

Ads Can Do the Body Good

But regulations and lawsuits discourage business from marketing healthful food.

**Food
and
Drug Law** | A Practice Focus

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The need to market healthy food choices to the American public may never have been greater. Unfortunately, the current regulatory regime discourages companies from marketing a greater variety of healthful food products. That should change.

The scientific evidence establishing the power of healthy dietary practices to prevent obesity and other serious chronic diseases has been mounting for decades. Recently, in a 2008 report, the Centers for Disease Control and Prevention stated that good nutrition can help lower risk for “many chronic diseases, including heart disease, stroke, some cancers, diabetes, and osteoporosis.”

At the same time, the CDC emphasized that “a large gap remains between healthy dietary patterns and what Americans actually eat.” In 2007, an estimated 25.6 percent of the population qualified as “obese,” a percentage that has dramatically increased over the last 20 years.

There is growing interest among public health experts in the role food marketing can play in promoting widespread adoption of healthy dietary practices by the public. But to encourage companies to market the greater variety of healthful food products that would have more diverse appeal, some regulatory obstacles—including the flawed standards governing product benefit claims and the inadequate scope of federal pre-emption—will have to be overcome.

MARKETING CLAIMS

Federal laws, under largely harmonized Food and Drug Administration and Federal Trade Commission regimes, currently allow the nutritional benefits of food products to be represented through three basic types of marketing claims: nutrient content claims, health claims, and structure/function claims.

- Nutrient content claims expressly or impliedly characterize the level of a nutrient in the food (e.g., “light,” “low fat”). Federal regulations prescribe the particular wording and provide nutritional requirements for the foods bearing the claims.

Importantly, federal law establishes national uniform standards, enforceable by both the FDA and state officials, along with federal pre-emption to preclude states from establishing inconsistent standards.

With the benefit of clear standards for compliance and the statutory protection from federal pre-emption, nutrient content claims are widely used. On the other hand, the requirements that ban all but a short list of FDA defined nutrient content claims terms to describe product benefits raises significant First Amendment concerns because it restricts the freedom of expression constitutionally protected in commercial speech and vastly limits the opportunities of food marketers to convey valuable nutritional information to the public in the most effective ways.

- Health claims expressly or impliedly characterize the relationship between a food substance and a disease or health-related condition. (For example, “Drinking fluoridated water may reduce the risk of tooth decay;” “Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low fat, low saturated fat, and low cholesterol diet and not resulting in increased calorie intake, may reduce the risk of coronary heart disease.”) They are subject to pre-market clearance by the FDA, which specifies health claims language characterizing the scientific evidence that the agency regards as relevant, along with any limitations considered to be material.

As with nutrient content claims, the federal legal framework establishes national uniform standards, which are enforceable by both the FDA and the states, along with federal pre-emption to preclude states from establishing inconsistent standards. Yet the costly and burdensome pre-market clearance requirements, coupled with the limited marketing value of the authorized health claims language, has had a chilling effect on the use of health claims for food marketing purposes, as well as raising significant First Amendment concerns.

- Structure/function claims convey the benefits of food in supporting the growth and maintenance of normal bodily structures and functions, including specific health promotion benefits attributable to nutritious food choices (e.g., “helps maintain healthy weight;” “promotes strong bones and teeth”).

Structure/function claims have a particularly promising role to play in fostering healthy diets. Unfortunately, the current legal framework fails to provide adequate legal protections and incentives for well-substantiated claims.

On the positive side, the absence of FDA pre-market clearance requirements gives food marketers greater opportunity to convey the benefits of nutritious foods in ways meaningful to a diverse range of consumers. Yet the absence of clear and objective national uniform compliance standards and of federal pre-emption to protect companies from enforcement under inconsistent state laws discourages the use of structure/function claims.

THE RIGHT STANDARDS

Structure/function claims, in general, require substantiation in the form of “competent and reliable scientific evidence.” Although the “competent and reliable scientific evidence standard” arguably is sufficiently flexible to accommodate any distinctive issues relating to the substantiation of health promotion claims, there is no objective national uniform compliance standard that allows marketers to determine with certainty that a structure/function claim is compliant with federal law.

Unfortunately, to the extent that the FDA has attempted to articulate standards to characterize the nature and amount of scientific evidence needed to substantiate health benefits of food products, the agency has borrowed too much from models developed to evaluate the efficacy of drug treatments in clinical medicine.

This approach treats evidence from randomized controlled trials—which, as the name suggests, assigns the test substance to study subjects at random and includes control group subjects who do not receive the test substance—as the gold standard regardless of the nature of the relationship between the food and health benefit that is being evaluated.

Although such trials are useful in minimizing sources of bias and establishing causal relationships between discrete substances and isolated health-related outcomes, they are poorly suited to characterize the more complex, subtle, and yet powerful nutritional relationships that promote health and wellness.

As one of us (Roller) and Dr. Robert Heaney of Creighton University have discussed more fully in “Nutrition, Health Policy, and the Problem of Proof” in *Nutrition in the Prevention and Treatment of Disease* (2008), regulatory policies need to account for several important distinctions that exist between the evaluation of drug benefits and nutritional benefits:

- Contrast groups: Testing the use of a drug against a drug-free state provides a straight-forward measurement. Nutrients, by contrast, can essentially never be tested against a nutrient-free state, either in the body or diet.

- Primary outcome variables: The primary outcome variables in randomized, controlled drug trials tend to be discrete (e.g., “Do beta blockers improve survival after myocardial infarction?”). The questions in nutrition testing typically are as multiple as the variables underlying “good health” and disease prevention.

- Helper agents: Randomized controlled trials typically exclude co-therapies to allow clearer definition of the drug effects. In evaluating a nutrient, ensuring intakes of other nutrients is often critically important if the test nutrient is to exert a measurable effect. (For example, many of the protective effects of vitamin D depend on adequate intakes of protein and calcium.)

- Effect size: Drug effects, by design, are measurably large and, thus, can be shown using a relatively small sample size. Nutrient effects tend to be measurably small, at times requiring at least 1,000 subjects to demonstrate any effect.

- Ethical concerns: The placebo group in a randomized controlled trial must either not ingest the test substance or ingest inadequate levels. Depriving control subjects of a nutrient known to benefit some systems to test effects on another system requires investigators to harm the control subjects.

- Cost: Unlike drugs, foods have limited profit margins and opportunities for patent protection and market exclusivity.

As a result, the standard for substantiating structure/function claims, while remaining flexible, must more fully account for the distinctive features of the nutritional relationships that explain the benefits of healthy dietary practices.

PRE-EMPTION NEEDED

In the past several years, increasing numbers of consumer deception lawsuits have been filed or threatened against food companies under broad and ill-defined state consumer protection laws. These lawsuits have targeted a number of companies responsibly marketing dairy products, chicken, and other healthful foods in a manner consistent with federal guidelines.

Many of the plaintiffs have been interest groups seeking to compel companies to abandon well-substantiated marketing claims through the threat of costly litigation challenging the adequacy of claim substantiation. These lawsuits commonly target implied claims and thereby open the door to a particularly value-laden inquiry into the “true” meaning of the claim being challenged as allegedly deceptive. Given the expensive and the unpredictable nature of these suits, abandoning well-substantiated claims in settling even groundless cases becomes a reasonable business decision. And under the onslaught, the chilling effects extend far beyond the specific companies targeted.

In sum, for food marketing to live up to its potential to foster healthy dietary practices, policy changes will be needed to dramatically strengthen the legal protections and incentives for companies marketing nutritious foods. Foremost is the need for a national uniform objective compliance standard to enable companies to be sure that their well-substantiated structure/function claims comply with federal law and for federal pre-emption to protect companies from becoming the targets of lawsuits under inconsistent state laws.

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