Government perspective: food labeling\textsuperscript{1–3}

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**ABSTRACT**

The Food and Drug Administration acknowledges the severity of the obesity epidemic. The Food and Drug Administration recognizes the importance of food labeling as a vehicle for dietary messages and, thus, enforces stringent guidelines to maintain the integrity of the food label. As food labels await another upgrade to make them more effective and easier to understand, the Food and Drug Administration considers what information will be most useful for consumers to make healthy choices. The causal relationship between food labels and subsequent diet choice is not well understood; more research in this area is needed. The Commissioner of the Food and Drug Administration has recently appointed an Obesity Working Group to develop proposals on pertinent topics of obesity, including the role of food labeling as a dietary guide. \textit{Am J Clin Nutr} 2005; 82(suppl):262S–4S.

**KEY WORDS** Food labels, nutrition labels, Food and Drug Administration, dietary guide, Obesity Working Group, calories count, health claims, consumer advice

**INTRODUCTION**

The Food and Drug Administration (FDA) recognizes the obesity epidemic as an urgent public health issue, and we are committed to the search for solutions. The experience of the Food and Drug Administration regarding the utility of food labeling as a dietary guide is an important component of the blueprint for a healthier United States. The FDA’s attempt to use the food label for dietary advocacy goes back to 1989. At that time, the food label had not been updated for almost 20 y, its format was anybody’s choice, and labeled health claims were both exuberant and undocumented. The Surgeon General’s Report on Nutrition and Health in 1988 instigated the label change. The FDA decided to develop a new food label that would be uniform, science based, and rigorously truthful. The updated food label would inaugurate a new era in food labeling by telling shoppers the main ingredients in every manufactured food item and how much of that food was good for their health. The Nutrition Facts Panel is now a familiar component of the food label.

After Congress endorsed this effort in the Nutrition Labeling and Education Act of 1990 (1), the FDA launched one of the most extensive undertakings in its history. The agency held nationwide hearings to gather facts and expert views, considered scores of scientific documents and studies, drafted nearly 900 pages of proposed regulations, analyzed 40 000 comments submitted by leaders in food science and industry, and, in 1993, produced a food label that was designed to help the public chose a low-fat, high-fiber daily diet of 2000 or 2500 calories. The climax of the effort was a coast-to-coast, multi-lingual educational campaign launched in March 1994 and delivered the FDA’s message into virtually every American household. It was projected that the new label would save the nation up to $26 billion in health care costs over 20 y and prevent many of the 300 000 deaths per year that were then associated with diet. The results have not lived up to the early expectations entirely, but they have not been uniformly bleak either.

Surveys report 60–80% of food shoppers had read food labels before buying a new food item, and 30–40% said the label had influenced their choice. The surveys also revealed frequent misunderstanding of the meaning of the daily/value column that shows how each nutrient fits into a healthy diet (2–6). There was also considerable confusion caused by the frequently conflicting dietary advice by nutritionists, fad diet advocates, and studies reported by the media. This bewilderment has generated distrust of all dietary recommendations and a corresponding desire for nutrition information that is clear, authoritative, and easy to understand.

**UPGRADING THE FOOD LABEL**

The FDA decided to undertake an effort to make the food label a more effective vehicle for dietary messages. Our first step was a proposal, issued in December 2002, to relax the enforcement of a provision of the Nutrition Labeling and Education Act requiring that all health claims on food labels be supported by a "significant scientific agreement." This standard has been so difficult to achieve that the FDA has approved only 12 unqualified cause-and-effect health claims in the past 10 y, such as the linkage between calcium and osteoporosis, fat and cancer, and folic acid and neural tube defects. Two more health claims were added under a new law that allows such labeling based on an "authoritative statement" from the National Academy of Sciences or a scientific body of the federal government. The legislated restrictions have prevented manufacturers from labeling claims based on emerging, and therefore incomplete, scientific evidence, such as the well-documented findings that omega-3 fatty acids in certain kinds of fish can help reduce the risk of coronary heart disease (7).

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In our opinion, labeling statements of this type should be permissible because they can bring two important benefits: they can make consumers better informed and more health conscious when they shop for food, and they can motivate industry to develop more healthful products and use their potential health effects as a competitive factor, alongside price, taste, and the convenience of packaging. Thus, the FDA proposed to allow food firms to make, in addition to the unqualified health claims authorized by the law, certain qualified health claims that would be truthful, nonmisleading, and preapproved by the FDA on the basis of a new standard defined as “the weight of scientific evidence” (8).

The FDA took two additional steps to upgrade the food label: we issued a requirement for the listing of trans fatty acids on the nutrition facts panel, and we described the four categories of the health claims we intend to allow on food packages. The top category, A, is for unqualified claims supported by significant scientific agreement. The B category is for qualified claims that are supported by substantial but inconclusive evidence. The C category covers claims based on evidence that is limited and not conclusive. D, the lowest category, is for claims for which there is little scientific evidence.

THE OBESITY WORKING GROUP

The FDA reached the conclusion that the obesity epidemic is likely to require additional measures both by our agency alone and in concert with others, including the government, academia, industry, health care providers, and consumers. Commissioner McClellan appointed an Obesity Working Group in August 2004 and charged it with the development of a comprehensive blueprint of the steps that could and should be taken to confront this public health issue. See the FDA’s website at http://www.cfsan.fda.gov/~dms/owg-rpt.html for more information about the Obesity Working Group and their “Counting Calories” report (9). This project was subsequently endorsed and given department-wide scope by Secretary Thompson. The Obesity Working Group has been asked to develop proposals for 5 pertinent topics. (Table 1).

The Obesity Working Group found little evidence that indicates the effects the food label may have on obesity (10). There seems to be a need for well-controlled studies that examine the effects of food labeling on diets. Current labeling, on the product level, does not facilitate learning about diets, which come from a combination of products. Therefore, the Obesity Working Group considered restaurant labeling as a partial remedy to this problem by labeling entire meals rather than single products. We also considered better labeling of diets and weight-loss products. Consumers spend billions of dollars per year on these products, although many studies show that diets fail for 95% of those who try. If diets are “treatments” for weight reduction, then the “intent-to-treat effects” of these treatments are very poor, partly attributable to the difficulties with compliance or adherence to the treatment prescribed. The following question arises: if consumers were better informed of the intent-to-treat effects of these products, would the demand remain as high?

The Obesity Working Group, in conjunction with advice from its stakeholders, questioned how the current Nutrition Facts Panel on packaged food could better persuade or influence consumers to maintain their energy balance. The suggestions confirmed that food labeling should be an effective vehicle for raising the public’s consciousness of the importance of calories when making dietary decisions. For example, the FDA was urged to encourage manufacturers to indicate the total caloric content on the food label of an entire food package if it is likely to be consumed in one sitting. The FDA was also asked to urge food firms to print the caloric count in bold digits on the face of each food package, to encourage labeling statements suggesting alternative food choices with fewer calories, and to develop labeling statement that would inform the consumer how much exercise would be necessary to burn the calories in the food package. A label was also proposed that would list the health consequences of eating too much, something similar to the Surgeon General’s warning on packs of cigarettes. These ideas require substantial research on consumer responses to labeling.

CONCLUSION

The FDA invites any and all present behavioral scientists who are interested in these issues to assist us. We need better-controlled studies of the effects of labeling on the demand for different foods. There are many studies on this topic, but most of them focus on correlations of labeling use and diet choice. Such correlations may be spurious when unobserved factors drive both the demand for label information and diets. This would be the case when health-conscious people, who already have healthy diets without the label, are observed to have healthy diets when using the label. We also need better-controlled experimental designs to assess predemand and postdemand behavior surrounding a change in labeling, randomly assigned to different parts of the consumer population. Such studies would be extremely helpful; the FDA hopes to work with manufacturers to conduct them in the future.

The use of food labeling for dietary advocacy is an endeavor the FDA intends to advance very intensively, imaginatively, and as efficiently as possible, but also with great care. Without solid scientific conclusions bearing on the issues of food labeling and the obesity epidemic, the proposals would not be in the interest of public health or in the tradition of a science-based agency such as the FDA.

TP is the senior economic advisor to the Commissioner of the Food and Drug Administration. There are no conflicts of interest.

REFERENCES


### TABLE 1

<table>
<thead>
<tr>
<th>The Obesity Working Group topics</th>
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<tr>
<td>● An effective public health message about the need to balance food intake with expended energy</td>
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<td>● A consumer education program with the same aim</td>
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<td>● Better food labeling</td>
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<td>● Research on consumer behavior in regards to food consumption</td>
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<td>● Enhancement of the development of effective weight-loss and weight-control drugs and devices</td>
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1Source: Reference 9.