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Harnessing the Power of Food Labels for Public Health

Jennifer L. Pomeranz, JD, MPH,[1] Peter G. Lurie, MD, MPH[2]

INTRODUCTION

Change is coming to food labeling. Rules that require calorie content on menus at chain restaurants, movie theaters, and similar venues went into effect in early May 2018. A revised Nutrition Facts label, including more prominent calorie listings, added sugars, and updated serving sizes, is already appearing on food packages and will be required by 2020 and 2021, depending on company size. Against this backdrop, the Food and Drug Administration (FDA) initiated a Nutrition Innovation Strategy in July 2018, under which the agency is seeking public comments on several strategies intended to modernize food labels.[1]

The FDA enforces a long list of regulations related to packaged food labels, including product names, standards of identity (which include various ingredient, compositional, and manufacturing standards), ingredient lists, allergen disclosure, and a range of guidelines for making certain claims. Nonetheless, very little of the front of the package is actually regulated, leaving manufacturers to use it primarily for marketing and promotional purposes.

Under the Nutrition Innovation Strategy, the FDA is seeking to update its rules in light of advances in food technology, nutritional science, fortification practices, and marketing trends.[2] Specifically, the agency is considering a "healthy" icon for food labels; revising the review process for qualified health claims (a subset of claims described in detail below), permitting new or enhanced claims or labeling statements to support production of more healthful foods and consumer choices; modernizing standards of identity to provide manufacturers more flexibility to develop healthier products, while ensuring consumers have accurate information; making ingredient information "more helpful to consumers"; and engaging in an educational campaign on the updated Nutrition Facts label.[1]

From a public health and consumer protection perspective, the current state of food labeling reveals many marketing trends, in particular, that provide cause for concern. Food aisles are filled with sugary cereals and baked desserts, like processed pastries, carrying claims that they are "good" or "excellent" sources of vitamins and minerals, as well as cereals, candy, and salty snacks touting healthful ingredients like whole grain, fruit, or kale, even though they contain miniscule amounts of these foods. Other products are marketed with misleading names and statements about their composition, likely confusing consumers. This article discusses issues with current food labels, highlighting marketing trends that are cause for concern related to specific claims, ingredient statements, and naming practices that are ripe for FDA attention under its Nutrition Innovation Strategy.

FOOD CLAIMS

Perusing a food aisle today indicates that much needs to be done to address the current state of food labeling claims. As explained in further detail in Table 1, the FDA draws distinctions in how it regulates four different types of claims. The two types of claims subject to the most regulation are utilized the least on food labels[6]; these are health claims and qualified health claims, both of which characterize the relationship between a food or food component and a reduced risk of disease or health-related condition.[3] Although health claims require significant scientific agreement supporting the claim and FDA approval for manufacturers to use them, qualified health claims do not need to meet this scientific standard so they must include a disclaimer indicating a reduced level of evidentiary support. Neither health claims nor qualified health claims can be made on products containing disqualifying levels of total fat, saturated fat, cholesterol, or sodium.

The vast majority of claims on food are nutrient content claims and structure function claims.[6] Nutrient content claims may be made when a food meets specific

From the [1]College of Global Public Health, New York University, New York, New York; and [2]Center for Science in the Public Interest, Washington, District of Columbia

Address correspondence to: Jennifer L. Pomeranz, JD, MPH, College of Global Public Health, New York University, 715 Broadway, 10th Floor, New York NY 10003. E-mail: jlp284@nyu.edu.

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Table 1. FDA Defined Claims for Food Labels and Opportunities for Improvement

Claim and definition	FDA requirements	Examples	Opportunities for the FDA to strengthen
Health claims[3] characterize the relationship of a substance to a disease or health-related condition and must be based on a "significant scientific agreement" standard.	• Preapproval required through a petition process. • Food may not meet or exceed disqualifying nutrient levels of total fat (13 grams), saturated fat (4 grams), cholesterol (60 milligrams) or sodium (480 milligrams).	• "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect."	• FDA should reevaluate the disqualifying nutrient list, potentially removing "total fat" requirements, and adding limits for "added sugar."
Qualified health claims[3] are permitted when "credible evidence supporting the claim" of a relationship between a food and reduced risk of a disease or health-related condition, but the evidence does not meet the more rigorous "significant scientific agreement" standard.	• Manufacturer must apply for preapproval but qualified health claims are not approved under the statutory standard; rather the FDA issues a Letter of Enforcement Discretion. • Claims are required to use a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. • Food may not meet or exceed disqualifying nutrient levels of total fat (13 grams), saturated fat (4 grams), cholesterol (60 milligrams) or sodium (480 milligrams).	• "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."	• The FDA should reassess the qualified health claim framework, which was based on federal appellate court case (1999) on dietary supplement labels,[4] in light of new evidence that such disclaimers do not seem to enhance consumer understanding. • FDA should reevaluate the disqualifying nutrient list, potentially removing "total fat" requirements, and adding limits for "added sugar."
Nutrient Content Claims[3] expressly or implicitly characterize the level of a nutrient of the type required to be disclosed in nutrition labeling.	• Must be made in accordance with Reference Amounts Customarily Consumed or the Recommended Daily Value of a food or nutrient. • No disqualifying nutrient list applies, but if the food meets the disqualifying standards for health claims (noted above), the label must state: "See nutrition information for [subject nutrient] content."[5]	• "low fat" • "high in Vitamin D"	• FDA should reevaluate the disqualifying nutrient list, potentially removing "total fat" requirements, and adding limits for "added sugar," and apply it to nutrient-content claims. • The FDA should also use its authority to address untruthful and misleading statements to reign in misleading nutrient content claims.
Structure/Function Claims[3] describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body.	• Do not need preapproval and there are no specific requirements for their use.	• "Calcium builds strong bones"	• FDA should regulate structure/function claims and/or Congress should provide express authority for the agency to do so. • FDA should also reevaluate the disqualifying nutrient list, potentially removing "total fat" requirements, and adding limits for "added sugar," and apply it to structure/function claims. • The FDA should also use its authority to address untruthful and misleading statements to reign in false and misleading structure/function claims.

FDA, U.S. Food and Drug Administration.

thresholds for that nutrient (e.g., "excellent source of vitamin C," "fat free").[3] For nutrient content claims, there is no disqualifying level of other nutrients, so unhealthy food that is high in sugar or sodium, for example, can nonetheless tout healthy levels of other nutrients.

Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the body (e.g., "DHA omega-3 supports brain health").[3] There are no regulations related to the use of structure/function claims on food labels. Therefore, they—like all claims—are simply required to be truthful and not misleading. Similar to nutrient content claims, there is no requirement that a food carrying a structure/function claim meet any criteria for healthfulness, so, as for nutrient content claims, manufacturers can highlight positive attributes of otherwise unhealthy products.

FDA's differing treatment of these claims creates a confusing labeling landscape for consumers and an inconsistent framework that is not always science-based. Research indicates that consumers cannot differentiate among different types of claims or distinguish the level of evidence supporting them,[6,7] and consumers actually find structure/function claims more convincing than health claims.[8] Therefore, in addition to enhancing the requirements for qualified health claims, the FDA should consider updating and strengthening the requirements for nutrient content and structure function claims. For example, the European Union requires, what it calls "health" and "functional" claims, to meet the same scientific standard and that food manufacturers obtain specific authorization for their use.[9] The FDA should similarly apply more uniform and science-based standards for nutrition content and structure/function claims and should include a disqualifying nutrient list as a prerequisite for making any such claim.

INGREDIENT STATEMENTS

In the FDA's effort to make ingredient information more helpful to consumers, the agency should focus on misleading statements and names of foods that contain healthy ingredients but are not actually healthy overall or not primarily composed of the promoted ingredient. Many examples like this exist, such as labels indicating that a food is "made with whole grain," when it is predominantly composed of refined grains[10]; fruit-flavored candy made to appear healthy by adding concentrated fruit sugars (along with corn syrup and flavoring) and marketing them as containing fruit[11]; and the addition of small amounts of healthful components (e.g., kale and berries) to otherwise unhealthy products (e.g., chips and sugary cereals) alongside promotion of the product based on the healthful ingredient. Consumers purchase and consume these generally unhealthy products based on misleading statements and names, while producers of more healthful foods may lose market share.

FDA should create requirements to ensure that all such ingredient references are not misleading. For example, the FDA can address the whole-grain labeling issue by requiring that foods making whole-grain claims disclose the relative percentages or grams of whole grains versus refined grains per serving.[12] FDA should also require manufacturers to disclose that products "contain no real fruit or vegetables" or "contain insignificant amounts of fruits or vegetables" when this is so or when the ingredient comes solely in the inconsequential form of powders, pastes, and concentrates.

PRODUCT NAMES

The FDA stated it will consider updating standards of identity, but the FDA could also regulate product names to support informed choices and reduce consumer confusion. Two product categories stand out as examples. First, juice blends may be named according to any juice that is a component of the product no matter how insignificant. For example, "pomegranate blueberry flavored blend of five juices," is permitted even though the product is 99.4% apple and grape juice and the disclaimer that the product is actually a "flavored blend of five juices," may be written in tiny font on the product label.[13] The FDA should consider amending its regulation to require the most prominent juices, or all the juices in order of prominence, be identified in the name in equal font size.

Another example is the manufacturer created statements of identity for older-infant and toddler drinks with various names, such as infant and toddler formula, toddler formula, toddler milk, and milk drinks.[14] These products are not infant formulas but are branded to appear similar to infant formulas and are not recommended by WHO or U.S. physician groups. Unlike infant formulas, there are no FDA regulations for names, ingredients, or labels, potentially leading to consumer confusion and risky feeding practices. The FDA should directly regulate this relatively new class of products using a similar framework as for infant formula because it is promoted along this feeding continuum.

ADDITIONAL AUTHORITIES AND LIMITATIONS FOR FOOD LABELS

In the past, Commissioner Gottlieb, among others, argued that the First Amendment's protection for commercial

speech should lead the FDA to use disclaimers to correct any potentially misleading speech on food labels.[15] However, unlike factual disclosures, disclaimers (e.g., "FDA has determined that this evidence is limited and not conclusive") in the context of food have not generally been found to clarify consumer confusion over the scientific underpinning of various types of claims.[3] In other words, deceptive claims accompanied by a disclaimer remain deceptive.[16] The First Amendment does not protect misleading or deceptive commercial speech.[17–19] Therefore, the First Amendment is not a barrier to FDA regulation of confusing and deceptive claims, ingredient statements, and product names.

Beyond the FDA, Congress can revise the Nutrition Labeling and Education Act to directly address misleading claims and ensure that food meets appropriate standards. In fact, several members of Congress introduced a bill called the Food Labeling Modernization Act, which would provide enhanced direction and authority to the FDA to regulate products and evaluate claims, including creating regulations for structure/function claims and addressing misleading descriptors like "whole grain," among other promising revisions.[20] However, this has yet to progress through Congress.

CONCLUSIONS

The goal of supporting public health and alleviating consumer confusion should drive new FDA rules. The FDA has taken a public health approach to other products under its authority (e.g., reducing nicotine content of tobacco products) and it is encouraging to see it wield its powerful toolbox on food labeling to improve public health. To fulfill the FDA's goal of supporting informed consumer decision making, the agency should ensure that food labels are truthful, not misleading, and provide true clarity for consumers seeking a healthy diet.

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