ²⁶¹ The required nutrition information must be prominently displayed, and front-of-package labels must also indicate what percentage of the recommended daily intake the measures represent, 262 in line with the GDA system. As long as all of the requisite elements are prominently displayed on the front-of-package label, food producers are free to decide *how* they wish to display the information.²⁶³ Further, EU member states would still be able to promote and use complementary national front-of-package labeling systems, such as the UK's Traffic Light system, as long as they do not conflict with the requirements of the EC regulation.²⁶⁴ Both the European Heart Network, an alliance of thirty cardiovascular health organizations in twenty six EU countries, and BEUC, the European Consumers' Organization, endorse the regulation and support mandatory front-of-package labeling in European countries.²⁶⁵ But the proposed regulation is controversial because it will impose additional labeling requirements, and thus costs, on food manufacturers doing business in Europe.²⁶⁶ The European Commission is currently scrutinizing and debating the proposed regulation pursuant to a process known as "co-decision," which has no definitive end date. ²⁶⁷ The proposal will require the approval of EU member nations and the European Parliament.²⁶⁸ A mandatory EU front-of-package labeling system, if adopted, is likely to impact the future of front-of-package labeling in the United States. Many multi-national food corporations sell their products in both Europe and the U.S., and thus they will likely seek uniformity in their labeling requirements.

FDA Regulation of Point-of-Purchase Food Labeling: Implications for Nutrition Rating Systems

Overview of FDA's Regulatory Authority Over Food Labeling

The Food and Drug Administration has primary, although not exclusive, jurisdiction over food labeling in the United States.²⁶⁹ The FDA's authority to regulate food labeling derives from three statutory sources: the federal Food Drug and Cosmetic Act, 270 as amended by the Nutrition Labeling and Education Act;²⁷¹ the Fair Packaging and Labeling Act;²⁷² and the Public Health Service Act. 273 Further, to the extent that nutrition labeling requirements may compel or suppress speech, the agency's exercise of its labeling authority must also be consistent with the First Amendment.²⁷⁴ Pursuant to its statutory authority over food labeling, the FDA has promulgated detailed regulations which mandate that certain information be placed on packaged food labels in a standardized format, including nutrient, ingredient, and other content information that consumers can use to make informed dietary choices and avoid allergens.²⁷⁵ In addition to prescribing the format of the Nutrition Facts panel, FDA regulations define when and how food manufacturers may voluntarily make either nutrient content²⁷⁶ or health²⁷⁷ claims, both of which may appear on the front labels of packaged foods and be interwoven into nutrition symbols and ratings. While the Nutrition Labeling and Education Act was passed, in part, to prevent deceptive and misleading claims on food labels, its legislative history indicates that Congress intended to permit some nutrient content and health claims as a vehicle for educating consumers and assisting them in making healthier dietary choices.²⁷⁸ FDA regulations, in turn, are designed to establish consistency in the expression of nutrient content claims (for example, by defining "low fat") and to protect consumers from unfounded health claims.

FDA regulations guiding when and how nutrient content and health claims may be made by food manufacturers are complex, and a full discussion of this regulatory scheme is beyond the scope of this paper. Briefly speaking, a nutrient content claim characterizes the level of a particular nutrient in a given food item (e.g., "low sodium"), while a health claim describes the health-related effects of consuming a food item (e.g., "heart healthy") or characterizes the relationship of a certain nutrient to a disease or health condition (e.g., "consuming calcium reduces the risk of osteoporosis"). Nutrient content claims may be express or implied.²⁷⁹ Express nutrient content claims generally state that a food contains a high or low level of, or is a good source of, a particular nutrient, 280 while implied nutrient content claims generally suggest that a nutrient is present or absent²⁸¹ (e.g., "contains no oil" could imply that a product is fat-free). FDA regulations governing nutrient content claims are designed to ensure some degree of consistency for consumers in how such claims are expressed. The purpose of the agency's regulations governing health claims is to allow foods to bear certain science-based assertions about the benefits of their consumption.²⁸² The logos, icons, and numeric scores used by front-of-package labeling and grocery shelf rating systems typically aim to provide a snapshot of the information on the Nutrition Facts panel – that is, a brief synopsis of a food product's nutritional quality – and thus may be viewed as express or implied nutrient content claims.

Amount Per Serving			
Calories 100			
- District	%	Daily Value*	
Total Fat 0g		0%	
Saturated		0%	
Cholesterol		0%	
Sodium 0mg	-	21%	
Potassium 7 Total Carbot		and the second	
Dietary Fib	er 3g	12%	
Sugars 3g			
Protein 4g			
Vitamin A 09	• Vitam	in C 45%	
Calcium 2%	• Iron 6	196	
and the second second	Diboff	lavin 2%	
Thiamin 8%	· THEFT		
The same of the sa	- Autoria	in B _e 10%	
Thiamin 8% Niacin 8% Folate 6%	• Vitam	in B ₆ 10% phorous 6%	

But front-of-package labels and grocery shelf ratings may also contain health claims.²⁸³ As such, front-of-package labeling and grocery rating systems are subject to federal regulations regarding both how nutrient content and health claims may be expressed.

The FDA is entrusted with ensuring that all domestic and imported foods sold in the U.S. are labeled accurately and in accordance with federal law. The FDA's food labeling authority stems primarily, although not exclusively, from the federal Food Drug and Cosmetic Act (FDCA),²⁸⁴ as amended by the Nutrition Labeling and Education Act (NLEA).²⁸⁵ Section 403(a) of the FDCA, as amended, prohibits the "misbranding" of food, which includes, among other things, labeling that is false or misleading or fails to list the amounts of certain nutrients.²⁸⁶

When consumer groups or individuals believe that food labeling information is false or misleading, or that changes to federal food labeling requirements are advisable in the interests of public health, they may petition the FDA to issue regulations or provide other guidance to the food industry to ameliorate the problem. While evidence of false or misleading food labeling may come to the FDA's attention through consumer reports, the agency is responsible for independently monitoring industry compliance with federal food labeling requirements as part of its oversight mission. The agency's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for overseeing all food labeling within the FDA's jurisdiction. Within CFSAN, the Office of Nutrition, Labeling and Dietary Supplements promulgates regulations and publishes less formal guidance on federal food labeling requirements. It also provides policy interpretations of federal statutes and regulations pertaining to food labeling.

To monitor and enforce federal food labeling requirements, the FDA's Office of Regulatory Affairs (ORA) conducts inspections of both domestic and imported foods and initiates enforcement activities. PDA directs its inspectors to focus primarily on food safety, but also to review the labels of at least three food products of any manufacturer or processor during every food safety inspection. Given the immensity of the task of inspecting the nation's food supply, the agency contracts with states to conduct food safety inspections. To test the accuracy of labeling information, investigators may send food samples to FDA laboratories for analysis. The agency also follows up on complaints from groups or individuals who believe that they have identified misbranded food.

When mislabeled food is identified, the FDA has a number of administrative tools²⁹⁵ for responding to food labeling violations, including voluntary recall, issuance and publication of formal and informal warning letters, seizure, and injunction.²⁹⁶ First, the FDA may request a voluntary recall and ask companies to withdraw any mislabeled food that has already entered the distribution chain.²⁹⁷ Second, the FDA may send a letter to a food manufacturer, which serves as a notice that the agency may take enforcement action if corrections are not made. The agency has a choice in issuing such a regulatory letter; it may either issue a formal warning letter, which suggests a violation so serious that it constitutes a threat to public health and requires immediate remedial action, or it may send an untitled letter (known as a "Dear Manufacturer" letter), which is an informal communication that suggests a less severe violation.²⁹⁸ At any point in the

process, the FDA may demand a meeting with a food manufacturer to resolve a labeling violation, or may otherwise work with a company to obtain voluntary compliance with FDA regulations.²⁹⁹ If violations are not corrected, the FDA may seize and remove mislabeled food from the marketplace (a seizure),³⁰⁰ or take action to enjoin a company from continuing a practice that violates federal food labeling statutes or FDA regulations (an injunction).³⁰¹ Seizures are much less common than warning letters, and injunctions are a fairly extraordinary remedy.³⁰²

To say that the FDA has an immense responsibility for ensuring the safety of the nation's food supply, of which oversight of food labeling is only one element, is an understatement. Several public interest groups and lawmakers have expressed concern about the agency's ability to fulfill its food safety mission, 303 alongside its equally substantial responsibilities for guaranteeing the safety of over-the-counter and prescription drugs, medical devices, cosmetics, and dietary supplements. Moreover, federal funding and staffing of FDA and USDA have not kept pace with the volume of foods entering the U.S. marketplace. 304 According to the Government Accountability Office (GAO), the FDA has limited assurance that domestic and imported foods are complying with federal food labeling requirements because while the number of food firms has steadily increased over the past decade, the number of inspections, warning letters, and enforcement actions to address violations have remained constant or declined. 305

As the FDA has become increasingly overburdened and underfunded, calls have increased for the agency to improve the nation's food labeling system. Key public health and consumer protection organizations have identified a number of measures they believe will mitigate misleading food labeling, help consumers make better food purchasing decisions, and improve dietary outcomes. High on this list of priorities is the recommendation that the FDA develop a uniform system of symbols for front-of-package labeling claims, to indicate the nutritional quality of packaged foods. ³⁰⁶ As explained more fully below, the FDA recently announced its intent to more closely monitor front-of-package labeling and grocery shelf rating systems, develop regulatory standards to guide the food industry's use of point-of-purchase labeling, and if necessary, mandate the use of a uniform front-of-package labeling system. It now appears that regulatory standards for point-of-purchase labeling in the United States will be issued within the next year or two.

Past FDA Activity Surrounding Front-of-Package Labeling and Nutrition Rating Systems

Over the past several years, the FDA has been moving toward requiring some consistency, if not uniformity, in front-of-package labeling and nutrition scoring approaches. The agency held public hearings to address front-of-package food labeling in 2007, which illuminated the variety of different nutrition rating systems on the market and the lack of a research base to support any one given approach. Identification of these research gaps led the agency to conduct focus groups and begin to design studies to examine front-of-package labeling and nutrition rating approaches. Generally, however, the agency's myriad other responsibilities and lack of resources seemed to hinder its ability to focus on the private sector's food labeling and scoring systems. This appears to be changing

under the current administration. By late 2009, the FDA had demonstrated its intent to actively monitor and, if necessary, take corrective action against the nutrition rating claims made by food manufacturers and retailers.

The Center for Science in the Public Interest (CSPI) has been very active in pushing for FDA activity on front-of-package labeling and nutrition rating systems. In November 2006, CSPI petitioned the FDA to develop a standardized system of symbols for front-of-package nutrition claims.³⁰⁷ CSPI's petition recognized the potential of food rating systems to help consumers make better dietary choices, but argued that the rapid proliferation of different rating schemes without any guiding standards was creating a climate ripe for consumer confusion and deception.³⁰⁸ CSPI asserted that agency rulemaking was necessary to develop a national set of symbols and move towards standardization of front-of-package labeling approaches. Several notable nutrition experts and physicians joined CSPI's petition, ³⁰⁹ and the organization's request was also endorsed by Senator Tom Harkin (D-IA), who went on record as saying that he would pursue legislative action to address the problem if the FDA did not act. 310 Indeed, within a matter of months, Senator Harkin authored legislation that would have required the agency to solicit comments on whether consumers would be better served by the establishment of a uniform front-of-package labeling system regulated by the FDA, or, alternatively, by allowing food companies, retailers, and other entities to continue to develop their own systems, but subject to certain standards. 311 The bill would have also required the agency to either promulgate regulations establishing a single, standardized front-label system, or to set the conditions under which food manufacturers and retailers could continue to develop their own rating systems.312

Shortly thereafter, the FDA issued a notice of public hearing³¹³ and held two days of hearings in September 2007 to solicit comments on front-of-package symbols and other nutrition rating systems.³¹⁴ These hearings afforded industry, consumers, health organizations, and other interested parties the opportunity to provide comments and present research findings on the use of symbols to communicate nutrition information. The FDA's public hearing notice outlined three main issue areas and posed specific questions pertaining to each one of the following issues: (1) the types of foods that bear nutrition symbols and ratings, and the underlying nutritional criteria for these systems; (2) research and data on consumer understanding and use of nutrition symbols and ratings; and (3) the economic impacts of nutrition symbols and ratings. At the hearings, the agency heard from a variety of food manufacturers, food retailers, trade organizations, health experts and organizations, and international representatives.³¹⁵

In April 2009, the agency published a summary of the testimony received at the September 2007 public hearings, as well as the written comments submitted to the docket. ³¹⁶ In its summary, the FDA stated that the nutrition rating systems presently in use in U.S. markets are "diverse in their messages, presentation, and nutritional basis," and because of the variance in their nutritional claims and underlying criteria, "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." The agency's summary also noted that "FDA received little information regarding consumer studies intended to assess consumers' understanding of these various symbols" and "the public hearing produced little

usable research" on consumer perceptions of the presence of multiple symbols on different food products within the same food category, or competing nutrition messages on a single food product.³¹⁸

As a result of the information gaps revealed at the September 2007 public hearings, the FDA developed a plan for evaluating issues relating to the use of nutrition symbols and ratings in food labeling. The agency's current plans are two-fold. First, it intends to evaluate individual nutrition rating systems in relation to applicable federal regulations and statutes, including analyzing whether their claims are compliant with FDA regulations governing nutrient content and health claims. Second, it plans to conduct quantitative research into consumer use and understanding of front-of-package symbols and other nutrition rating systems. According to the agency, it is interested in understanding whether consumer use of nutrition symbols and ratings is restricted to comparing products within given food categories, or whether consumers might also use symbols and ratings to compare products across food categories. 221

As the first step in its consumer research plan, in April 2008 the FDA commissioned a focus group study on existing and alternative symbolic nutrition rating systems. The focus group study examined consumers' exposure to, understanding of, and use of existing food rating systems; consumer confusion caused by the variety of rating approaches; and the perceived merits and deficiencies of the various systems. Interestingly, some focus group participants felt that shelf tag ratings were not as trustworthy as the symbols placed directly on the product package. Several participants said they thought the variety of different symbols and ratings could be confusing, and they would prefer a standardized system. According to the FDA, the information obtained from the focus group study furthered the agency's understanding of the role that nutrition symbols play in consumers' dietary decisions and how they interact with other nutrition information on food packages. The agency plans to conduct additional quantitative consumer research based, in part, on the focus group study findings.

Next, in August 2009, the FDA published a notice in the Federal Register calling for an internet survey to assess barriers to consumers' use of food labels. The survey was prompted by research showing a sharp decline in food label use between 1994 and 2002 among American consumers, particularly younger consumers (under age thirty five). Its purpose is to explore possible explanations for this decline in food label use, and to inform the agency's efforts in improving consumer understanding and use of food labels. Front-of-package symbols and grocery shelf ratings are likely to be considered in the survey, as the FDA has taken note of research showing that consumers are less likely to check the Nutrition Facts panel when front-of-package labels and other nutrition ratings are present.

FDA's increased activity surrounding nutrition rating systems is also evidenced by a December 2008 "Dear Manufacturer" letter regarding front-of-package symbols, and more recently, an August 2009 warning letter to the manager of the Smart Choices Program. In December 2008, the FDA sent an advisory, non-binding "Dear Manufacturer" letter "to remind food manufacturers and distributors about current regulatory schemes and requirements with regard

to nutrition claims in light of the expanding use in the marketplace of front-of-package symbols on food products."³³¹ The letter advised that the agency was closely following the use of front-of-package symbols and their claims and "consider[ing] whether any regulatory changes are necessary to ensure that these claims are not false or misleading."³³² Specifically, the letter stated that "FDA feels it is imperative to remind its constituents that front-of-package symbols can at times constitute nutrient content claims that are subject to the requirements of [federal regulations]."³³³ It recommended that food manufacturers using front-of-package symbols take care to ensure that their claims are consistent with federal law. Finally, it cautioned that FDA "will notify manufacturers when we see any front-of-package symbols that are explicit or implied nutrient content claims that are not consistent with current requirements or where such front-of-package symbols are used in a manner that is false or misleading."³³⁴

FDA's December 2008 "Dear Manufacturer" letter foreshadowed its more targeted August 19, 2009 letter to the Smart Choices Program. Jointly authored by the FDA and USDA, the letter noted that "competing front-of-package symbols on food labels have proliferated" in recent years, and "[c]onsumer research suggests that these competing symbols, which are based on different nutrient criteria, are likely to confuse consumers." The letter warned the program that the agencies would be monitoring Smart Choices-labeled products as they appear on the market, and evaluating their effects on consumers' food choices and perceptions. Notably, the letter stated:

FDA and FSIS would be concerned if any [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.³³⁸

From the outset of the program's launch, FDA and USDA warned the Smart Choices Program that they would be watching closely to ensure that the claims made by its labels were not misleading and were not attempting to make processed foods appear as healthy as unprocessed, whole foods. Despite the agencies' increased monitoring activity, few industry observers predicted the scope of the controversy that would erupt over Smart Choices in the late fall of 2009 and how it would accelerate the FDA's plans for regulating front-of-package labeling.

Recent and Future FDA Activity Surrounding Point-of-Purchase Food Labeling

While some agency observers have criticized the FDA's rather deliberate approach in responding to conflicting front-of-package labels and grocery rating systems, there now appears to be a concerted interagency effort to address the issue. In addition to funding consumer perception research and stepping up its monitoring of nutrition rating systems, the FDA is evaluating its potential role in developing and regulating a uniform front-of-package food guidance system to complement the Nutrition Facts panel. The events of the fall of 2009 illustrate that federal regulation of nutrition rating systems is not far on the horizon.

On September 21, 2009, Congresswoman Rosa DeLauro (D-CT) sent a letter to FDA Commissioner Margaret Hamburg urging the agency to conduct an official investigation into the Smart Choices Program. Representative DeLauro's letter urged the FDA to investigate whether Smart Choices-labeled products are misbranded under the FDCA. The letter noted that the FDA was already monitoring the claims made by Smart Choices, but called on the agency to take more aggressive action, if necessary, to prevent Smart Choices from making false or misleading nutrition claims that may confuse consumers. It also encouraged the FDA and USDA to work with the Institute of Medicine to identify, through consumer behavior research, the most effective front-of-package labeling or other nutrition rating approach for helping consumers make healthier food choices. In response to Representative DeLauro's letter, an FDA spokesperson provided the following statement: "We share the congresswoman's concerns and will continue to look very hard at . . . Smart Choices as well as front-of-pack nutrition labeling programs overall." Smart Choices as well as front-of-pack nutrition labeling programs overall."

Roughly one month later, on October 19, 2009, FDA Commissioner Margaret Hamburg responded directly to Representative DeLauro's concerns about Smart Choices.³⁴⁴ In that letter, Commissioner Hamburg stated that the FDA has serious concerns about point-of-purchase labeling, including both front-ofpackage labeling and grocery shelf labeling, and is striving to develop a sound, consistent approach to nutrition-related labeling.³⁴⁵ The letter noted that the FDA believes that point-of-purchase labeling can be an effective vehicle for educating consumers about their food choices and helping them construct healthier diets.³⁴⁶ However, it also noted that the agency's research has shown that with front-of-package labeling, consumers are less likely to consult the Nutrition Facts panel. 347 "It is thus essential that both the criteria and symbols used in front-of-package and shelf-labeling systems be nutritionally sound, well-designed to help consumers make informed and healthy food choices, and not false or misleading."348 Commissioner Hamburg stated that the FDA is currently analyzing front-of-package labels that appear to be misleading, as well as looking for symbols that make express or implied nutrient content claims that are not authorized by the agency's regulatory criteria. 349 Lastly, Commissioner Hamburg's letter stated that the agency is developing a proposed regulation that would more clearly define the nutritional criteria that would have to be met by manufacturers making front-of-package or shelf label claims, with the goal of providing "standardized, science-based criteria on which [front-of-package] nutrition labeling must be based."350

Next, on October 20, 2009, the FDA issued a "Guidance for Industry" letter advising food manufacturers that it will be investigating whether front-of-package logos and shelf ratings violate federal nutrition labeling laws.³⁵¹ The letter stated that FDA has an interest in ensuring that the information on the Nutrition Facts panel matches the nutritional claims made on the front of the package, and will be analyzing front-of-package claims that appear misleading.³⁵² As the agency's letter explained:

It is important to note that nutrition-related FOP [front-of-package] and shelf labeling, while currently voluntary, is subject to the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined

in FDA regulations. Therefore, FOP and shelf labeling that is used in a manner that is false or misleading misbrands the products it accompanies. Similarly, a food that bears FOP or shelf labeling with a nutrient content claim that does not comply with the regulatory criteria for the claim as defined in Title 21 Code of Federal Regulations (CFR) 101.13 and Subpart D of Part 101 is misbranded. We will consider enforcement actions against clear violations of these established labeling requirements.³⁵³

The agency recommended that manufacturers and distributors of food products that include front-of-package labels take care to ensure that label claims are consistent with federal law and FDA regulations.³⁵⁴ The letter also stated that the agency is currently researching the various labeling systems and exploring the potential benefits of taking an approach similar to that used in the United Kingdom, where the government established criteria for front-of-package labeling and retailers took the initiative to voluntarily implement such labeling in their stores.³⁵⁵ The FDA's letter stated that if voluntary action by the food industry does not result in a common, sound approach to front-of-package and grocery shelf labeling, the agency will use its regulatory tools toward that end.³⁵⁶ Finally, the letter stated that the FDA will be working with its sister public health agencies and the USDA to pursue regulation of front-of-package labeling.³⁵⁷

Although the FDA did not name specific products or provide a timeline for promulgation of regulations in its Guidance for Industry Letter, Commissioner Hamburg provided more details in a telephone press conference on the day of the letter's release. Commissioner Hamburg noted that "[t]here are products that have gotten the Smart Choices check mark that are almost 50% sugar," while other products bear symbols indicating that they supply a high percentage of the recommended daily vegetable requirements and other nutrients, but neglect to mention that they also contain 80% of the recommended daily fat intake. 358 According to Hamburg, "[t]here's a growing proliferation of forms and symbols, check marks, numerical ratings, stars, heart icons and the like. There's truly a cacophony of approaches, not unlike the tower of Babel."359 Therefore, the FDA plans to develop a series of proposed standards that companies must follow when using point-of-purchase nutrition labels. Under the regulatory changes being discussed, using front-of-package nutrition labels would continue to be voluntary, but if manufacturers choose to do so, then they would have to comply with FDA regulations.³⁶⁰ According to one source, the proposed rules could be issued within a few months, with plans to release to release the final rules by the end of 2010.361

Also on October 20, 2009, the FDA posted a backgrounder on point-of-purchase labeling on its website. This backgrounder states that the agency's "research suggests FOP labels can give consumers an overrated view of a food's healthfulness, and make it less likely that consumers will read the complete Nutrition Facts information on the back." Regarding the FDA's future plans to exercise its regulatory authority, it states:

FDA is developing a proposed regulation that would define the nutritional criteria that would have to be met by manufacturers making broad FOP or shelf label claims concerning the nutritional quality of a

food, whether the claim is made in text or in symbols. FDA's intent is to provide standardized, science-based criteria on which FOP nutrition labeling must be based.³⁶⁴

Finally, the backgrounder notes that the nutrition community will have the opportunity to weigh in on issues related to point-of-purchase labeling through an Institute of Medicine study on front-of-package labeling, which the FDA, USDA, and the Centers for Disease Control and Prevention (CDC) are assisting the IOM in developing.³⁶⁵

There has been a push for an Institute of Medicine study on front-of-package food labeling for several years that has come to fruition. The IOM study is titled Examination of Front-of-Package Nutrition Rating Systems and Symbols, and is co-sponsored by the FDA and the CDC.³⁶⁶ On January 11, 2010, the IOM announced the members appointed to the study committee and outlined the committee's plans for undertaking a comprehensive review of front-ofpackage nutrition rating systems.³⁶⁷ In Phase I of the study, the IOM intends to identify the various front-of-package systems being used in the United States and abroad; consider the purposes and merits of front-label nutrition icons; and consider the advantages and disadvantages of the various approaches, for both adults and children.³⁶⁸ Using information gained from this assessment, the IOM will plan Phase II of the study, which will "consider the potential benefits of a single, standardized front-of-package food guidance system regulated by the Food and Drug Administration," as well as "develop conclusions about which system(s) are most effective in promoting health and how to maximize the use and effectiveness of the system(s)."369 The IOM committee's Phase I report is expected in 2010.³⁷⁰

This two-phase IOM study may require considerable time for investigation, synthesis, and publication, which raises the question of whether the FDA intends to wait for the IOM committee's recommendations before taking regulatory action on front-of-package labeling and other nutrition rating systems. If so, federal regulation of nutrition rating systems could still be a few years away, and, in the interim, consumers may continue to be faced with competing, potentially confusing nutrition claims. This possibility has prompted Marion Nestle to suggest that the FDA issue a moratorium on the use of front-of-package labels until the IOM committee has completed its work.³⁷¹

As demonstrated by the preceding discussion, there now appears to be a concerted federal effort underway to tackle the problems posed by competing nutrition rating systems, and to improve the nation's food labeling system in general. It will be interesting to watch the FDA and its sister public health agencies navigate these uncharted waters, and to strike a balance between encouraging industry innovation and product reformulation, while also requiring industry accountability.

Role of State Consumer Protection Laws in Addressing Misleading Food Labeling

While the FDA has primary responsibility for taking enforcement action when front-of-package labeling makes misleading or unauthorized nutrient content claims, state attorneys general may play an equally important role in addressing potentially misleading food labeling practices. Attorneys general are responsible for enforcing state consumer protection statutes, of which every state has some variety. While state consumer protection statutes vary, they generally bar marketing or advertising practices that are unfair and/or deceptive. According to one commentary, consumer protection statutes are becoming increasingly popular vehicles for bringing claims against companies marketing unhealthy food products to children.³⁷² While consumer protection litigation against the food industry has not been very successful to date, in terms of judgments obtained, it may bring other benefits. For instance, the negative publicity that often accompanies litigation could influence food industry defendants to make voluntary changes in their food marketing practices.

A recent example from the Smart Choices controversy highlights the impact that attorney general investigations and threats of potential litigation may have on food marketing practices. On October 15, 2009, Connecticut Attorney General Richard Blumenthal announced that his office was launching an investigation of the Smart Choices Program.³⁷³ The investigation aimed to determine if Smart Choices violates state consumer protection laws barring false or misleading claims. In letters to the program's participating manufacturers, Attorney General Blumenthal expressed concern that Smart Choices was "overly simplistic, inaccurate and ultimately misleading."³⁷⁴ As he explained in a press release:

These so-called Smart Choices seem nutritionally suspect – and the label potentially misleading ... Our investigation asks what objective scientific standards, research or factual evidence justify labeling such products as 'smart.' ... What is so smart about mayonnaise, Froot Loops and Cocoa Puffs? ... Busy moms and dads deserve truth in labeling – particularly when their children's' health is at stake. ... At a time when healthcare efforts rightly focus on prevention of obesity and malnutrition, false and misleading labels may derail, destroy and delay such laudable national goals. Meaningful nutritional information is welcome, but not faux food facts.³⁷⁵

The Connecticut Attorney General's Office requested information from the Smart Choices Program, the organizations that administer the program (American Society for Nutrition and NSF International), and food manufacturers whose products bore the Smart Choices label.³⁷⁶ The investigation sought details about the consumer research and selection criteria underlying the Smart Choices Program, the fees involved in administering the program, and any payments or other developmental role that major food manufacturers might have provided the program.³⁷⁷

As mentioned previously, the Connecticut Attorney General's investigation into Smart Choices garnered widespread publicity in mid-October 2009.³⁷⁸ In interviews with the press, Attorney General Blumenthal said that he had discussed his office's investigation with attorneys general from other states and

several had expressed interest in joining his effort.³⁷⁹ The New York Times noted that in other prominent consumer protection cases, states have worked together to pursue corporations or industries, such as tobacco manufacturers and subprime lenders, over deceptive marketing charges.³⁸⁰ James E. Tierney, Director of the National State Attorneys General Program at Columbia Law School, noted that state attorneys general frequently act on consumer issues that might take federal regulators much longer to address, thereby prompting changes in industry practices on a much sooner basis.³⁸¹ Tierney also lauded Blumenthal's efforts, commenting that protecting consumers against unfair and deceptive marketing practices is the core duty of state attorneys general.³⁸² Within days after Attorney General Blumenthal issued a press release calling on all participating manufacturers to stop using the Smart Choices logo,³⁸³ all had agreed to do so, including ConAgra Foods, General Mills, Kellogg's, Kraft Foods, PepsiCo, Riviana Foods, Sun-Maid, and Unilever.³⁸⁴

To date, consumer protection litigation against food companies has been relatively rare, and many cases have failed to survive the dismissal or summary judgment stage and actually proceed to trial. However, this does not mean that consumer protection litigation may not become an attractive strategy to bring attention to misleading food industry marketing practices in the future. Moreover, as Connecticut Attorney General Blumenthal's investigation of Smart Choices demonstrates, the exercise of investigatory authority and the mere threat of litigation may have a powerful impact on potentially deceptive marketing schemes, leading to increased consumer awareness and voluntary changes in corporate practices. As one commentary has noted: "From a public health standpoint, successful litigation does not always require a victory in court; the goal of litigation can be to change public perception of an industry and ultimately to induce a change in industry practices." 385

Conclusion

Front-of-package labels and grocery shelf rating systems have the potential to make nutrition information more readily accessible, inform consumers' food purchasing decisions, and improve the overall quality of Americans' diets. Select corporate sales data suggests that nutrition rating systems influence consumers' food choices in a positive way. Nutrition rating systems also hold the potential to positively influence food manufacturing practices by encouraging product reformulation, as menu labeling in chain restaurants has reportedly done.³⁸⁶

But the efficacy and validity of nutrition rating systems still needs to be tested in the marketplace. Solid data is lacking about whether nutrition rating systems actually succeed in improving consumers' food choices and helping them to construct healthier diets. On one hand, numerous studies have demonstrated that it is difficult to gauge consumer responsiveness to nutrition labeling and some research suggests that consumers' use of nutrition labels is declining. On the other hand, one might argue that nutrition rating systems will succeed in making an impression on consumers where the Nutrition Facts panel has failed because their colorful, graphic messages are harder to ignore and easier to comprehend. Of course, resonating with consumers will only be helpful if a front-of-package label or grocery shelf rating provides an accurate synopsis of a food's overall nutrition quality, since research has shown that consumers tend to truncate their search for nutrition information if symbols or other nutrient content claims are present.³⁸⁷

Additional research is needed to determine which nutrition rating approaches appeal most to consumers and have the greatest potential to influence their food purchasing decisions.³⁸⁸ At present, we simply do not know which kind of nutrition rating format works best in educating consumers – is it a single checkmark, a traffic light system, a range of one to three stars, or a numeric score from one to 100?³⁸⁹ Further, aside from the question of which format consumers appear to prefer is the more important issue of whether nutrition rating systems actually impact the overall quality of consumers' diets. Unless consumers use nutrition symbols and ratings to consistently make healthier food purchasing decisions that result in more balanced diets and improved health outcomes, their only real utility will be as marketing tools.

While existing research suggests that front-of-package symbols and grocery shelf ratings can influence consumers to select the labeled items, it is not known whether this effect is consistent across different demographic groups. It is also unclear whether, in the long term, front-of-package labels and shelf ratings will have a significant enough impact on consumer behavior and dietary choices to contribute to the prevention of obesity and diet-related diseases. Future research efforts might also be directed at measuring the synergistic effect of front-of-package and shelf labeling at the grocery store with menu labeling at restaurants, and how the greater accessibility of nutrition information in both venues might impact Americans' diets. Restaurant food purchasing decisions are important because an estimated 46% of Americans' food dollars are spent and roughly one-third (32%) of our calories are consumed in away-from-home settings. While a potentially promising strategy for obesity prevention, at present, studies on the efficacy of menu labeling in curbing calorie intake

present somewhat mixed results.³⁹² In sum, considerable research is necessary to determine how to best present nutrition information to consumers in a way that will lead to the selection of healthier foods, improve the quality of Americans' diets, and result in better overall health outcomes in the United States.³⁹³

Because each nutrition rating system utilizes a unique scoring approach and is based on underlying criteria that place different values on a wide variety of nutrients, it appears essential to achieve some degree of standardization to prevent consumer confusion. As long as multiple and varied nutrition rating systems are competing against each other, it is unlikely that nutrition experts, industry representatives, and consumer activists will agree on the best format or set of underlying nutritional criteria. Perhaps the best solution is the development and federal regulation of a standardized nutrition rating system that can be used in all American markets and rigorously evaluated for its validity and efficacy. As one nutritionist has stated, "[c] onsumers do not need to be bombarded with more confusing nutrition information." 394

APPENDIX A: What's in a Label?

	What it is	How it works	Who uses it	How it rates	Example: Frosted Flakes
Guiding Stars guidingstars.com	Launched in 2006, Guiding Stars is an in-store nutrition rating system developed by an advisory panel of doctors, scientists, and dieticians to help consumers identify healthier foods. Guiding Stars labels are placed on shelf tags, aisle signage, and private label brand packaging.	Foods are given a rating of 1 ("good"), 2 ("better"), or 3 ("best") stars. Guiding Stars uses four different algorithms to assess foods. The system is point-based, crediting points for positive nutrition attributes and debiting points for negative attributes.	Hannaford Bros., Bloom, Food Lion, Sweet Bay	Foods are rated using the same system regardless of price, brand, or manufacturer. The stars system is easy to use and understand. Sales data suggest the system can influence consumer purchasing behavior. However, not all products in the store are rated.	Would not qualify for any stars
NuVal nuval.com	Launched in 2008, NuVal was developed by a team of nutrition and medical experts to help consumers recognize healthier food choices. NuVal scores are displayed on shelf tags and aisle signage.	NuVal scores foods on a scale of 1 to 100 using an algorithm called the Overall Nutritional Quality Index (ONQI). The higher the NuVal score, the higher the nutritional quality of the food.	Price Chopper, Hy-Vee, Meijer	NuVal is an independent rating system, reportedly developed without food manufacturer or retailer influence. NuVal allows shoppers to compare similar food items within the same product category, as well as across different product categories.	22 out of 100
Healthy Ideas stopandshop.com healthy ideas	Giant Foods and Stop & Shop supermarkets launched the Healthy Ideas shelf tag system in early 2009 with the goal of making it easier for consumers to select healthy foods.	Healthy Ideas' criteria are based on FDA and USDA guidelines. To earn a symbol, a food must have limited cholesterol, sodium, total fat, and saturated fat and must contain at least 10% of the federal nutrition guidelines for one or more specified nutrients. Fresh produce automatically qualifies.	Giant Foods, Stop & Shop	Nutritional criteria are based on accepted federal nutritional guidelines. The symbol is easy for consumers to use and recognize. The system does not assess foods of low nutritional value (e.g., candy, ice cream, cookies) or most beverages.	Would not qualify for symbol
nutrition iQ nutritioniq.com	Nutrition iQ is a color-coded shelf labeling system that aids shoppers in choosing low fat, high fiber, and other healthy foods. Nutrition iQ labels began appearing in SuperValu stores in 2009.	Based on the FDA's criteria for nutrient content claims, nutrition IQ evaluates whether an item is an "excellent" or "good" source of fiber, calcium, and protein. It also takes sodium, fat, and calories into account. For example, this colorcoded system assigns a yellow tag to foods that are an excellent source of protein.	SuperValu grocery stores nationwide, including Jewel-Osco, Cub Foods, Albertson's	Nutrition IQ provides consumers with an at-a-glance snapshot of the nutritional value of foods. However, the color-coded signage could be confusing, as information regarding the significance of the colors may not be readily available to or understood by consumers.	Would not qualify for symbol
Smart Choices smartchoicesprogram.com	Smart Choices is a pan-industry effort, developed by a coalition of manufacturers, retailers, nutrition experts and health organizations, to promote a standardized benchmark for front-of-package (FOP) labeling.	To qualify, a product must meet certain criteria based on the Dietary Guidelines for Americans. Foods are divided into 19 different food or product categories, each of which has its own customized nutritional criteria, and Smart Choices selects qualifying products within each category.	Initially endorsed by a variety of manufacturers, including General Mills, Kellogg's, Kraft, and Con Agra. Currently suspended.	Despite its collaborative development, critics questioned the program's nutritional criteria and its funding mechanism. Smart Choices suspended operations after the FDA announced it would be investigating whether such systems comply with federal nutrition labeling laws.	Would qualify for symbol

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- ³ CAROLYN L. ENGELHARD ET AL., URBAN INST., REDUCING OBESITY: POLICY STRATEGIES FROM THE TOBACCO WARS 34 (2009); Josephine M. Wills et al., Exploring Global Consumer Attitudes Toward Nutrition Information on Food Labels, 67 NUTRITION REV. S102, S105 (2009).
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- ¹⁵ *Id*.
- Rachel K. Johnson et al., Dietary Sugars Intake and Cardiovascular Health: A Scientific Statement From the American Heart Association, 120 Circulation 1011, 1014 (2009), available at http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.109.192627. See also Press Release, The American Heart Ass'n, Association Recommends Reduced Intake of Added Sugars (Aug. 24, 2009), available at http://americanheart.mediaroom.com/index.php?s=43&item=800.
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- ²⁸ Press Release, General Mills, *supra* note 26.
- ²⁹ Id. In practice, however, this twelve gram "limit" permits a cereal to be comprised of over 40% sugar per serving. RUDD CTR. FOR FOOD POLICY & OBESITY, CEREAL F.A.C.T.S.: EVALUATING THE NUTRITION QUALITY AND MARKETING OF CHILDREN'S CEREALS 11 (2009).
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- William Neuman, Food Label Program to Suspend Operations, N.Y. TIMES, Oct. 23, 2009, available at http://www.nytimes.com/2009/10/24/business/24food. html.
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- ⁶⁰ Id.
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- 87 Id.
- Timothy M. Martin & Janet Adamy, Low-Fat, Aisle 2: Grocer to Flag Health-ful Foods, Wall St. J., Jan. 15, 2009, available at http://online.wsj.com/article/SB123198101192383923.html. See also Matt McKinney, Signs Point the Way to Healthful Eating, Mpls. Star Trib., July 13, 2009, available at http://www.startribune.com/business/50682482.html; Press Release, American Dietetic Ass'n, Supermarkets Get in the Game of Nutrient Profiling: Shelf Tags Could Be Displaying More Than Prices As Store Chains Launch Nutrition Symbols to Help Shoppers Indentify Healthy Foods (May 26, 2009), available at http://www.eatright.org/Media/content.aspx?id=1250.
- 89 Cub Foods Makes Smart Eating Easy & Colorful, Bus. Wire, Jul. 14, 2009; Nutrition iQ Comes to Cub Foods, Supermarket News, Jul. 15, 2009.
- ⁹⁰ Knowing the Score, supra note 50.
- 91 See Stop & Shop, Healthy Ideas, http://www.stopandshop.com/living_well/healthy_living.htm (last visited Aug. 17, 2009).
- 92 Id
- ⁹³ Stop & Shop, Healthy Ideas, About the Program, http://www.stopandshop.com/living_well/healthy_living/about_program.htm (last visited Aug. 17, 2009).

- 94 Stop & Shop, Healthy Ideas, Healthy Ideas Criteria, http://i4.peapod.com/ wp/media/living_well/hi_criteria_sns-1.0.1.pdf.
- 96 Deardorff & Mills, supra note 48.
- ⁹⁷ Id.
- 98 Press Release, American Dietetic Ass'n, supra note 88.
- 100 See Kunkel & McKinley, supra note 11, at S27 (stating that "[t]he likely problems associated with a diverse landscape of idiosyncratic definitions of 'healthful' food include consumer confusion"); Eileen Kennedy et al., Alternative Approaches to the Calculation of Nutrient Density, 66 NUTRITION REV. 703, 704 (2008).
- ¹⁰¹ Andrew Martin, Some Big Food Companies Adopt Nutrient Standards, N.Y. Times, Oct. 28, 2008, available at http://www.nytimes.com/2008/10/28/ business/28food.html.
- 102 The Keystone Ctr., Food and Nutrition Roundtable, http://www.keystone. org/spp/health-and-social-policy/chronic-disease-healthy-lifestyles (last visited Aug. 21, 2009); The Keystone Ctr., Keystone Food and Nutrition Roundtable Fact Sheet (Jan. 2008), available at http://www.americanheart. org/downloadable/heart/1213390083589Keystone%20Roundtable%20 Fact%20Sheet-Jan%20%2008.pdf. For a list of the stakeholders that participated in the Keystone Food and Nutrition Roundtable, see Susan Borra's presentation, A Coalition Approach to Front-of-Pack Labeling, delivered at the Tufts University Friedman School's 2008 Symposium, https://secure.nutrition.tufts.edu/lectures/symposium_2008/borra/(slide 6, Who Is Involved?). It should be noted that not all of the stakeholders that participated in the Keystone Roundtable ended up endorsing Smart Choices. For instance, the Center for Science in the Public Interest (CSPI) withdrew its support for the initiative over concerns about Smart Choices' nutritional criteria. See Letter from Michael Jacobson, Executive Director of the Ctr. for Science in the Public Interest, to Brad Sperber, Senior Associate, The Keystone Ctr. (Oct. 2, 2008) (on file with author).
- 103 See The Keystone Ctr., Keystone Food and Nutrition Roundtable Factsheet (Jan. 2008). See also Press Release, The Keystone Ctr., New Front-of-Pack Nutrition Labeling Program Designed to Help Shoppers Make More Nutritious Food and Beverage Choices (Oct. 27, 2008).
- 104 For a complete list of the food manufacturers that pledged to adopt Smart Choices as of August 2009, see the program's brochure at http://www.smart-choicesprogram.com/pdf/Smart_Choices_Program_Insert.pdf.
- 105 See Smart Choices Program, http://www.smartchoicesprogram.com/index. html (last visited Aug. 21, 2009).
- 106 Paul Swiech, Smart Choices Program Debuts With Labels on Foods, So. WIRE Serv., Aug. 1, 2009.
- 107 Press Release, Unilever, Unilever Products Qualify for Smart Choices Program (Aug. 5, 2009), available at http://www.unileverusa.com/ourcompany/ newsandmedia/pressreleases/2009/Unilever-Products-Qualify-for-Smart-Choices-Program.asp.
- 108 Smart Choices Program, http://www.smartchoicesprogram.com/index.html (last visited Aug. 21, 2009); Smart Choices Program, Guiding Smarter Food & Beverage Choices - Brochure, available at http://www.smartchoicesprogram.com/pdf/Smart_Choices_Program_Insert.pdf.
- 109 See infra pp. 19-20.
- 110 See infra pp. 37-38.
- ¹¹¹ Letter from Michael Jacobson to Brad Sperber, supra note 102.
- 112 Smart Choices Program, For Health Professionals, http://www.smartchoicesprogram.com/professionals.html (last visited Aug. 21, 2009).
- ¹¹³ Knowing the Score, supra note 50, at 2.
- ¹¹⁴ *Id*.
- 116 A matrix explaining the Smart Choices Program's nutritional criteria is available on the program's website. See Smart Choices Program, Nutrition Criteria, Nutrition Criteria for the Smart Choices Program, ttp://www.smartchoicesprogram.com/pdf/Smart%20Choices%20Program%20Nutrition%20 Criteria%20Matrix.pdf.
- 117 Karen Kaplan, Froot Loops: A Nutritious Part of a Complete Breakfast?, L.A. Times, Sept. 10, 2009, http://latimesblogs.latimes.com/booster_ shots/2009/09/smart-choices-sugary-cereal.html; William Neuman, For Your Health, Froot Loops, N.Y. Times, Sept. 5, 2009, available at http://www. nytimes.com/2009/09/05/business/05smart.html?emc=eta1.

- 118 Smart Choices Program, Nutrition Criteria and Calorie Indicator, http:// www.smartchoicesprogram.com/nutrition.html (last visited Aug. 21, 2009).
- 120 Id.
- ¹²¹ *Id*.
- ¹²² *Id*.
- ¹²³ Knowing the Score, supra note 50, at 2.
- ¹²⁴ Smart Choices Program, Nutrition Criteria for the Smart Choices Program, http://www.smartchoicesprogram.com/pdf/Smart%20Choices%20Program%20Nutrition%20Criteria%20Matrix.pdf.
- ¹²⁵ *Id*.
- 127 Smart Choices Program, Nutrition Criteria and Calorie Indicator, supra note 118.
- ¹²⁸ *Id*.
- 129 Id.
- ¹³⁰ *Id*.
- 131 Kaplan, supra note 117; Neuman, supra note 117.
- 132 Neuman, supra note 117. Eileen T. Kennedy, Dean of the Friedman School of Nutrition Science & Policy at Tufts University and member of the Smart Choices Board of Directors, has defended the program's nutritional criteria as being based on government dietary guidelines and accepted nutritional standards. *Id.* However, according to Dr. Walter Willett, Chair of the Nutrition Department at the Harvard School of Public Health, the criteria employed by Smart Choices are seriously flawed, as evidenced by unhealthy products like sugary cereals and salty snack foods qualifying for the symbol. Id. Dr. Marion Nestle, Professor of Nutrition, Food Studies, and Public Health at New York University, has also sharply criticized the Smart Choices Program's nutritional criteria. See Randall Pinkston, Experts Say Industry Food Labels Deceptive: Manufacturers Add "Smart Choices" Labels to Packages, Mimicking Government Nutrition Labels; Bid to Push Processed Foods?, CBS EVENING News, Sept. 6, 2009, http://www.cbsnews.com/stories/2009/09/06/eveningnews/main5291352.shtml?tag=cbsnewsTwoColUpperPromoArea.
- 133 Are Smart Choices' nutritional criteria too permissive when it comes to added sugars? Critics have questioned whether the program's criteria selectively permit the labeling of sugary cereals marketed primarily to young children. Although there is no tolerable upper intake level for sugar, most nutritionists would agree that calories from added sugars should be limited. The Institute of Medicine recommends that added sugars comprise no more than 25% of all calories consumed. See Inst. of Med., Dietary Reference Intakes FOR ENERGY, CARBOHYDRATE, FIBER, FAT, FATTY ACIDS, CHOLESTEROL, PROTEIN, AND AMINO ACIDS, supra note 45. Yet Smart Choices allows cereal products to contain up to twelve grams of added sugars, allowing Kellogg's Frosted Flakes and Froot Loops and General Mill's Reese's Puffs to qualify for the Smart Choices logo, despite the fact that they derive a significant proportion of their calories from sugar. Neuman, supra note 117. The Dietary Guidelines for Americans caution that "added sugars supply calories but few or no nutrients" and recommend that children avoid "excessive amounts of calories from added sugars." U.S. Dep't of Health & Human Serv. & U.S. DEP'T OF AGRIC., DIETARY GUIDELINES FOR AMERICANS 35, 37 (6th ed. 2005). Smart Choices' allowance of twelve grams of added sugar in cereal products constitutes over 30% of the total amount of added sugar the USDA recommends for adults who eat a 2,000 calorie a day diet. *Id.* at 36 (noting that a 2,000 calorie a day diet allows for only 267 discretionary calories; "at 29% of calories from total fat ... then only 8 teaspoons (32 g) of added sugars can be afforded"). For young children, twelve grams of added sugar would constitute an even higher percentage, particularly if the recommended serving size was exceeded. Kaplan, supra note 117.
- ¹³⁴ Nutritionists would likely agree that it would be preferable for a nutrition rating system to promote greater fresh fruit and vegetable consumption over eating "healthy" snack foods, even if processed or fortified for optimal nutrition. But nutrition rating systems are typically funded by processed food manufacturers, so profit motive cannot be ignored. For example, FritoLay and its parent company, PepsiCo, may encourage consumers to eat baked Fritos because they are "better for you," but ultimately, their goal is likely to get consumers to buy more chips. Industry-funded nutrition rating systems are ultimately marketing tools. See Marion Nestle, "Better" Junk Food About Marketing, Not Health, S.F. Chron., July 24, 2009, available at http://www. sfgate.com/cgi-bin/article.cgi?f=/c/a/2009/07/26/FDVK18ITKJ.DTL.
- 135 U.S. Dep't of Agric., MyPyramid, Inside the Pyramid, What's in the Grain Group?, http://www.mypyramid.gov/pyramid/grains.html (last visited Dec. 17, 2009).

- ¹³⁶ Neuman, supra note 117.
- ¹³⁷ Nightline, Food Label Fight: Are Supermarket Products Boasting "Smart Choice" Labels Really Healthier? (ABC News television broadcast Sept. 18, 2009), http://abcnews.go.com/video/playerIndex?id=8617369 (statement of Mark Bittman, New York Times food columnist and cookbook author).
- ¹³⁸ U.S. Dep't. of Health & Human Services/U.S. Dep't of Agriculture, Dietary Guidelines for Americans 2005, Key Recommendations for the General Population, http://www.health.gov/dietaryguidelines/dga2005/recommendations.htm (last visited Dec. 17, 2009).
- ¹³⁹ Neuman, supra note 117.
- 140 Id.
- ¹⁴¹ Neuman, supra note 117.
- 142 Id. (quoting Marion Nestle).
- ¹⁴³ Neuman, supra note 47. It may be noted that the Keystone Food and Nutrition Roundtable meetings began in 2007, around the same time that the FDA held public hearings on front-of-package food labeling and requested comments on whether the agency should develop standards for a uniform front-of-package labeling system. See infra p. 34.
- ¹⁴⁴ A list of the individuals currently serving on the Smart Choices' Board of Directors can be found on the program's website. Smart Choices Program, For Media, Smart Choices Program Elects Board of Directors, http://www.smartchoicesprogram.com/pr_090624_bod.html (last visited Aug. 21, 2009). For the next year, the ninth, "neutral" seat will be held by Michael Hughes, Vice President and Director of the Center for Science and Public Policy at the Keystone Center. *Id.*
- ¹⁴⁵ See, e.g., Marion Nestle, Open Letter to Nutrition Colleagues, Food Politics Blog, http://www.foodpolitics.com/2009/05/open-letter-to-nutrition-colleagues/ (May 11, 2009).
- ¹⁴⁶ Nestle, *supra* note 134 (stating that the best way to sell more junk foods is to make them appear healthier, and "[t]he best way to do that is to entice nutrition experts to create easier standards").
- ¹⁴⁷ McKinney, supra note 88.
- ¹⁴⁸ Rebecca Ruiz, Smart Choices Foods: Dumb As They Look?, Forbes, Sept. 17, 2009, http://www.forbes.com/2009/09/17/smart-choices-labels-lifestyle-health-foods_print.html.
- 149 Id.; Neuman, supra note 117. The fees associated with Smart Choices, even though sliding scale, may deter smaller food companies and natural foods manufacturers from participating in the program, which may give consumers the false impression that their products are not "better for you" choices. The omission of nearly all natural and organic food companies from front-of-package labeling is problematic, because their products might be among the healthiest choices within product categories, but the average consumer might not know it
- ¹⁵⁰ Marion Nestle, Kellogg's Asks for a Froot Loops Correction. More on Smart (?) Choices, Food Politics Blog, http://www.foodpolitics.com/2009/09/kelloggs-asks-for-a-froot-loops-correction-more-on-smart-choices/ (Sept. 5, 2009).
- 151 Ruiz, supra note 148.
- ¹⁵² Id. This \$700,000 contribution from food companies reportedly covered Keystone Center staffing, as well as meeting and travel costs for the Keystone Roundtable process. It was not a service fee for, nor a profit to, the Keystone Center
- ¹⁵³ *Id*.
- 154 The Keystone Ctr., Insights and Outcomes: The Keystone Center Annual Report 08 16 (2008), available at http://keystone.org/files/file/about/annual-report/KeystoneCenter-2008-annual-E-EDITION.pdf. The Keystone Center's 2008 annual report lists the following food corporations has having donated \$50,000 or more: Con Agra Foods, Kellogg Company, Kraft Foods, Nestle USA, The Coca Cola Company, and Unilever Bestfoods. The General Mills Foundation and the PepsiCo Foundation are listed has having donated between \$25,000-\$49,999.
- 155 According to Michael Jacobson, Executive Director of the Center for Science in the Public Interest (CSPI), the panel of experts that developed the Smart Choices program was dominated by food industry representatives, whose interests skewed the panel's decisions. Neuman, supra note 117 (quoting Jacobson as stating: "It was paid for by industry and when industry put down its foot and said this is what we're doing, that was it, end of story."). See also Mary MacVean, "Smart Choices" Food Label: A Sign of Nutrition or Marketing?, L.A. Times, Sept. 29, 2009, available at http://www.latimes.com/news/nationworld/nation/la-sci-smart29-2009sep29,0,5784705,print.story. CSPI participated in the Keystone Food and Nutrition Roundtable process until September 2008, when it withdrew, citing concerns about the Smart Choices

- Program's nutritional criteria. See Letter from Michael Jacobson to Brad Sperber, supra note 102.
- ¹⁵⁶ MacVean, supra note 155.
- 157 Ruiz, supra note 148.
- ¹⁵⁸ Jeffrey Blumberg, Professor, Tufts Univ. Friedman Sch. of Nutrition Science & Policy, Guiding Stars Program Update, Presentation at the 4th Annual Friedman School Symposium: Nutrition Agenda 2009 & Beyond (Sept. 11, 2009).
- 159 MacVean, supra note 155 (quoting Smart Choices board members Michael Hughes (Keystone Center) and Celeste Clark (Kellogg's), as well as guidelines committee member Joanne Lupton (Texas A&M University)); Randall Pinkston, Experts Say Industry Food Labels Deceptive: Manufacturers Add "Smart Choices" Labels to Packages, Mimicking Government Nutrition Labels; Bid to Push Processed Foods?, CBS Evening News, Sept. 6, 2009, http://www.cbsnews.com/stories/2009/09/06/eveningnews/main5291352.shtml?tag=cbsnewsTwoColUpperPromoArea (quoting Dr. Richard Kahn, former Chief Scientific and Medical Officer for the American Diabetic Association and current Smart Choices board member).
- 160 MacVean, supra note 155 (noting that almost all of Kellogg's breakfast cereals qualify for the Smart Choices label, in part, because some were reformulated to reduce their sugar content and increase their fiber content).
- ¹⁶¹ See, e.g., Nightline, supra note 137; Ruiz, supra note 148.
- ¹⁶² MacVean, *supra* note 155.
- ¹⁶³ For example, the activist group Change.org launched a letter-writing campaign asking medical and nutrition experts, academic institutions, and health organizations to rescind their support for the Smart Choices Program. See Change.org, Don't Let Kellogg's Buy Scientists: Froot Loops Aren't a Healthy Breakfast, http://www.change.org/actions/view/dont_let_kelloggs_buy_scientists_froot_loops_arent_a_healthy_breakfast (last visited Sept. 29, 2009). By late September 2009, the petition had received over 4,000 signatures. Id.
- ¹⁶⁴ U.S. Food & Drug Admin., Ctr. for Food Safety & Applied Nutrition, Guidance for Industry: Letter Regarding Point of Purchase Food Labeling (Oct. 2009), available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208. htm.
- ¹⁶⁵ Sarah Skidmore, Industry Halts Food Label Program Over FDA Concern, Wash. Post, Oct. 23, 2009, available at http://www.washingtonpost.com/ wp-dyn/content/article/2009/10/23/AR2009102302368.html; Rebecca Ruiz, Smart Choices Fails, Forbes, Oct. 23, 2009, available at http://www. forbes.com/2009/10/23/smart-choices-labeling-lifestyle-health-fda-food-labeling.html.
- 166 Press Release, Smart Choices Program, Smart Choices Program Postpones Active Operations (Oct. 23, 2009), available at http://www.smartchoicesprogram.com/pr_091023_operations.html.
- ¹⁶⁷ Id.
- ¹⁶⁸ *Id*.
- 169 Id.
- ¹⁷⁰ Hughlett, supra note 34; Matt McKinney, General Mills to Drop Sullied Smart Choices Product Label, Mpls. Star Trib., Oct. 27, 2009, available at http:// www.startribune.com/business/66588042.html?page=1&c=y.
- 171 Hughlett, supra note 34.
- ¹⁷² McKinney, supra note 170.
- 173 Ruiz, supra note 165.
- ¹⁷⁴ Neuman, supra note 47.
- ¹⁷⁵ Levy & Fein, *supra* note 2, at 214-15.
- 176 Ingrid Borgmeier & Joachim Westenhoefer, Impact of Different Food Label Formats on Healthiness Evaluation and Food Choice of Consumers: A Randomized-controlled Study, 9 BMC Pub. Health 184 (2009). However, Borgmeier & Westenhoefer note that there is a different between perceived or subjective understanding and actual or objective understanding of nutrition information. At present, there is little research assessing consumers' objective understanding of the information on front-of-package labels, and "virtually no insight into how labelling information will be used in a real-world shopping situation and how it will affect consumers' dietary patterns." Id. at 185.
- ¹⁷⁷ McKinney, supra note 88.
- ¹⁷⁸ Nestle, *supra* note 134.
- ¹⁷⁹ Deardorff & Mills, supra note 13.
- 180 Smart Choices Program, http://www.smartchoicesprogram.com/index.html (last visited Aug. 21, 2009).

- ¹⁸¹ U.S. Dep't of Health & Human Serv. & U.S. Dep't of Agric., Dietary Guidelines for Americans (6th ed. 2005).
- ¹⁸² Janet C. King et al., The Report of the Dietary Guidelines Advisory Committee on Dietary Guidelines for Americans, 2005, App. G-1 (2004), available at http:// www.health.gov/dietaryguidelines/dga2005/report/HTML/G1_Glossary. htm.
- ¹⁸³ Johnson, supra note 16, at 1014.
- ¹⁸⁴ *Id*. at 1017.
- ¹⁸⁵ Margaret Sova McCabe, Loco Labels and Marketing Madness: Improving How Consumers Interpret Information in the American Food Economy, 17 J.L. & Pol'y 493, 512 (2009).
- ¹⁸⁶ Chad Terhune, Pepsi Sales Force Tries to Push "Healthier" Snacks, WALL STREET J., Oct. 5, 2006 (noting that for the first half of 2006, sales of PepsiCo's Smart Spot-labeled items, like Baked Lays, grew by 15%).
- ¹⁸⁷ McKinney, supra note 88.
- ¹⁸⁸ Kunkel & McKinley, supra note 11, at S27.
- ¹⁸⁹ Nestle, supra note 134.
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- ¹⁹¹ Peggy Blitz, Nutrition Rating Systems Enter Marketplace, DAIRY Foods 136 (Jan. 2009).
- ¹⁹² Ninya Maubach et al., The Effect of Front-of-Package Nutrition Information and Product Claims on Consumers' Attitudinal Evaluations and Choice Behavior 2 (2009) (paper presented at the Univ. of Notre Dame Mendoza College of Business 2009 Marketing & Public Policy Conference, May 30, 2009) (citing Alexandra Lewin et al., Food Industry Promises to Address Childhood Obesity: Preliminary Evaluation, 27 J. Pub. Health Pol'y 343 (2006)).
- ¹⁹³ Jennifer Huget, New System Could Help Us Compare Apples and Oranges, Wash. Post, Oct. 7, 2008; Martin, supra note 74 (quoting Professor Adam Drewnowski).
- ¹⁹⁴ Nutrient Rich Foods Coalition, Understanding Nutrient Density, http:// www.nutrientrichfoods.org/for_health_professionals/understanding_nutrient_density.html (last visited Aug. 21, 2009).
- ¹⁹⁵ See U.S. Dep't of Agric., My Pyramid, http://www.mypyramid.gov/ (last visited Aug. 21, 2009).
- ¹⁹⁶ Nutrient Rich Foods Coalition, The Nutrient Rich Foods Approach, http://www.nutrientrichfoods.org/documents/media/nrfc_approach.pdf.
- ¹⁹⁷ Nutrient Rich Foods Coalition, About the Nutrient Rich Foods Coalition, http://www.nutrientrichfoods.org/about_nrfc/index.html (last visited Aug. 21, 2009).
- 198 Huget, supra note 193.
- 199 Blitz, supra note 191.
- ²⁰⁰ Adam Drewnowski & Victor Fulgoni III, Nutrient Profiling of Foods: Creating a Nutrient-rich Food Index, 66 Nutrition Rev. 23 (2007); Victor L. Fulgoni III et al., Development and Validation of the Nutrient-Rich Foods Index: A Tool to Measure Nutritional Quality of Foods, 139 J. Nutrition 1549 (2009).
- ²⁰¹ Blitz, supra note 191.
- ²⁰² Kennedy, supra note 100, at 708.
- ²⁰³ Sylvia Rowe et al., Funding Food Science and Nutrition Research: Financial Conflicts and Scientific Integrity, 109 J. Am. DIETETIC ASS'N 929 (2009).
- ²⁰⁴ Id. at 932-33.
- $^{205}\,\mathrm{Martin},$ supra note 74.
- ²⁰⁶ Deardorff & Mills, *supra* note 13.
- ²⁰⁷ See Rice Krispies Complete With Snap, Crackle and Immunity, Wall St. J., July 29, 2009. In 2009, Kellogg's was widely criticized for placing claims on the front labels of Rice Krispies' packages which read, "Now Helps Support Your Child's Immunity." On October 27, 2009, San Francisco City Aptorney Dennis Herrera invoked his authority under California's Unfair Competition Law and sent a letter to Kellogg's demanding substantiation of this purportedly science-based claim. See Press Release, Office of the City Attorney of San Francisco, Herrera Takes on Kellogg's Over Health Claims in Cocoa Krispies' Marketing (Oct. 27, 2009), available at http://www.sfcityattorney.org/index.aspx?page=248. Roughly one week later, Kellogg's announced that it would pull the immunity claims from Rice Krispies' packages in the face of growing public concern about the H1N1 virus. See Bruce Horovitz, Kellogg Pulls Immunity Claim From Rice Krispies, USA Today, Nov. 4, 2009, available at http://www.usatoday.com/money/industries/food/2009-11-04-kellogg-immunity_N.htm.

- ²⁰⁸ Deardorff & Mills, supra note 13; Huget, supra note 193 (quoting Marion Nestle: "The public is bewildered ... There's a tremendous amount of evidence showing that people say they're confused by the multiple messages.").
- ²⁰⁹ Sarah Hills, Labels For Nutrients Food Contains, Not What It Lacks, foodnavigator-usa.com, Oct. 2, 2008, http://www.foodnavigator-usa.com/Financial-Industry/Labels-for-nutrients-food-contains-not-what-it-lacks.
- ²¹⁰ U.S. Food & Drug Admin., Notice of Agency Information Collection Activities, Internet Survey on Barriers to Food Label Use, 74 Fed. Reg. 42676 (Aug. 24, 2009) (stating that analyses of survey data show a sharp decline in food label use in the U.S. between 1994–2002, particularly among consumers younger than 35 years old).
- ²¹¹ Nat'l Acad. of Sci., Inst. of Med., Food Marketing to Children and Youth: Threat or Opportunity? 325 (2006).
- 212 Id
- ²¹³ Carey, supra note 55; Phil Lempert, Nutrition Ratings: Helpful or Confusing, MSNBC News, Dec. 5, 2007, http://www.msnbc.msn.com/id/22114551/ns/today-today_food_and_wine/.
- ²¹⁴ Press Release, Ctr. for Science in the Public Interest, FDA Urged to Create New "Healthy Food" Labeling System (Nov. 30. 2006), available at http:// www.cspinet.org/new/200611301.html.
- ²¹⁵ U.S. Gov't Accountability Office, Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods (GAO-08-597) 35 (Sept. 2008). European Commission Regulation No. 1924/2006 establishes standards governing when nutrition and health claims can be made, and requires that if a nutrition or health claim is made about a food product, then the manufacturer must provide on-package nutrition information to substantiate the claim. See Corrigendum to Regulation (EC) No. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims Made on Foods, Official Journal of the European Union (2007), available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/1_012/1_01220070118en00030018.pdf.
- ²¹⁶ U.S. Gov't Accountability Office, *supra* note 215, at 35.
- ²¹⁷ Press Release, European Comm'n, Commission Proposal to Overhaul EU Food Labelling Rules, IP/08/112, (Jan. 30, 2008). Under the EC's proposed regulation, front-of-package labeling would be mandatory for all packaged foods sold in the EU. Specifically, the proposed regulation requires that energy (calories), total fat, saturated fat, carbohydrate, sugar, and sodium content per 100 ml/g or per serving size of the product are displayed clearly on the front-of-package label. In addition, the proportion of these nutrients to the reference intakes (Recommended Daily Allowance) must be indicated on the front-of-package label. *Id*.
- ²¹⁸ See, e.g., Feunekes et al., supra note 9; Grunert & Wills, supra note 10 (reviewing consumer research conducted in Europe from 2003-2006 on how consumers perceive, understand, like, and use nutrition information on food labels, including front-of-package labels); Borgmeier & Westenhoefer, supra note 176. See also Josephine M. Wills et al., Exploring Global Consumer Attitudes Towards Nutrition Information on Food Labels, 67 NUTRITION Rev. S102 (2009).
- ²¹⁹ Bridget Kelly et al., Consumer Testing of the Acceptability and Effectiveness of Front-of-Pack Food Labelling Systems for the Australian Grocery Market, 24 HEALTH PROMOTION INT'l 120, 121 (2009).
- ²²⁰ Stephen Castle & Elisabeth Rosenthal, EU Introduces Food Labeling Plan to Cut Obesity Rates, N.Y. Times, Jan. 30, 2008, available at http://www. nytimes.com/2008/01/30/world/europe/30iht-fat.4.9621389.html.
- ²²¹ BBC News, Label Wars: GDA vs. Traffic Lights, Jan. 4, 2007, http://news.bbc.co.uk/2/hi/uk_news/6231137.stm.
- ²²² U.S. Gov't Accountability Office, *supra* note 215, at 37.
- ²²³ D.J. Van Camp, UK Food Manufacturer Responses to Voluntary Front of Package Nutrition Schemes (June 2009) (unpublished thesis, Ohio State Univ., Dept. of Agricultural, Environmental and Development Economics) (on file with author).
- ²²⁴ HM Government, UK Dep't of Health, Healthy Weight, Healthy Lives: A Cross Government Strategy for England 18 (2008), available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_084024.pdf.
- ²²⁵ Kelly, supra note 219, at 121. For information about the European Regulation (EC) No. 1924/2006 on Nutrition and Health Claims, see sources cited supra note 215
- ²²⁶ McCabe, *supra* note 185, at 513 and n. 85.

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- ²²⁸ Food Standards Agency, Front of Pack Traffic Light Signpost Labelling Technical Guidance 3 (Nov. 2007), available at http://www.food.gov.uk/multimedia/pdfs/frontofpackguidance2.pdf (last visited Dec. 17, 2009).
- ²²⁹ Maubach, supra note 192, at 2.
- ²³⁰ Confederation des Industries Agro-Alimentaires de L'UE (CIAA) Confederation of the Food and Drink Industries of the European Union, About CIAA, http://www.ciaa.eu/asp/about_ciaa/index.asp (last visited Dec. 17, 2009).
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- ²³² Guideline Daily Amounts, GDAs Explained, http://gda.ciaa.eu/asp2/gdas_explained.asp (last visited Dec. 17, 2009).
- 233 Id.
- ²³⁴ Van Camp, *supra* note 223.
- ²³⁵ BBC News, EU Backs Rival Food Label Scheme, Jan. 30, 2008, http://news.bbc.co.uk/2/hi/health/7217198.stm.
- ²³⁶ Press Release, UK Food Standards Agency, Agency Consults on Front of Pack Labelling Scheme to Help Consumers Make Healthier Choices (Nov. 16, 2005), available at http://www.food.gov.uk/news/pressreleases/2005/ nov/frontofpackreleasenov05.
- ²³⁷ Id. In June 2005, the FSA surveyed more than 2,600 UK consumers to find out which front-of-package labeling system helped the majority of consumers identify more healthful food choices when grocery shopping. The Traffic Light system performed the best out of four options. The GDA system was also very popular, but results suggested that respondents from lower socioeconomic and minority groups had difficulty using the percentages employed by the GDA system to identify whether a food had high, medium, or low levels of problematic nutrients like fat, saturated fat, salt, and sugar. Further, the majority of consumers said the simple color-coding of the TL system made it easier to gauge nutrient levels at a glance. Id.
- ²³⁸ Kelly, *supra* note 219, at 125.
- ²³⁹ U.S. Gov't Accountability Office, supra note 215, at 37; Jason Switt, Labeling Around the Globe, Helping to Direct Food Flow, 107 J. Am. DIETETIC Ass'n 199 (2007) (stating that data from UK retailer Sainsbury's suggests that the TL system has had a quick, significant impact on consumers' food choices, with sales of food products bearing green or yellow traffic light labels showing a much greater increase than products with red light labels).
- $^{240}\,U.S.$ Gov't Accountability Office, $\it supra$ note 215, at 37.
- ²⁴¹ See infra p. 34 and note 307.
- ²⁴² Andreas C. Drichoutis, Consumers' Use of Nutritional Labels: A Review of Research Studies and Issues, 9 Acad. Marketing Sci. Rev. 12 (2006), available at http://www.amsreview.org/articles/drichoutis09-2006.pdf.
- ²⁴³ *Id*.
- 244 Id.
- ²⁴⁵ Food Standards Agency, Front-of-Pack Nutrition Labelling Policy Review, http://www.food.gov.uk/foodlabelling/signposting/policyreview/ (last visited Dec. 18, 2009).
- ²⁴⁶ Food Standards Agency, Independent Signpost Evaluation Study, Project Management Panel (PMP), http://www.food.gov.uk/foodlabelling/signposting/signpostevaluation/pmpanel/ (last visited Dec. 18, 2009).
- ²⁴⁷ Food Standards Agency, Expert Panel Presents Report on Front-of-Pack Nutrition Labelling, http://www.food.gov.uk/news/newsarchive/2009/may/ pmp (last visited Dec. 18, 2009).
- ²⁴⁸ Project Management Panel, Comprehension and Use of UK Nutrition Signpost Labelling Schemes (May 2009), available at http://www.food.gov.uk/ multimedia/pdfs/pmpreport.pdf.
- 249 U.S. Gov't Accountability Office, supra note 215, at 37.
- ²⁵⁰ Choices International Foundation, Qualifying Criteria, http://www.choices-international.org/index.php?option=com_content&task=view&id=31&Item id=54 (last visited Dec. 18, 2009).
- ²⁵¹ U.S. Gov't Accountability Office, *supra* note 215, at 37.
- ²⁵² Choices International Foundation, What is Choices?, http://www.choicesinternational.org/index.php?option=com_content&task=view&id=30&Itemid=53 (last visited Dec. 18, 2009).
- ²⁵³ Choices International Foundation, Qualifying Criteria, *supra* note 250.

- ²⁵⁴ Mariska Dötsch-Klerk & Léon Jansen, The Choices Programme: A Simple, Front-of-pack Stamp Making Healthy Choices Easy, 17 ASIA PAC. J. CLINICAL NUTRITION 383 (2008), available at http://apjcn.nhri.org.tw/server/APJCN/ Volume17/vol17suppl.1/383-386W5-3.pdf.
- ²⁵⁵ National Food Admin. of Sweden, Food Labelling, The Keyhole Symbol, http://www.slv.se/en-gb/Group1/Food-labelling/Keyhole-symbol/ (last visited Dec. 18, 2009).
- ²⁵⁶ U.S. Gov't Accountability Office, *supra* note 215, at 37.
- 257 Id
- ²⁵⁸ Ctr. for Science in the Public Interest, Petition for Advance Notice of Proposed Rulemaking on the Use of Symbols on the Principal Display Panel to Communicate the Healthfulness of Foods, Nov. 30, 2006, at 20, available at http://www.cspinet.org/new/pdf/healthy_symbol_petition.pdf..
- ²⁵⁹ Norden, About the Keyhole, http://www.norden.org/en/nordic-council-of-ministers/council-of-ministers-for-fisheries-and-aqua-culture-agriculture-food-and-forestry-mr-fjls/keyhole-nutrition-label (last visited Dec. 18, 2009).
- ²⁶⁰ Comm'n of the European Communities, Proposal for a Regulation of the European Parliament and of the Council on the Provision of Food Information to Consumers, Jan. 30, 2008, available at http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/proposal_regulation_ep_council.pdf.
- ²⁶¹ *Id*.
- ²⁶² Comm'n of the European Communities, Questions and Answers on Food Labelling (Memo/08/64), available at http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/memo-08-64_en1.pdf.
- 263 Id
- ²⁶⁴ Comm'n of the European Communities, *supra* note 260.
- ²⁶⁵ Press Release, BEUC, EHN and EPHA Common Position on Nutrition Labelling (Aug. 28, 2008), available at http://www.ehnheart.org/files/ EHN-BEUC-EPHA-144811A.pdf; BEUC, Food Information to Consumers: Summary of the BEUC Position on the Commission Proposal, May 22, 2008, available at http://docshare.beuc.org/docs/1/CHNDLPABJJENEN-PDMHKNAIBDPDBG9DBYPG9DW3571KM/BEUC/docs/DLS/2009-00129-01-E.pdf. See also U.S. Gov't Accountability Office, supra note 215, at 38.
- ²⁶⁶ Castle & Rosenthal, supra note 220.
- ²⁶⁷ Comm'n of the European Communities, Provision of Food Information to Consumers – Proposed Legislation, Citizen's Summary, available at http:// ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/labelling_citizens_summary_310108_final_cab.pdf.
- ²⁶⁸ Castle & Rosenthal, *supra* note 220.
- ²⁶⁹ See generally U.S. Gov't Accountability Office, supra note 215. The FDA, USDA, and FTC share jurisdiction over labeling and advertising of food products pursuant to a complex regulatory scheme established by Congress through complementary statutes, including the federal Food Drug and Cosmetic Act (as amended by the NLEA), the Fair Packaging and Labeling Act, the Public Health Service Act, the Federal Trade Commission Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act. The USDA's Food Safety and Inspection Service (FSIS) has primary responsibility for ensuring the safety and labeling accuracy of meat and poultry products, while the FDA is responsible for overseeing the labeling of all other foods. GEOFFREY S. BECKER, CONG. RESEARCH SERV., THE FEDERAL FOOD SAFETY System: A Primer 2-3 (Apr. 8, 2009), available at http://www.nationalaglawcenter.org/assets/crs/RS22600.pdf. FDA labeling jurisdiction extends to over 80% of all food products sold in the U.S., plus dietary supplements. U.S. Gov't Accountability Office, GAO Highlights (GAO-08-597), FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE Oversight, and Effectively Use Available Data to Help Consumers SELECT HEALTHY FOODS (Sept. 2008), available at http://www.gao.gov/ highlights/d08597high.pdf. FDA and FTC have overlapping jurisdiction for regulating food advertising, labeling and promotion. Pursuant to a 1971 memorandum of understanding, the agencies agreed that the FTC would exercise primary responsibility for ensuring that food advertising is truthful and not misleading, while the FDA would have primary jurisdiction over regulating the accuracy of food labeling. Working Agreement Between Federal Trade Commission and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971). In a nutshell, despite concurrent jurisdiction with other federal agencies, the lion's share of responsibility for regulating food labeling falls to the FDA.
- ²⁷⁰ 21 U.S.C. §§ 301-399 (2008).

- ²⁷¹ Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified in part at 21 U.S.C. § 343(i), (q) and (r) (2008)).
- ²⁷² 15 U.S.C. §§ 1451-1461 (2008).
- ²⁷³ 42 U.S.C. §§ 201-239(h) (2008).
- ²⁷⁴ See, e.g., Pearson v. Shalala, 164 F.3d 650 (1999) (holding that the First Amendment does not permit the FDA to prohibit a potentially misleading health claim on the label of a dietary supplement, unless the agency considers whether a disclaimer on the product's label could negate the potentially misleading nature of that claim).
- ²⁷⁵ See 21 C.F.R. § 101.9 (2009).
- ²⁷⁶ See 21 C.F.R. § 101.13 (2009).
- ²⁷⁷ See 21 C.F.R. § 101.14 (2009).
- ²⁷⁸ House Comm. on Energy and Commerce, Nutrition Labeling and Education Act of 1990, H.R. Doc. No. 538, 101st Cong., 2d Sess. 9-10 (1990).
- ²⁷⁹ 21 C.F.R. § 101.13(b) (2009).
- ²⁸⁰ 21 C.F.R. § 101.13(b)(1) (2009).
- ²⁸¹ 21 C.F.R. § 101.13(b)(2) (2009).
- ²⁸² Health claims are also subject to FDA preapproval. 21 CFR § 101.14(a) (1) and (c) (2009). The Nutrition Labeling and Education Act (NLEA) established the FDA's authority to require preapproval of health claims based on "significant scientific agreement." 21 U.S.C. § 343(r)(3)(B)(i) (2008). Structure-function claims, on the other hand, which describe the role of a substance in maintaining the body's structure or a particular bodily function, do not require preapproval by the FDA. 21 CFR § 101.93(f) (2009).
- ²⁸³ For example, in May 2009, the FDA issued a warning letter to General Mills over its claim that Cheerio's Toasted Whole Grain Oat Cereal is "clinically proven to help lower cholesterol." Warning Letter to General Mills, Inc. from U.S. Food & Drug Admin., May 5, 2009 (on file with author), available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm162943.htm. According to the agency, such a claim requires FDA preapproval of the product as a drug, since such specific cholesterol-lowering claims can be made only for drugs under federal law. Id. The agency's letter warned that Cheerio's was misbranded in violation of the FDCA because it bears unauthorized health claims in its package labeling, and suggested that if General Mills wanted to keep the package label as is, it would need to file a new drug application for Cheerios. Id. The problem was that General Mill's cholesterol-lowering claims crossed the line in their specificity. See Jennifer Corbett Dooren, Cheerios' Health Claims Break Rules, FDA Says, Wall St. J., May 13, 2009, at B1, available at http://online.wsj.com/article/ SB124216077825612187.html. FDA regulations governing health claims establish parameters on what can be said about food (versus what can be said about drugs). According to the FDA, had General Mills used more general language about a reduction in heart disease risk resulting from consumption of whole grain foods, that may have been a permissible, FDA-authorized health claim, provided that certain language was used. (The FDA has issued a regulation authorizing a health claim associating fiber from whole oats with a reduced risk of coronary heart disease. See 21 C.F.R. § 101.81 (2009).) The FDA's warning letter directed General Mills to promptly correct the labeling violations outlined in the letter or the agency would take enforcement action, including seizure of misbranded products or an injunction against the company. By late July 2009, the FDA reported that General Mills was responding to the agency's concerns and fully cooperating with the agency's directive to correct its Cheerios labels. Posting of Shirley S. Wang to WALL St. J. Health Blog, Rice Krispies Complete With Snap, Crackle and Immunity, http://blogs.wsj.com/health/2009/07/29/rice-krispies-complete-with-snapcrackle-and-immunity/ (July 29, 2009, 12:39 p.m. EST).
- ²⁸⁴ 21 U.S.C. §§ 301-399 (2008).
- ²⁸⁵ Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).
- ²⁸⁶ 21 U.S.C. § 343(a) (2008).
- 287 21 C.F.R. \S 10.30 (2009) (explaining the requirements for submitting a citizen petition to the FDA).
- ²⁸⁸ U.S. Food & Drug Admin., About the Center for Food Safety and Applied Nutrition, http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/default. htm (last visited Sept. 29, 2009).
- ²⁸⁹ Id.
- ²⁹⁰ U.S. Food & Drug Admin., About the Office of Regulatory Affairs, http://www.fda.gov/AboutFDA/CentersOffices/ORA/default.htm (last visited Sept. 29, 2009).
- ²⁹¹ U.S. Gov't Accountability Office, *supra* note 215, at 2.
- ²⁹² Id.

- ²⁹³ Id.
- ²⁹⁴ Id.
- ²⁹⁵ There is no private right of action under the FDCA. See Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 810 (1986). Instead, the FDCA and its implementing regulations are enforced by the FDA through administrative proceedings, although litigation and judicial adjudication may ensue if agency action is contested.
- 296 See generally U.S. Gov't Accountability Office, supra note 215.
- ²⁹⁷ 21 C.F.R. § 7.40 (2009).
- ²⁹⁸ U.S. Gov't Accountability Office, *supra* note 215, at 2.
- ²⁹⁹ Id.
- 300 21 U.S.C. § 334 (2008).
- 301 21 U.S.C. § 332 (2008).
- ³⁰² U.S. Gov't Accountability Office, supra note 215, at 22 (noting that since 1998, FDA has initiated only twenty one seizures and two injunctions for food labeling violations).
- ³⁰³ See, e.g., Trust for America's Health, Keeping America's Food Safe: A Blueprint for Fixing the Food Safety System at the U.S. Department of Health and Human Services (March 2009), available at http://healthyamericans.org/assets/files/2009FoodSafetyReport.pdf.
- ³⁰⁴ U.S. Gov't Accountability Office, *supra* note 215, at 6-7.
- 305 *Id.* at 13.
- 306 *Id.* at 33.
- ³⁰⁷ Ctr. for Science in the Public Interest, Petition for Advance Notice of Proposed Rulemaking on the Use of Symbols on the Principal Display Panel to Communicate the Healthfulness of Foods, Nov. 30, 2006, available at http://www.cspinet.org/new/pdf/healthy_symbol_petition.pdf. CSPI's petition was docketed as No. FDA-2006-P-0455.
- ³⁰⁸ Ctr. for Science in the Public Interest, *supra* note 307, at 2-3.
- 309 Id. at 27, App. I.
- ³¹⁰ Press Release, Ctr. for Science in the Public Interest, FDA Urged to Create New "Healthy Food" Labeling System (Nov. 30, 2006), available at http:// www.cspinet.org/new/200611301.html.
- 311 Healthy Lifestyles and Prevention America Act ("HeLP America Act"), S. 1342, 110th Cong. § 421 (2007). The bill was referred to the Senate Finance Committee on May 9, 2007 and did not progress out of committee.
- 312 Id.
- ³¹³ U.S. Food & Drug Admin., Notice of Public Hearing, Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria, 72 Fed. Reg. 39815 (July 20, 2007).
- ³¹⁴ Audio Recording: Food Labeling: Public Hearing on Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria, held by U.S. Food & Drug Admin., Ctr. for Food Safety & Applied Nutrition (Docket No. FDA-2007-N-0198), Sept. 10–11, 2007, available at http://www.connectlive.com/events/fda0907/index.html.
- 315 Representatives of the following food manufacturers, food retailers, and trade organizations, among others, participated in the FDA's September 2007 hearings: Kraft Foods, PepsiCo, General Mills, Kellogg's, Unilever, Hannaford Brothers, Giant Foods, the National Dairy Council, and the Grocery Manufacturer's Association. Health and consumer advocacy organizations such as the American Heart Association, the American Dietetic Association, and the Center for Science in the Public Interest also provided comments. In addition, foreign government and NGO participation included representatives of the United Kingdom's Food Standards Agency, the Dutch Ministry of Health, the European Food Information Council, and the Heart and Stroke Foundation of Canada. For a complete list of commentators and participants, see U.S. Food & Drug Administration, Public Hearing on Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria, Meeting Agenda, at http://www.cfsan.fda.gov/~dms/labsymb2.html.
- 316 U.S. Food & Drug Admin., Office of Nutrition, Labeling, & Dietary Supplements, FDA Comments on Symbols Public Hearing and Current Plans for Addressing Issues (Docket No. FDA-2007-N-0198), Apr. 21, 2009, available at http://www.iflr.msu.edu/Docs/FDA-NutritionSymbols.pdf. See also Press Release, U.S. Food & Drug Admin., Ctr. for Food Safety & Applied Nutrition, Constituent Update: FDA Announces Availability of Comments on Symbols Public Hearing, Apr. 28, 2009, available at http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm161773.htm.
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- ³²⁶ Barbara Schneeman, Vincent de Jesus, & Chung-Tung Jordan Lin, U.S. Food & Drug Admin., Ctr. for Food Safety & Applied Nutrition, Presentation at FDA Nutrition Roundtable: Front of Pack Symbols (Dec. 12, 2008).
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- ³²⁹ Id.
- 330 See Letter from Michael R. Taylor, Senior Advisor, U.S. Food & Drug Admin., & Jerold R. Mande, Deputy Under Secretary for Food Safety, U.S. Dep't of Agric., to Sarah Krol, Gen. Mgr., Smart Choices Program (Aug. 19, 2009), available at http://www.fda.gov/Food/LabelingNutrition/Label-Claims/ucm180146.htm.
- ³³¹ U.S. Food & Drug Admin., Ctr. for Food Safety & Applied Nutrition, Guidance for Industry: Dear Manufacturer Letter Regarding Front-of-Package Symbols (Dec. 2008), available at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm120274.htm.
- 332 Id.
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- 339 Press Release, Congresswoman Rosa L. DeLauro, DeLauro Calls for FDA Investigation into "Smart Choices" Labeling (Sept. 21, 2009), available at http://delauro.house.gov/release.cfm?id=2653.
- ³⁴⁰ *Id*.
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- ³⁴³ MacVean, supra note 155.
- ³⁴⁴ Letter from Margaret Hamburg, Commissioner of Food and Drugs, to Representative Rosa DeLauro, Chairwoman of the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (Oct. 19, 2009) (on file with author), available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm187369.htm.
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- ³⁶⁰ William Neuman, FDA to Clarify Standards for the Front of Food Labels, N.Y. Times, Oct. 21, 2009, available at http://www.nytimes.com/2009/10/21/ business/21food.html.
- 361 Layton, supra note 358.
- ³⁶² U.S. Food & Drug Admin., Background Information on Point of Purchase Labeling (Oct. 2009), available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm187320.htm.
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- ³⁷¹ Marion Nestle, *Update on Not-so-Smart Choice Labels*, Food Politics Blog, http://www.foodpolitics.com/2009/09/update-on-not-so-smart-choice-labels/ (Sept. 23, 2009).
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- ³⁷³ Press Release, Connecticut Attorney General's Office, Attorney General Investigates "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.
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- ³⁷⁵ Press Release, Connecticut Attorney General's Office, *supra* note 373.
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- 387 See Neal Hooker & Ratapol Teratanavat, Dissecting Qualified Health Claims: Evidence From Experimental Studies, 48 CRITICAL REV. IN FOOD SCI. & NUTRITION, 160, 162 (2008).
- 388 Grunert & Wills, supra note 10, at 17-19 (outlining suggestions for future research on nutrition labeling).

- ³⁸⁹ Hobson, supra note 73.
- ³⁹⁰ Indeed, one German study has suggested that while front-of-package traffic light labels appear to influence consumers' perceived healthiness of a food product, such changes in perception are unlikely to impact food choice and consumption, and thus, are unlikely to contribute to the prevention of obesity and diet related diseases. Borgmeier & Westenhoefer, supra note 176, at 192-94. These researchers concluded: "Despite the fact that food labels may influence the perceived healthiness of foods by consumers, this is unlikely to have a major impact on food choice and consumption. Thus, there is little reason to assume that signpost food labels will be an effective instrument in the prevention of overweight and diet related diseases." *Id.* at 194.
- ³⁹¹ The Keystone Ctr., The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity Final Report 14-15 (May 2006), available at http://208.72.156.157/~keystone/files/file/about/publications/Forum_Report_FINAL_5-30-06.pdf. See also Jayachandran Vaiyam, U.S. Dep't of Agric., Econ. Research Serv., Nutritional Labeling in the Food-Away-From-Home Sector: An Economic Assessment 1 (2005) (explaining that according to USDA food intake surveys, between 1977–78 and 1994–96, the amount of daily caloric intake from food consumed outside the home increased from 18% to 32%).
- ³⁹² Compare Bryan Bollinger et al., Calorie Posting in Chain Restaurants (Jan. 2010), available at http://www.gsb.stanford.edu/news/StarbucksCaloriePostingStudy.pdf (finding that mandatory calorie posting did influence consumer purchasing behavior at Starbucks chains in New York City, Boston and Philadelphia, causing average calories per transaction to decrease by 6%), with Brian Elbel et al., Calorie Labeling and Food Choices: A First Look at the Effects on Low-income People in New York City, 28 HEALTH AFFAIRS w1110 (2009) (finding that purchasing behavior among consumers in low-income and minority neighborhoods in New York City was essentially unaffected by mandatory calorie posting, because price is a stronger determining factor than caloric content in the food purchasing decisions of low-income and minority populations). See also David Morgan, New York Study Says Menu Labeling Affects Behavior, Reutuers.com, Oct. 26, 2009, http://www.reuters.com/ article/healthNews/idUSTRE59P4O720091026; Anemona Hartocollis, Calorie Postings Don't Change Habits, Study Finds, N.Y. Times, Oct. 6, 2009, available at http://www.nytimes.com/2009/10/06/nyregion/06calories.html. Finally, see generally, Lisa J. Harnack & Simone A. French, Effect of Point-ofpurchase Calorie Labeling on Restaurant and Cafeteria Food Choices: A Review of the Literature, 5 Int. J. Behavioral Nutrition & Physical Activity 51
- ³⁹³ Fulgoni III et al., supra note 200, at 1553.

³⁹⁴ Carey, supra note 55.