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Evidence for Health Claims on Food: How Much Is Enough?

Health Claims in the United States: An Aid to the Public or a Source of Confusion?[1–3]

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Abstract

Health claims in the United States have been a topic of intense controversy since the mid-1980s. Three categories of claims can currently be used on food and dietary supplement labels in the United States: *1*) health claims, *2*) nutrient content claims, and *3*) structure/function claims. Structure/function claims were authorized under the Dietary Supplement Health and Education Act and describe the effect of a dietary supplement on the structure or function of the body. Nutrient content claims are used to describe the percentage of a nutrient in a product relative to the daily value. Health claims describe a relation between a food, food component, or dietary supplement ingredient and reducing risk of a disease or health-related condition. Health claims are based on a very high standard of scientific evidence and significant scientific agreement. Are U.S. health claims really benefitting public health? Recent evidence suggests that this mode of communication has had limited success and in fact may be misleading to consumers. J. Nutr. 138: 1216S–1220S, 2008.

Introduction

In the United States, label claims have been a topic of intense controversy for more than 2 decades. Before the mid-1980s, food labels were banned from making any statement linking a dietary component to disease risk reduction. In 1984, the Kellogg Company began a partnership with the National Cancer Institute, a branch of the NIH, to disseminate information about the role a low-fat, high-fiber diet may play in reducing the risk of colon cancer. This was a revolutionary development in that it was the first time any major food company had used the word cancer on a food product, in this case All-Bran cereal (1). The U.S. FDA took no regulatory action, however, because the statement was truthful, not misleading, and provided a significant public health benefit. It has been estimated that health claims in advertising and labeling during 1985–1987 caused 2 million more households to consume high-fiber cereals (2). Unfortunately, however, a plethora of unsubstantiated health claims soon began to appear in the marketplace, prompting the *Business* Week magazine cover story of October 9, 1989: "Health Claims for Foods are Becoming Ridiculous" (3). Soon afterward Congress passed the Nutrition Labeling and Education Act (NLEA)[4] of 1990 (4), which required health claims only with FDA approval.

Three categories of claims

Three categories of claims can currently be used on food and dietary supplement labels in the United States: *1*) health claims, *2*) nutrient content claims, and *3*) structure/function claims. The objective of the present review is to focus primarily on health claims with only a brief mention of the latter 2 categories.

Structure/function claims were authorized under the Dietary Supplement Health and Education Act of 1994 (5). Such statements describe the effect of a dietary supplement on the structure or function of the body. An example of a structure/function claim is "helps promote bone health." Such claims do not require preapproval by the FDA before being used on labels and must be accompanied by the following disclaimer: *"This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."*

A second claim category is nutrient content claims (6). Such claims are used to describe the percentage of a nutrient in a product relative to the daily value (DV). The DV indicates the

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[3] Supplemental Table 1 is available with the online posting of this paper at jn.nutrition.org.

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[4] Abbreviations used: CHD, coronary heart disease; DV, daily value; NLEA, Nutrition Labeling and Education Act.

TABLE 1 Health claims meeting the standard of significant scientific agreement authorized by the NLEA of 1990

Dietary saturated fat and cholesterol and risk of CHD
Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of CHD
Sodium and hypertension
Dietary lipids (fat) and cancer
Fiber-containing grain products, fruits, and vegetables and cancer
Fruits and vegetables and cancer
Calcium and osteoporosis
Folate and neural tube defects

TABLE 2 Health claims meeting the standard of significant scientific agreement authorized between 1997 and 2006 by the FDA in response to petitions submitted to the agency

Whole oat soluble fiber and CHD
Sugar alcohol and dental caries
Psyllium seed husk and CHD
Soy protein and CHD
Sterol and stanol esters and CHD
Oatrim and CHD
Barley soluble fiber and CHD

amount of a nutrient that is provided by a single serving of a food item. An example of a nutrient content claim is "good source of calcium." To state that a product is a "good source" of calcium, this nutrient must provide 10% of the DV. To say "excellent" source, calcium must be 20% of the DV.

The third category of claims, health claims, was authorized under the NLEA of 1990. Health claims describe a relation between a food, food component, or dietary supplement ingredient and reducing risk of a disease or health-related condition (7). An example of an NLEA-approved health claim is *"Food containing 0.7 g or more of Plant Stanol Esters per serving eaten* two *to* three *times a* day *with meals may reduce the risk of heart disease as part of a diet low in saturated fat and cholesterol. A serving of BENECOL® Spread contains 1.7 g of Plant Stanol Esters."*

Health claims require a high standard of evidence

Health claims are based on a very high standard of scientific evidence. First, the totality of the publicly available evidence must support the diet-disease relation that is the subject of the claim, and second, there must be significant scientific agreement among qualified experts that the relation is valid. The FDA authorizes these types of health claims based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition. The NLEA mandated that the FDA review 10 substance-disease relations. Of these, significant scientific agreement was determined to exist for 8 of the relations, and health claims describing these relations on food labels were authorized in 1993 and are outlined in **Table 1.**

The NLEA also permits any interested person or company to petition the FDA for a health claim. Between 1997 and 2006, 7 health claims meeting the standard of significant scientific agreement were authorized in response to petitions from industry or trade associations, as shown in **Table 2.** All but 1 link a dietary component to reduced risk of coronary heart disease (CHD).

The question of what constitutes significant scientific agreement has been a matter of great debate. The FDA has outlined a scheme for assessment of the strength and consistency of scientific evidence leading to significant scientific agreement as shown in **Figure 1** (8).

Without question, randomized, controlled clinical intervention trials are the "gold standard" for health claim approval. This still leaves the following question unanswered, however:

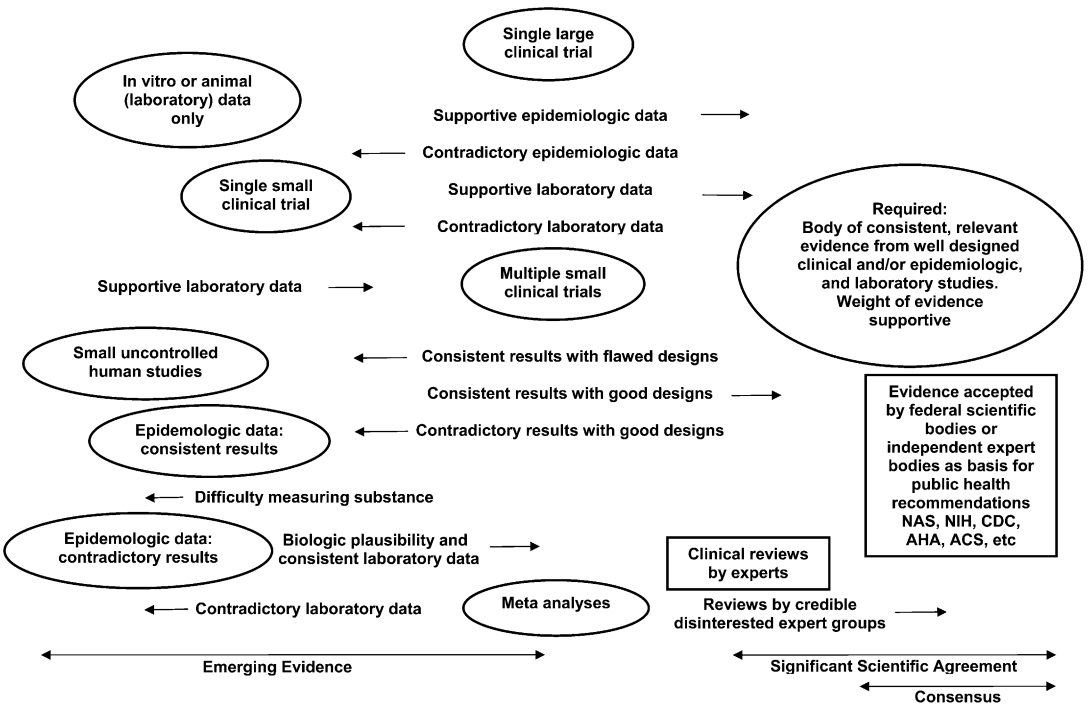

FIGURE 1 Schema for assessing strength and consistency of scientific evidence leading to significant scientific agreement.

"How *many* randomized, controlled clinical intervention trials are required for a health claim based on this rigorous standard?" The numbers of clinical intervention trials submitted in petitions for 7 different claims are shown in **Table 3**. They range from as many as 37 in the case of whole oats and CHD to as few as 5 for the product Oatrim.

Significant scientific agreement claims are also allowed based on statements published by certain government authorities. The Food and Drug Administration Modernization Act of 1997 (9) provides an expedited route to health claim approval by allowing "authoritative statements" from a scientific body of the U.S. Government or the National Academy of Sciences to be used as a health claim. A petition can be submitted based on this statement, and the FDA has 120 d to notify the petitioner whether or not the proposed claim meets the statutory requirements. If the FDA does not deny the claim within the 120-d time frame, the claim may be used on products. One nutrient content claim and 5 health claims have been authorized through the Food and Drug Administration Modernization Act (Supplemental Table 1).

The development of qualified health claims resulted from a 1999 Court of Appeals Decision, *Pearson v. Shalala*, which successfully challenged the rigid standards of evidence applied to NLEA health claims (10). The court ruled that it was unconstitutional for the FDA not to allow health claims on 4 dietary supplements that did not meet the standard of significant scientific agreement. In 2003, qualified health claims were extended to conventional foods when the FDA announced the 2003 Consumer Health Information for Better Nutrition Initiative (11).

With qualified health claims, the FDA established a ranking system from moderate/good, "B" level, to very low, "D" level, which reflects the relative weight of the scientific evidence supporting the proposed claim (**Table 4**). Unqualified "A" levels claims are those that meet the standard of significant scientific agreement (Table 1). Currently, 16 qualified health claims are approved in 5 different disease categories for foods and dietary supplements, including heart disease [B vitamins, certain tree nuts, walnuts, (n-3) fatty acids, olive oil, canola oil, corn oil]; cancer (tomato products, calcium, green tea, selenium, certain antioxidant vitamins); cognitive function (phosphatidylserine); diabetes (chromium picolonate); hypertension (calcium); and neural tube defects (folate).

Consumer confusion over health claims

Are U.S. health claims truly a public health boon, or do they just appear to consumers to be overlapping and possibly confusing messages? The 2007 Food & Health Survey from the International Food Information Council (12) showed that consumers are relying less on health and nutrition information on package labels when they make purchase decisions. The IFIC evaluated the consumer understanding of qualified health claims in a web-based survey of 5642 U.S. adults in 2005 (13). They found that consumers had trouble distinguishing the 4 distinct levels of science behind the FDA-proposed 4 levels of health claims regardless of which of several language options were used to describe them. More specifically, 78% of consumers could not correctly sort 4 levels of claims as to the scientific evidence, e.g., unqualified, "B" claim, "C" claim, "D" claim.

TABLE 3 Scientific substantiation supporting currently approved health claims

Diet–disease relation	Clinical trial support	Allowed health claim	Effective level
Whole oat soluble fiber and CHD	37 submitted 33 reviewed[1] 17 priority[2]	Diets low in saturated fat and cholesterol that include soluble fiber from whole oats may reduce the risk of heart disease.	3 g/d; 0.75 g/serving 4 times/d
Psyllium seed husk soluble fiber and CHD	21 submitted 21 reviewed 7 priority	Soluble fiber from foods such as [name of food], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies [*x*] grams of the soluble fiber necessary per day to have this effect.	7 g/d; 1.7 g/serving 4 times/d
Oatrim and CHD	5 submitted 1 reviewed	Diets low in saturated fat and cholesterol that include soluble fiber from Oatrim may reduce the risk of heart disease.	0.75 g/serving
Barley soluble fiber and CHD	11 submitted 5 reviewed	Soluble fiber from foods such as [name of food], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies [*x*] grams of the soluble fiber necessary per day to have this effect.	3 g/d
Soy protein and CHD	43 submitted 41 reviewed 14 priority	Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides 6.25 grams of soy protein.	25 g/d; 6.25 g/serving
Plant sterol esters and CHD	15 submitted 9 reviewed 8 priority	Plant sterols: Foods containing at least 0.65 grams per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 1.3 grams as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies [*x*] grams of vegetable oil sterol esters.	1.3 g/d; 0.65 g/serving
Plant stanol esters and CHD	24 submitted 15 reviewed 14 priority	Plant stanol esters: Foods containing at least 1.7 grams per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies [*x*] grams of plant stanol esters.	3.4 g/d; 1.7 g/serving

[1] The FDA conducts its own independent review of the literature.
[2] The FDA excludes studies that do not meet crucial study design criteria.

TABLE 4 Scientific ranking and proposed qualifying language for qualified health claims

Level of scientific evidence	FDA category	Proposed qualifying language
High	A	Category A health claims are unqualified claims that meet the significant scientific agreement standard
Moderate/good	B	``Scientific evidence suggests but does not prove…''
Low	C	``Some scientific evidence suggests…; however, FDA has determined that this evidence is limited and not conclusive.''
Lowest	D	``Very limited and preliminary scientific research suggests…; FDA concludes that there is little scientific evidence supporting this claim.''

Recently, the FDA released preliminary findings from its report on what consumers understand from health claims on food packages (14). The study examined 18 front-panel label examples, which varied in types of diet-disease relations including those presumed to be well known, calcium-osteoporosis, less well known, potassium-hypertension, and 1 involving a fictitious nutrient, lysoton, and heart disease. Preliminary findings indicate that when a health benefit is well known, e.g., calcium and osteoporosis, the format presented has no bearing on how strongly consumers believe in the stated benefit. Respondents are also more likely to consider buying the product when the health claim they see mentions the nutrient responsible for the benefits. The FDA concluded there is little difference in how likely respondents are to recognize the difference between a nutrient mentioned in a food-specific claim, a structure-function claim, or a dietary guidance claim.

The road to health claim approval is lengthy, expensive, and, as recent evidence would suggest, not particularly useful. The FDA requires an overwhelming body of evidence for a significant scientific agreement, unqualified health claim, and qualified health claims with less evidence are very wordy and confusing to consumers. Thus, some leading food manufacturers are highlighting their foods as being "better for you" using on-package logos. For example, Pepsi's Smart Spot indicates that the product puts limits on total, saturated, and *trans*-fats, cholesterol, sodium, and sugar. Kraft uses their "sensible solution" logo on foods that provide beneficial nutrients or otherwise deliver a functional benefit. More recently, Hannaford Brothers Grocers in the Northeast United States (http://www.hannaford.com/) launched the first-ever storewide nutrition navigation system designed to provide shoppers a quick, at-a-glance guide for consumers seeking foods with more nutrition for the energy (15). The "Guiding Stars" program evaluates >27,000 edible items, all brands, according to their nutritional value. Guiding Stars uses a proprietary rating formula, patent pending, to credit a food's score for the presence of vitamins, minerals, fiber, and/or whole grains and debit a food's score for the presence of *trans*- and/or saturated fats, cholesterol, added sugars, and added sodium. The resulting score determines whether the item receives 1 (good nutritional value), 2 (better nutritional value), 3 (best nutritional value), or no stars. However, there is concern among some experts that propriety rating formulas established by food manufacturers, grocery stores, trade organizations, and health organizations that result in additional logos, icons, and shelf markers on food products may be adding to consumer confusion. In September 2007, the FDA announced a pubic hearing concerning the use of symbols to communicate nutrition information on food labels (16).

In conclusion, the intent of label claims is to provide consumers more scientifically valid information about the foods they eat to improve their health and well-being. However, evidence to date suggests that this mode of communication has had limited success and in fact may be misleading to consumers with regard to understanding of scientific evidence as well as overall diet choices.

Other papers in this supplement include references (17–26).

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