Front-of-Package Food and Beverage Labeling
New Directions for Research and Regulation
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Introduction

Nutrition-related labeling of packaged food is of increasing interest in the U.S. and internationally due to concerns about obesity and other nutrition-related diseases. Obesity has reached epidemic proportions globally, and nutrition-related labeling is considered to be a method to both inform consumers and encourage product reformulation. In the U.S., there are labeling regulations guiding the use of claims on food and beverage (hereinafter “food”) packaging, but manufacturers still have great leeway in making such claims. The food industry also developed various front-of-package (FOP; see Table 1 for a list of acronym definitions) icons and schemes in an effort to draw attention to specific qualities of their products. The proliferation of icons and schemes, and both authorized and questionable claims, stimulated several entities within the federal government to reassess labeling regulations to ensure that labels provide factual, non-misleading information to assist consumers.

Background

In 1990, Congress amended the Food, Drug and Cosmetic Act of 1938 (FDCA) by enacting the Nutrition Labeling and Education Act (NLEA), which authorized the Food and Drug Administration (FDA) to regulate nutrition labeling and disclosure statements. The purpose of the NLEA is one of lasting concern: Labels should provide accurate, non-misleading information to reduce confusion and allow consumers to make comparisons and healthful choices. Despite these goals, food labels have become unwieldy from a consumer, health, and regulatory perspective.

The FDA reported receiving an increasing number of complaints that current packaging trends present a misleading picture of the health benefits of processed foods. The agency thus announced its intention to increase enforcement of current regulations and enact new voluntary guidelines and mandatory regulations for an FOP scheme. The FDA Commissioner explained that “ready access to reliable information about the calorie and nutrient content of food is even more important [today], given the prevalence of obesity and diet-related diseases.” In October 2009, the Commissioner authorized the FDA to (1) examine food labels for violations of current rules prohibiting false and misleading labels; (2) draft a new regulation providing a single set of science- and nutrition-based criteria for FOP labeling to ensure that consumers understand the actual healthfulness of food; (3) launch consumer research to determine the best method to convey information; and (4) work with industry regarding a single FOP symbol to enhance healthy choices. In 2010, the FDA announced a new initiative to address food and beverage package labeling because of an increasing concern that current labels give consumers a misleading picture of the health benefits of such products.

When regulating product packaging, government must consider First Amendment implications. Truthful labels are considered “commercial speech,” protected by the First Amendment. Often, when industry is threatened by government regulations pertaining to commercial speech, it challenges such actions in court as a violation of its First Amendment rights. However, government can restrict false, deceptive, and misleading speech in the commercial context; such speech is not protected by the First Amendment. Also, government can compel the disclosure of factual commercial information, because First Amendment values are based on increased availability of information in the marketplace. Further, government can restrict commercial speech only if it has a substantial interest in doing so and can show that such a restriction will directly and narrowly advance this interest. Thus, despite industry objections, First Amendment considerations do not present a strong obstacle to government regulations ensuring that the public is provided with clear and accurate health-related information on food product labels.

Emerging evidence indicates that many labels are misleading in conveying properties of food products and bear a wide array of confusing messages. In light of these developments, three areas are of particular importance and are explored below: FOP schemes, health and nutrition claims, and enforcement activities. The research community has a role to play in each context for the development of proposed and future regulations to en-
ensure that the best options are adopted to convey accurate nutrition information and promote industry compliance and product reformulation.

Front-of-Package Schemes

In response to the proliferation of FOP schemes developed by food companies (e.g., General Mills’ “Nutrition Highlights,” a nutrition information panel), third-party organizations (e.g., “Smart Choices,” a check mark with calorie and serving data), and retailers (e.g., Hannaford’s “Guiding Stars,” an icon with one to three stars indicating increasing healthfulness), the FDA is creating a uniform, science-based FOP graphic to ensure that consumers are not enticed by labels representing a food as being healthier than it actually is. Current schemes highlight allegedly positive attributes of a product deemed healthy according to industry-created definitions generated through a nontransparent process. The FDA announced it would first address a uniform system through voluntary guidelines and then consider a mandated approach if necessary. Such uniform disclosure requirements are consistent with First Amendment interests in increasing levels of factual information in the marketplace.

There has much been research on FOP schemes internationally, and less in the U.S., indicating mixed results for efficacy, comprehension and use of the schemes tested (including those promoted by governments outside the U.S.). Internationally, the food industry has voluntarily embraced schemes that do not designate products as “bad,” for example, as indicated by a red label. In countries where uniform schemes are prevalent, reformulation and the introduction of new products resulted in reduced sodium and increased fiber, saturated fat was reduced mainly in dairy products, and results were mixed for sugar and calories.

The FDA is working to develop a nutrition-based FOP algorithm and gathered consumer research data to create a usable FOP graphic that will foster nutritious choices, be accessible to consumers with varying education and backgrounds, supplement the Nutrition Facts Panel, and encourage industry reformulation.

In October 2010, the IOM reported its Phase-1 conclusions that the FOP system should display calories, serving sizes, saturated fat, trans fat, and sodium. Two weeks later, the Grocery Manufacturers Association announced that food and beverage manufacturers and retailers are developing their own FOP system. Because the industry would not have to comply with a voluntary FDA scheme, it could use this new system instead. This latest announcement highlights the necessity of an FDA-mandated, science-based FOP scheme.

Once the FOP scheme is developed, the FDA should re-evaluate it on a continual basis, as is done with the Dietary Guidelines for Americans. Continuous research is essential. Key areas include analyzing the validity of the FOP scheme to provide sound guidance, consumer comprehension and use of the scheme to positively influence diet, levels of voluntary industry compliance, and whether companies reformulate or create new, healthier products. Mandatory federal regulations will be necessary if studies reveal low levels of adoption by industry. A revised algorithm or FOP scheme will be necessary if scientific advances render the original scheme invalid or unsuitable, consumer confusion or incomprehension persists, or reformulation results in reduced nutrient content or positive labeling for foods that are not actually healthier.

Health and Nutrition Claims

Current food packaging bears a considerable amount of permissible, impermissible, and arguably unsubstantiated health and nutrition claims. The FDA has not announced a plan to re-evaluate the rules and regulations governing these claims beyond increased enforcement of current law. Health and nutrition claims have been shown to increase consumers’ perception of healthfulness and willingness to purchase the products. However, studies indicate that these claims are misleading and confusing, detract from the use of the Nutrition Facts Panel, generate inaccurate inferences, and often convey healthiness for products that do not meet objective nutrition standards. For example, a Yale University study revealed that cereals with very poor nutrient profiles bore three to four health claims per box.

The FDA allows food manufacturers to make structure/function, nutrient content, and health claims on their food packaging, each according to different rules. A structure/function claim describes the role of a nutrient or ingredient of the food that affects or maintains normal structure or function in the body; for example, “calcium builds strong bones.” The manufacturer is responsible for ensuring the accuracy of such claims and does not need pre-approval by the FDA for their use on the food label.

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Nutrient Content Claims characterize the level of a nutrient of the type required to be disclosed in nutrition labeling, such as “low sodium.” Each claim has a specific guideline for its use. Disclaimers are required if the statement implicitly characterizes the level of the nutrient in food but is not consistent with the allowance for the claim, such as “only 200 mg of sodium per serving, not a low-sodium food.”

Health Claims characterize the relationship of a substance to a disease- or health-related condition; for example, “diets with adequate folate may reduce a woman’s risk of having a child with a brain defect.” Health claims cannot be made if the food contains “disqualifying nutrient levels,” which means that the levels of total fat, saturated fat, cholesterol, or sodium are too high (i.e., 13 g, 4 g, 60 mg, 480 mg, respectively). The more-robust health claims are authorized after the FDA determines that the nutrient–disease relationship meets “the significant scientific agreement standard,” or if the claim is based on an “authoritative statement” from a designated scientific body. The FDA originally rejected claims not meeting this standard but in 1999 a federal court mandated the FDA to allow claims meeting a lower threshold of support from scientific evidence, providing the claim is qualified with a disclaimer.17 Qualified health claims (QHCs) emerged from this case and are now permitted when there is “credible” or limited scientific evidence supporting such a relationship, and a disclaimer is included.18 For example: “very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.”

Government entities and public health professionals have called for revised regulations and even a ban on such claims.19,20 Approximately 30 countries prohibit the use of claims making reference to disease.21 In the U.S., factual, non-misleading claims are protected by the First Amendment, but if claims are proven to be misleading, the government can restrict them. If the claims are considered potentially misleading, the government may require that they appear in a format that reduces confusion or mandate disclosures to further explain the claims (as in the case of nutrient content disclaimers).22 Science is mounting to support the argument that many claims on processed food products are misleading. However, given that they are perceived to be factual, and that there is judicial protection for commercial speech, additional studies that reveal that health and nutrition claims are confusing to consumers are likely warranted to support restrictions consistent with the First Amendment.

In the case of QHCs, there may already be sufficient evidence that they are misleading and can therefore be subject to greater government restriction without violation of the First Amendment. Consistent with earlier research, the FDA’s 2009 study tested four permitted QHCs with 7440 respondents and found that “none” of the schemes were “entirely effective at conveying the intended levels of scientific evidence” supporting the claims.23,24 If consumers cannot evaluate QHCs, then the disclaimers are not effectively clarifying the confusing nature of the scientific evidence. QHCs have been criticized globally and rejected in Europe because of their low level of scientific substantiation.25 The federal court that mandated QHCs did so at a time when there were no studies to indicate that they were confusing and ineffective at accurately conveying the scientific evidence. This is no longer the case. Thus, the FDA or Congress should consider this area for future regulation.

Further research to expose the misleading nature of the remaining claims and support stricter regulation is also needed. Such data could, for example, support pre-approval requirements and strict nutrition-based criteria for the use of all claims, to guarantee that they are factually based and supported by current scientific standards of healthfulness. Contrary to national and international guidelines, the U.S. does not restrict claims on products that contain high levels of sugar.26,27 All claims should be disallowed if the food contains disqualifying nutrients, and this list could be strengthened by including sugar limits. Research that continues to uncover these and other limitations of the current system would support new and more-robust federal regulation of all claims.

Enforcement

Food packaging that fails to conform to the FDCA or bears a “false or misleading” label is considered “misbranded.” The FDA has jurisdiction to address misbranded packaging, and the Federal Trade Commission (FTC) is responsible for the same types of statements in food advertisements. State laws allow for the state attorneys general, and sometimes private citizens, to enforce federal regulations under statutes that make it unlawful for businesses to engage in unfair and deceptive activity.28 The public health, consumer advocate, and legal communities have been and continue to be essential in their role of identifying egregious practices and bringing them to the attention of the FDA, FTC, or their state and city attorneys to pursue.

Such legal action can bring national attention to an issue and spur federal enforcement action. For example, Connecticut’s Attorney General began an investigation into the “Smart Choices” program out of concern that it misleadingly labeled nutritionally suspect foods as healthy, in violation of state consumer-protection laws. Within 1 week, the
FDA began its own investigation, and the companies voluntarily discontinued the program. If the industry’s latest FOP system is similarly misleading, comparable enforcement actions would be warranted to protect consumers.

Local action can also fill gaps when there is federal inaction. San Francisco’s City Attorney began investigating whether the “Immunity” claim by Kellogg’s on its cereals violated California law. Within 1 week, Kellogg’s discontinued the use of this claim. Although the FDA had concurrent jurisdiction, it likely did not address it because “Immunity” is considered a structure/function claim subject to lenient rules. However, the FTC did admonish Kellogg’s for its related advertising campaign and ordered the company to refrain from making misleading claims not supported by scientific evidence.

Conclusion

As of 2010, food packaging conveys an excessive amount of information and misinformation, creating consumer confusion and distrust. When the FDA and industry finalize their FOP schemes, research will be needed to assess their scientific validity, their efficacy for consumer use and comprehension, and whether a mandatory FOP scheme is necessary. Research is also warranted to reveal the limitations of current laws pertaining to health and nutrition claims to support strengthening the scientific basis and nutritional requirements for making a claim. Finally, groups that identify false, deceptive, and misleading food labels and related advertising should bring these practices to the attention of appropriate government entities. As scientific evidence increases to support further regulation, the FDA and Congress should act accordingly. The First Amendment may be a consideration when government regulates commercial speech, but it does not pose an obstacle to ensuring that consumers have clear and valid factual information about food in the marketplace, a needed link in the effort to combat the global obesity epidemic.

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References