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Regulating Front of Package Labeling: An Exercise in Futility?

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Though presented as a way to reduce rates of obesity and chronic disease and help the American public select healthier foods, front-of-package labeling is an inefficient tool that operates within a processed food paradigm, thereby providing the food industry with yet another strategy to market nutritionally inferior foods to the general public.

KEYWORDS food policy, front-of-package labeling, Nutrition Labeling & Education Act

INTRODUCTION

As obesity and chronic disease rates in the United States continue to rise, the US government has decided that it is time to improve federal regulations for front-of-package (FOP) labeling for processed foods. This need comes as the result of excessive food industry marketing strategies causing confusion among consumers as to what is a healthy food.

The idea promoted by both government and industry is that placing specific nutrition information on the front of a food product's packaging will make Americans more aware of what they are purchasing and eating and will help them make healthier choices. In this article, we will explain why FOP labeling is an ineffective public health tool.

We will argue that FOP labeling merely repeats what is already stated on the nutrition facts label of all packaged foods, does not address the most important causes of obesity and chronic disease, and ultimately allows food companies to reformulate their products in such a way that still delivers minimal nutrition and questionable ingredients.

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FRONT-OF-PACKAGE LABELING: A HISTORY (1990–2009)

Front-of-package labeling is classified by the Food and Drug Administration (FDA) as point-of-purchase labeling, meaning that it is “voluntary information that is intended to convey to consumers the nutritional attributes of a food.”¹

Enacted in 1990, the Nutrition Labeling and Education Act (NLEA) mandates that the nutrition facts panel be displayed on the side or back panel of all packaged foods.² In addition to standardizing information pertaining to serving sizes, calories, macronutrients, and micronutrients, the NLEA established rules regarding FOP labeling—particularly in regards to evidence-based health claims that could be stated on the front of food packages. The NLEA allowed manufacturers to “characterize a relationship between a food, a food component, dietary ingredient, or dietary supplement and risk of a disease (for example, ‘diets high in calcium may reduce the risk of osteoporosis,’ on the front of a product’s packaging), provided the claims meet certain criteria and are authorized by an FDA regulation.”³

Marketing Disguised as Nutrition?

It is important to understand FOP rules in the context of a decades-long battle of wills between the food industry and the FDA. The goal of the food marketers is to sell products. The goal of the FDA is to ensure that the public receives useful, science-based information. But the agency must also balance the demands of the food industry due to ever-present political pressures from congress. What comes out the other end is mostly an illogical array of rules and regulations.

The FDA currently divides FOP labeling into two categories—summary and nutrient specific. A summary-based FOP label uses “logos, numerical scores, or graphic schemes to communicate the overall nutritional quality of a food product,”¹ such as the American Heart Association’s heart check mark, which is awarded to companies (for a fee) whose products meet certain criteria for total fat, saturated fat, cholesterol, sodium, and/or fiber content.¹

Nutrient-specific FOP labels “provide quantitative, evaluative, or both kinds of information on selected nutrients in a product without comparing the product’s overall nutritional quality to that of its counterparts.”¹ One such example is the Whole Grain Council’s whole grains stamp, which informs consumers of the amount of whole grains found in a product. This stamp focuses solely on whole grain content and is awarded regardless of how much sugar, sodium, or trans fat a particular product offers.

The food industry fully recognizes the vast advertising power of FOP labeling. Prior to passage of the NLEA, food companies, concerned about

how the law would affect marketing, voiced many concerns to the FDA. For instance, the FDA's proposed rule that a product must offer half the amount of total fat as well as a third of the calories to advertise a reformulated product as light or "lite" did not sit well with the International Dairy Foods Association (IDFA), which argued that ice cream and cheese could meet one of those two criteria but not both without its flavor being severely sacrificed.⁴

Well aware that consumers often look for healthier alternatives (in this case, light or lite dairy products), the dairy industry wanted to take the opportunity to market ice cream to those becoming more aware of the calorie and fat content of certain foods. The FDA could have decided that cutting fat only to replace it with more sugar (as is the case with reduced-fat ice creams) does not impact a food's total caloric content and would therefore not classify it as light. Instead, the FDA bowed to industry pressure. According to current FDA guidelines, a company may market a product as lite or light if it meets the following conditions: "if 50% or more of the calories are from fat, fat must be reduced by at least 50% per RACC. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per RACC."⁵

The Wild West of Structure–Function Claims

Although food companies cannot legally make outright health claims about their products (ie, "Helps prevent heart disease"), they can make what are known as *structure–function* claims. The FDA allows such claims to "describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, 'calcium builds strong bones.'"³ Structure–function claims are particularly troublesome because they can be used in reference to one particular nutrient, even if the majority of the product is composed of ingredients that are questionable or downright unhealthful. For instance, an oat-based product can make a structure–function claim linking soluble fiber with heart health, even if the product also contains significant amounts of sodium and added sugar, both of which have been shown to have detrimental effects on cardiovascular health.⁶

In addition, the FDA does not preapprove the accuracy and truthfulness of these claims but does require that they be "truthful and not misleading."³ Moreover, the FDA does not require food companies to notify the agency about their claims, and no disclaimers are required.³ In other words, food companies are free to make nutritionally void foods, sprinkle in a few vitamins, and advertise these foods as healthful. To the extent that companies cross the line into deceptive marketing, the only recourse the FDA has is to go after each company individually and threaten legal action. With tens of thousands of food products on the market, the agency has nowhere near the resources needed to adequately police this system.

Industry Attempts to Skirt the Rules and Make Their Own

It should come as no surprise, then, that the food industry has sought every opportunity to skirt what little FDA FOP regulations do exist to suit their marketing needs. The first FOP labeling system was launched in 1995 not actually by the food industry but by the American Heart Association. As mentioned above, food companies pay a fee to get the check mark symbol.⁷ It was not until 2004 that the food industry created its own nutritional guidelines for an FOP symbol designating a “healthy choice.” Food and beverage giant PepsiCo led the way with the launch of Smart Spot.⁸ Described as a “simple labeling system that makes it easier for consumers to identify PepsiCo products that contribute to a healthier lifestyle,” the Smart Spot symbol now appears on more than 250 of the company’s products, including such questionably healthy brands as Baked Lay’s, Diet Pepsi, and Gatorade.^{9(p20)}

Not to be outdone, in 2005, Kraft Foods launched Sensible Solutions, another program where industry gets to define how products make the healthful grade. Kraft aimed to highlight healthful components found in hundreds of their products using statements such as “good source of vitamin C.” This requires that a product contain at least 10% of the daily value of the nutrient, regardless of whether or not the product inherently contains vitamin C or is simply fortified. Another is “cholesterol-free,” a given in any product that does not contain animal products, no matter how processed or nutritionally void.¹⁰ Sensible Solutions logos can be found on Kool-Aid (because it is fortified with vitamin C, even though it contains artificial dyes and significant amounts of sugar) and many of the Lunchables products (which, despite high sodium and sugar content, can be fortified with one or two vitamins to earn the label). These industry-defined systems were so financially viable for food companies that the number of such nutrition rating systems almost doubled from 2008 to 2009.⁷

Then in 2008 came the introduction of the largest industry-defined FOP labeling system yet. Fourteen corporations—including Unilever, Kraft, ConAgra, Coca-Cola, and Kellogg’s—spent a collective \$1.47 million to create the Smart Choices program, which also received funding from the American Heart Association and the American Diabetes Association.¹¹ The impetus behind its creation was a streamlined FOP labeling system that would allow all of the member food companies to advertise their respective brands with universal symbols and illustrations. But it was doomed to live a short life, ultimately voluntarily postponed following public outcry, media embarrassment, and FDA threats.¹² The program’s worst misstep came with the product Froot Loops. Despite providing 44% of calories from added sugar, Froot Loops displayed the Smart Choices logo on its boxes, citing the presence of fortified vitamins and minerals. The FDA, citing concerns of misleading advertising, suggested that industry better rethink Smart Choices.

Thought it initially seemed that the Smart Choices program would remain on hiatus until further notice, it ultimately disbanded when many of the food companies involved in its creation—including Kellogg's and Kraft—decided to abandon it.

Following the Smart Choices debacle, the FDA announced that it would review FOP labels and come up with a viable alternative to Smart Choices. Rather than declare FOP labels unnecessary or ineffective, the FDA stated: “We want to work with the food industry—retailers and manufacturers alike—as well as nutrition and design experts and the Institute of Medicine, to develop an optimal, common approach to nutrition-related FOP and shelf labeling that all Americans can trust and use to build better diets and improve their health.”¹

It seems that the FDA has high hopes for FOP labeling and its usefulness for Americans, describing it as “a way of promoting informed food choices and helping consumers construct healthier diets in accordance with the Dietary Guidelines for Americans.”¹ The FDA does, however, also warn “that nutrition-related FOP 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.”¹

With these somewhat conflicting statements, and with decades of confusing information on food packaging, the FDA seems determined to come up with a workable solution. But is it even worth the effort?

THE ARGUMENTS IN FAVOR OF FOP LABELING

Currently, 3 central arguments are used to justify the implementation of FOP labeling, at least by the FDA: it (1) “aims to maximize the number of consumers who readily notice, understand, and use point-of-purchase information to make nutritious choices for themselves and their families,” (2) “can make a big difference for public health . . . because of the large role diet plays in obesity and as a risk factor for chronic disease,” and (3) “may foster industry reformulation of products because some consumers may notice the information and make their product selection accordingly.”¹³ We will aim to show why each of these is flawed.

FOP Labeling Will Help Consumers Who Use Nutrition Information to Make Healthier Choices

Citing increased consumer awareness as a reason to advocate FOP labeling does not appear to accurately reflect the current marketing landscape. It certainly does not explain why we need anything in addition to already informative nutrition facts labels, which most Americans are already well

aware of. Even though not everyone understands the health implications of consuming excessive amounts of sodium or the particular role that fiber can play in helping to reduce cardiovascular disease, the nutrition facts panel is easy to find and displays information in a way that is clear, straightforward, and practical for the average shopper. If a consumer were to receive instructions from a health professional (ie, a registered dietitian) to consume no more than 1,500 milligrams of sodium a day, the nutrition facts panel easily provides that information without the need for additional information on the front of the package.

There is no scientific or anecdotal evidence to indicate that the public is in need of nutrition information on food packaging that is easier to understand, better organized, or placed in a different location than what is already available. Perhaps FOP labeling makes nutrition information more immediately available because it would allow customers to browse and compare a variety of different products on store shelves with one glance, rather than turning each one around separately. However, this does not mean that FOP labeling would provide a more thorough understanding or more efficient use of said information. Strangely, FOP labeling is framed as if the availability of nutrition information on food packaging were a new concept and never before available to the general population. Not only is nutrition information more available than ever before (via the Internet, mobile applications, and other electronic means), FOP labeling fails to offer anything new to consumers. It simply transfers the same information currently located on the back or side of a product to the front of the package and in a manner that is less precise, devoid of context, and, hence, less useful.

As history has shown, FOP labeling and claims often mislead and confuse more than they help. For example, a high-sugar cereal can boast about a certain number of grams of fiber per serving, even though these grams come from isolated fibers, rather than whole grains, which are not as healthful and offer significantly fewer health benefits. Similarly, FOP labeling allows food companies to boast about the inclusion of certain vitamins and minerals—through fortification—in otherwise nutritionally empty products, while products that offer these same nutrients intrinsically, and often in higher amounts (such as fruits and vegetables) do not get this free advertising opportunity.

FOP Labeling Is a Tool Against Obesity and Chronic Disease

It is unclear how exactly a labeling system that provides a powerful marketing advantage to processed, packaged foods over whole foods from nature can be considered an effective tool against rising rates of obesity and chronic disease. Consumption data show that, compared to 1970, when rates of obesity and chronic disease were significantly lower, Americans were eating fewer processed foods.¹⁴ Why then, does the government think that

encouraging the consumption of these foods will benefit the overall health of the American public?

The Institute of Medicine released a report on FOP labeling in 2010 that suggests one way to address FOP labeling is by mandating that food companies only list “nutrients of concern”—calories, saturated fat, trans fat, and sodium—on the front of their packaging.^{7(p76)} Though this seems like an efficient strategy to prevent food companies from solely advertising the positive attributes of their products (especially in light of the fact that average intake of calories, trans fat, and sodium in the United States is well above recommended guidelines), this, too, is a largely inefficient strategy. Although heart disease rates have increased over the past few decades, saturated fat intake has remained stable.¹⁴ More and more studies and reports point to higher intakes of omega-6 fatty acids as a significant factor in the development of heart disease.¹⁵ Omega-6 fatty acids are particularly high in corn, cottonseed, and soybean oils, all of which are used as the main oils in packaged processed food. This calls into question claims by food companies that their products made with these oils are a healthful choice because they are low in or do not contain saturated fats.

FOP Will Work Because It Encourages Industry Reformulation of Products

Reformulation of processed foods is reactive and does not necessarily yield a more healthful product. Replacing trans fats with the aforementioned oils high in omega-6 fatty acids is a slightly better alternative but not a healthful solution. Similarly, lowering sugar grams via the inclusion of artificial sweeteners does not promote good nutrition. Lowering milligrams of sodium in products that are already low in minerals essential for the regulation of blood pressure (mainly potassium and magnesium) is a moot point, particularly because plenty of nutrition research has demonstrated that increasing potassium intake—a mineral found in fruits, vegetables, whole grains, and legumes—is more effective than sodium reduction.

In addition, many children’s cereals bump up fiber grams by adding isolated fibers like inulin. Though these fibers can ease digestion, these products cannot be considered equivalent to a whole grain food, which offers minerals, phytonutrients, and antioxidants not found in these isolated fibers. Similarly, nutrition research has demonstrated that in order for vitamin E to work efficiently, it must be consumed within its appropriate food matrix (a food that naturally contains vitamin E, along with other compounds that aid vitamin E in performing its function in the human body). Once vitamin E is isolated and added to foods (as is the case with some of Kraft Foods’ Jell-O products), its health benefits are largely disabled.¹⁶

Reformulation also inherently provides a free advertising boost to food companies. A sugary cereal that decreases sugar grams per serving by one

can now place a “Now with less sugar!” banner on the front of their packaging, whereas products that are already—and always have been—healthful do not get that advantage. It is also plausible that a food company may reformulate a product to fit within desirable guidelines for certain nutrients and simultaneously include nutritionally suspect ingredients like chemical preservatives, artificial colorings, artificial sweeteners, genetically modified crops, and high-fructose corn syrup. Therefore, FOP labeling does not value a holistic approach; foods are not analyzed as a whole package but rather based on a handful of select nutrients.

CURRENT DEVELOPMENTS

Just when it seemed that the FDA’s FOP labeling plan was running smoothly, 2 additional developments took place in January of 2011—a scathing report by the Government Accountability Office (GAO) and the latest food industry voluntary announcement. The GAO report, *“Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers From False or Misleading Claims,”*¹⁷ argues that FOP labeling confuses consumers and is ripe for misinformation and sneaky marketing tactics by food companies. The GAO also requested that congress allow the body to access documentation that scientifically substantiates food companies’ health claims and step in as an objective third-party to ensure that food companies and the FDA exemplify transparency and scrutiny throughout the process. Congress has yet to address these requests.

In a suspiciously timed move, the Food Marketing Institute (FMI) and the Grocery Manufacturers of America (GMA)—2 food industry lobbying groups—announced on January 24, 2011, their own FOP labeling system (described as “monumental and historic”¹⁸), known as the Nutrition Keys. The GMA alone is composed of over 300 food companies, including Campbell Soup, Cargill, Coca-Cola, General Mills, and Kraft Foods.

All products that participate in the Nutrition Keys system will display calories, saturated fat, sodium, and total sugars per serving—both in numerical and percentage form—as well as 2 ‘nutrients to encourage,’ such as fiber, potassium, vitamin A, and, oddly enough, protein. We can expect the food industry to continue to push forward with the implementation of this FOP labeling system (which includes a \$50 million consumer education campaign), apparently unconcerned with any consequences or restrictions from the FDA.

CONCLUSION/VIABLE ALTERNATIVES

According to the IOM report, consumers purchase more products for which FOP labeling is present on grocery store shelves.⁷ That alone should be

reason enough to discourage the use of FOP labeling or at least provide significant pause to health professionals advocating for its implementation. FOP labeling will mainly benefit processed, convenience foods (cereals, crackers, cookies, ice cream, and frozen dinners, to name a few). If FOP labeling translates to increased sales, its implementation will lead American consumers to consume higher quantities of processed foods, the very foods that contain higher amounts of calories, omega-6 oils, trans fat, added sugars, and sodium. More effective nutrition policy would encourage and facilitate consumers to purchase higher quantities of fresh, whole foods.

If improved health is the main goal behind FOP labeling, why are other policies not being given higher priority? FOP labeling (1) does not introduce new information to consumers, (2) operates within a framework that facilitates the production—and normalizes the consumption—of highly processed foods, (3) and provides an easy “out” for food companies to advertise nutritionally inferior products as “better for you” options. A recent Yale University study found that cereals that offer very low amounts of nutrition contained an average 3 to 4 health claims on the front of their packaging.¹⁹ Unlike most European Union nations, the United States lawfully permits the use of FOP health claims on high-sugar foods (such as juice drinks and sugary cereals).¹⁹

The solution to helping consumers make healthier choices does not depend on repeating information on the nutrition facts panel on the front of food packaging, especially foods that are highly processed and do not impart significant nutrition. The FDA should also consider the implications of validating a system that propagates the consumption of highly processed foods, allowing food companies to highlight the inclusion of certain nutrients that can be found in whole, unprocessed foods like fruits and vegetables. At the very least, this system could be revised in such a way that would at least equalize the labeling field. One possible solution: mandate that all processed foods carry a highly visible label recommending that consumers prioritize fruits, vegetables, whole grains, and legumes in their diet over processed foods. Of course, the problem of overly zealous and outright deceptive marketing claims by industry remains and it is understandable that the FDA is struggling to address the problem. Government officials at both the FDA and the Federal Trade Commission (which regulates all forms of marketing) should be more aggressive with the food industry to stop such claims. Only when the food industry is not allowed to deceive the public will information be truly useful.

REFERENCES

1. Schneeman, BO *Guidance for Industry: Letter Regarding Point of Purchase Food Labeling*. Available at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm>. Accessed December 22, 2010.

2. Ensminger, A. *Food & Nutrition Encyclopedia*. Vol. 1. 2nd ed. Florence, Kentucky: CRC Press; 1994.
3. *Label Claims: Claims That Can Be Made for Conventional Foods and Dietary Supplements*. Available at: <http://www.fda.gov/food/labelingnutrition/labelclaims/ucm111447.htm>. Accessed January 25, 2011.
4. Van Wagner, LR. FDA reviewing deluge of NLEA comments. *Food Process*. 1992. 53(4): 8. Available at: <http://www.allbusiness.com/legal/laws/292348-1.html>. Accessed March 2, 2011.
5. 21 CFR 101.56(b) *Food Labeling Guide: Appendix A—Definitions of Nutrient Content Claims*. Available at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064911.htm>. Accessed February 16, 2011.
6. American Heart Association. *Obesity and Nutrition Health Policy*. Available at: <http://www.americanheart.org/presenter.jhtml?identifier=3068641>. Accessed February 16, 2011.
7. Food and Nutrition Board. *Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report (2010)*. Table 3-1: “Timeline of Selected Activities Related to Front-of-Package Nutrition Rating Systems and Symbols.” Available at: http://www.nap.edu/openbook.php?record_id=12957&page=38#p2001c5d29960038001. Accessed March 4, 2011.
8. Padilla, A. *Taking the Guesswork Out of Healthy Shopping*. Available at: <http://consumergoods.edgl.com/trends/Taking-the-Guesswork-Out-of-Healthy-Shopping49241>. Accessed February 16, 2011.
9. *Performance With Purpose: Creating a Better Future for Tomorrow's Generations*. Available at: http://www.pepsico.com/Download/Pepsico_2008_Sustainability_Report.pdf. Accessed February 12, 2011.
10. *Sensible Solutions—Nutrition Criteria*. Available at: <http://www.kraftrecipes.com/kf/healthyliving/sensiblesolution/nutritioncriteria.aspx>. Accessed March 4, 2011.
11. Ruiz, R. *Smart Choices Foods: Dumb as They Look?* Available at: <http://www.forbes.com/2009/09/17/smart-choices-labels-lifestyle-health-foods.html>. Accessed February 20, 2011.
12. Neuman, W. For your health, Froot Loops. *New York Times*. September 5, 2009;B1. Available at: <http://www.nytimes.com/2009/09/05/business/05smart.html>. Accessed March 12, 2011.
13. Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information. Available at: <http://www.federalregister.gov/articles/2010/04/29/2010-9939/front-of-pack-and-shelf-tag-nutrition-symbols-establishment-of-docket-request-for-comments-and>. Accessed October 20, 2011.
14. Wells HF, Buzby, JC. Dietary Assessment of Major Trends in US Food Consumption, 1970–2005. Available at: <http://www.ers.usda.gov/Publications/EIB33/EIB33.pdf>. Accessed February 4, 2011.
15. Ramsden C, Hibbeln J, Majchrzak S, Davis J. Omega-6 fatty acid-specific and mixed polyunsaturate dietary interventions have different effects on CHD risk: a meta-analysis of randomised controlled trials. *Br J Nutr*. 2010;104:1586–1600.

16. Schurks M, Glynn RJ, Rist PM, Tzourio C, Kurth T. Effects of vitamin E on stroke subtypes: meta-analysis of randomised controlled trials. *BMJ*. 2010;341:c5702.
17. Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers From False or Misleading Claims." Available at: <http://www.gao.gov/products/GAO-11-102> Accessed: March 1, 2011.
18. Marion Nestle's Food Politics blog. "Singing Kumbaya', GMA/FMI displays preemptive label design." Available at: <http://www.foodpolitics.com/2011/01/singing-kumbaya-gmafmi-displays-preemptive-label-design/> Accessed: January 25, 2011.
19. Pomeranz, J. Front-of-package food and beverage labeling: new directions for research and regulation. *Am J Prev Med*. 2011;40:382–385.