IOM Issues Phase I Report Regarding Front-of-Package Nutrition Rating Systems and Symbols

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In response to the disturbing rates of overweight, obesity, and diet-related chronic disease among Americans, Congress requested an Institute of Medicine (IOM) study that would examine "front-of-package" (FOP) nutrition labeling systems and symbols and the effects that FOP labeling could have on consumer food choices. With sponsorship from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), IOM launched the requested FOP labeling study to be conducted in two phases. On October 13, 2010, the results of the first phase of the IOM study (Phase I study) were published in a report entitled, "Examination of Front-of-Package Nutrition Rating Systems and Symbols: Phase I Report" (Phase I Report).

The report concluded, among other things, that for FOP labeling systems to be helpful to consumers in making food choices that are consistent with the Dietary Guidelines for Americans, FOP labeling should focus on conveying a limited set of information concerning the nutrients that are most strongly linked to significant diet-related disease risks that affect the greatest number of Americans. The Phase I Report identifies obesity, cardiovascular disease, Type 2 diabetes, and certain cancers as diet-related conditions that would meet this standard. Based on this conclusion, the Phase I Report further concludes that the most critical information to be conveyed through FOP labeling would characterize the amount of calories, saturated fat, trans fat, and sodium contained in the food. For a variety of reasons, the Phase I Report suggests that "it may not be essential or useful" for FOP labeling to characterize the levels of a number of other nutrients that may be of interest to consumers, including total fat, cholesterol, total carbohydrate, total sugars, added sugars, protein, fiber, vitamins, and minerals other than sodium (e.g., calcium, potassium, iron, etc.).

The study considered whether FOP labeling should convey calorie and nutrient information on the basis of a serving, and/or Daily Value, or should be characterized through the use of defined terms such as "low sodium" and "high saturated fat," and suggested options for further consideration. The study also considered whether uniform standards should apply across all food categories, or whether distinctive standards should be established for different food categories, identifying issues and options for further consideration. The study evaluated the possible use of summary indicators based on algorithms to convey an overall rating of a food based on calories, saturated fat, trans fat, and sodium content, ultimately concluding that "algorithm-based ratings would not constitute an ideal system" in this context. The study also concluded that designing FOP labeling systems to convey food group information (e.g., "10 percent of daily vegetable requirement" or "20 percent of daily dairy needs") would be inadequate to convey the nutritional quality of the food product and could misrepresent the nutritional quality of a food (e.g., a food may supply vegetables, but be high in sodium and saturated fat).

The Phase I Report lays important groundwork for the Phase II study, which will consider (1) which systems and symbols are most effective with consumer audiences and best promote public health, (2) how to maximize their use, and (3) the potential benefits of a single, standardized FOP labeling system to be regulated by FDA. The Phase II study is scheduled to be published in late 2011.The Phase I Report also recognizes that the findings and conclusions made by the IOM committee have significant implications not only for FDA regulations governing FOP labeling, but may require the agency to expand and modify regulations that currently govern nutrition labeling and nutrient content claims in order to ensure consistency between the information presented through FOP labeling and other product information, and to ensure that FDA regulations are founded on current and appropriate scientific evidence concerning nutritional needs and food intake.

Scope of Phase I Study

Phase I of the IOM study was conducted by an ad hoc "Committee on Examination of Front-of-Package Nutrition Labeling Systems and Symbols" (IOM Committee) which was charged with the following tasks:

- Identifying FOP labeling systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad;
- Considering the purpose and overall merits of front-label icons;
- Identifying the criteria underlying the systems and evaluate their scientific basis;
- Considering advantages and disadvantages of various approaches for adults and children; and
- Using knowledge gained from its compilation and assessment of FOP systems, plan the second phase study (Phase II), which must:

- Consider potential benefits of a single, standardized FOP food guidance system regulated by FDA;
- Assess which icons are most effective with consumer audiences; and
- Develop conclusions about the systems and icons that best promote health and how to maximize their use.

Key Principles Guiding Phase I Study

The IOM Committee evaluated 20 different FOP systems based on a set of guiding principles relating to the diet-related public health objectives FOP labeling systems ultimately should be designed to advance. The Phase I study was premised on the following key principles:

- FOP labeling should be considered one tool that can help promote dietary practices that are consistent with the Dietary Guidelines for Americans, along with other potential sources of nutrition information (e.g., Nutrition Facts) and dietary guidance (e.g., Food Pyramid);
- FOP labeling systems should be designed to focus on nutrients and food components that are most strongly associated with diet-related risks to public health affecting the greatest number of Americans (e.g., calories, saturated fats, trans fats, added sugars, sodium, Vitamin D, calcium, potassium, and fiber);

- The nutrition information that is highlighted in FOP labeling systems should be consistent with the information presented in the Nutrition Facts panel; and
- FOP labeling systems should be designed to apply broadly to as many foods as possible.

FOP Labeling Systems Examined in Phase I Study

The Committee reviewed 20 different FOP labeling systems which it concluded were reasonably representative of FOP systems currently in use in the marketplace in the U.S. and internationally. These included the following FOP labeling systems:[1]

FOP System Developer	FOP Program Name	FOP Labeling System Type[2]
Food Manufacturer	General Mills Nutrition Highlights	Nutrient Specific System
Food Manufacturer	General Mills Goodness Corner	Nutrition Specific System
Retailer	Harris Teeter Wellness Keys	Nutrition Specific System
Food Manufacturer	Kellogg's Nutrition at a Glance	Nutrition Specific System
Government Agency	UK Traffic Light	Nutrition Specific System
Retailer	Wegman's Wellness Keys	Nutrition Specific System
Non-industry Experts	Choices (EU)	Summary Indicator System
Retailer	Guiding Stars	Summary Indicator System
Nonprofit Organization	Canada's Health Check	Summary Indicator System
Retailer	Giant Food Healthy Ideas	Summary Indicator System
Nonprofit Organization	AHA Heart Check	Summary Indicator System
Non-industry Experts	Nutrient Rich Foods Index	Summary Indicator System
Non-industry Experts	NuVal	Summary Indicator System
Food Manufacturer	Kraft Sensible Solutions	Summary Indicator System
Industry and Non-industry Consortium	Smart Choices	Summary Indicator System
Food Manufacturer	PepsiCo Smart Spot	Summary Indicator System
Government Agency	Sweden National Food Administration Keyhole	Summary Indicator System
Industry and non-industry working group	Australia/New Zealand Tick Programme	Summary Indicator System
Industry and non-industry consortium	Whole Grain Council Whole Grain Stamp	Food Group Information System
Food Manufacturer	ConAgra Start Making Choices	Food Group Information System

Key Phase I Study Conclusions

Based on its review of the 20 FOP labeling systems listed above, the IOM Committee came to a number of key conclusions, which are highlighted below.

- "Nutrient-Specific Information Systems" and "Summary Indicator Systems" provide the most promising framework for developing a single uniform FOP labeling system to promote diet-related public health objectives.
- FOP rating systems and symbols should be geared toward the general population rather than particular subpopulations based on age or health condition.

- The FOP labeling systems should be designed to help consumers identify and select foods based on specific nutrients (e.g., calories, saturated fat, trans fat, and sodium) that are linked to the diet-related disease/health risks affecting the largest number of Americans (e.g., obesity, cardiovascular disease, Type 2 diabetes, certain cancers).
- There is insufficient evidence to suggest that it would be useful to include the following nutrients in all types of FOP labeling: total fat, cholesterol, total carbohydrate, total sugars, added sugars, protein, fiber, vitamins, and minerals other than sodium.
- Based on the Committee's review, several options exist for setting criteria for two types of rating systems (nutrient-specific information and a summary indicator based on nutrient thresholds), but further testing of consumer use and understanding is required to assess their overall viability.

Broader Changes in FDA Food Labeling Regulations Could Be Required to Support FOP Labeling Objectives

The Phase I Study concludes that current FDA labeling regulations have a number of limitations which may compromise the effectiveness of FOP labeling systems. The IOM Committee concludes that criteria governing certain nutrient content claims, Daily Values, and RACCs may need to be modified in order to support appropriate FOP labeling systems that apply to a broad range of foods, and promote consistency between FOP standards and those that govern nutrient content claims and information presented in the Nutrition Facts box. For example, the report emphasizes that "not all nutrients of primary interest to the public health-such as total calories, trans fat, and added sugars-have a Daily Value... [which] means not only that there is no basis for developing criteria for a nutrient content claim [for those nutrients] but also that there is no way to inform consumer whether the amount of a nutrient is ‘high' or ‘low.'" Other issues presented by current FDA food labeling standards include:

- The need to establish nutritional criteria to define "medium" levels of nutrients in foods (in addition to the "high" and "low" criteria, such as high in calcium and low in fat, that have already been established),
- The need to reexamine "many Daily Values based on dietary recommendations made 20 to 30 more years ago...to better reflect current science";
- The need to review the possibility that the criteria for "low" nutrient content claims "may be too strict for some products that might otherwise be consistent with a healthful diet, such as fatty fish, tree nuts, peanut butter, and most vegetable oils";
- The need to consider whether the fact that some products that qualify for nutrient content claims do not include labeling regarding such nutrient content claims may make it difficult for consumers, who do not know the nutrient amounts that qualify for a particular nutrient content claims, to make comparisons and decisions among products with and without a FOP nutrient-specific symbol; and
- The need for an automatic system for updating FDA food labeling standards in response to changes in the dietary guidance upon which such standards are based (e.g., Dietary Guidelines for Americans).

What Companies Should Expect

As part of the Phase II Study, IOM has scheduled a public workshop on October 26, 2010 to address "Consumer Behavior Research and Front-of-Package Nutrition Ranking Systems and Symbols-What do consumers know, understand and use?."

IOM is expected to publish the Phase II Study Report in late 2011.

Meanwhile, FDA is expected to continue to advance its FOP Labeling initiative.[3]

For more information regarding the Phase I Report or the regulatory landscape for food labeling, generally, please feel free to contact the attorneys listed below.

Kelley Drye & Warren LLP

Kelley Drye's team of Food and Drug lawyers strives to integrate our clients' business strategies with FDA compliance and to help resolve regulatory enforcement matters when they arise. Working side-by-side with business development and marketing professionals, we provide comprehensive regulatory counseling and assist in developing products, labels, and promotional materials that achieve our clients' goals without running afoul of regulatory requirements. With close knowledge of FDA's enforcement priorities and deep experience with the FTC's regulation of advertising, our team can provide comprehensive legal advice with an eye towards giving clients a competitive edge.

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[1] See IOM Report at pages S-4, S-5, S-6, and S-7 for system icons and other program information.

[2] "Nutrient-Specific Systems" display on the front of the food package the amount per serving of select nutrients from the Nutrition Facts panel or use symbols based on claim criteria. The information is given in percent daily values (%DV) or guideline daily amounts (%GDA), and the display may also include traffic-light colors or words to indicate that a product contains "high," "medium," or "low" amounts of specific nutrients. A declaration of calories per serving may also be provided on the front of the food package. Systems using symbols based on claim criteria may award multiple symbols on a product indicating it is "low fat," "high fiber," etc.

"Summary Indicator Systems" use a single symbol, icon, or score to provide summary information about the nutrient content of a product. No specific nutrient content information is given in these systems. The system may be based on nutrient thresholds or algorithms. Systems often use different criteria based on food categories (e.g., type of food or food product). Algorithm systems evaluate food products based on an equation that takes nutrients (positive and/or negative) into account. Products are given a numeric score (i.e., 1-100) or number of symbols (e.g., 0, 1, 2, 3) to indicate the nutritional quality of the product.

"Food Group Information Systems" use symbols that are awarded to a food product based on the presence of a food group or food ingredient. Some symbols indicate the presence of a serving (or partial serving) of a particular food group, while other symbols indicate the presence of ingredients considered to be important dietary components such as whole grains.

[3] FDA's Draft Strategic Priorities for 2011-2015 identifies improving nutrition labeling on food packages and restaurant menus through its Front-of-Package Initiative as a key priority for FDA from 2011-2015. FDA identified FOP labeling on food packages and restaurant foods as "essential tools for

consumers to construct healthier diets," and expressed an intent to use the Front-of-Package Initiative to address public health problems of obesity and chronic disease." See FDA, Strategic Priorities 2011-2015, "Responding to the Public Health Challenges of the 21st Century," Draft September 29, 2010 is available here.