



First Amendment Issues Facing the FDA

Maureen L. Storey, Ph.D
Acting Director

September 2002

The Center for Food and Nutrition Policy (CFNP) is an independent, non-profit, center chartered at Virginia Polytechnic Institute and State University. The CFNP mission is to advance rational, science-based food and nutrition policy, and it is recognized as a Center of Excellence on such matters by the Food and Agriculture Organization of the United



Center for Food and Nutrition Policy
1101 King Street, Suite 611
Alexandria, VA 22314
Phone: 703-535-8231 Fax: 703-535-8234
Email: mstorey@vt.edu

An FAO Center of Excellence for Food and Nutrition Policy

September 13, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**RE: Docket No. 02N-0209: First Amendment Issues
67 Fed. Reg. 34942 (May 16, 2002)**

The Center for Food and Nutrition Policy (“Center”) of Virginia Tech—Alexandria is an independent, non-profit research and education organization that is dedicated to advancing rational, science-based food and nutrition policy. It is recognized as a Center of Excellence on such matters by the Food and Agriculture Organization of the United Nations (FAO). The Center uniquely operates like an independent “think-tank,” while maintaining its academic affiliation with a major land-grant university. The research, education, outreach, and communications activities of the faculty are conducted in a relevant, time-sensitive manner that helps inform the public policy process on food and nutrition issues.

Encompassed in the center’s activities on nutrition policy are its interests in regulatory issues involving food labels, labeling, and advertising. As such, the Center respectfully submits the following comments in response to the Food and Drug Administration’s (FDA) request for comment on First Amendment issues, docket no. 02N-0209 as published in the Federal Register.¹

Overview of the Comments

The Center recognizes the critical importance of FDA’s role in protecting public health. The agency must balance competing interests and laws that appear to conflict or may be out-of-date with the science and current case law. Moreover, the Center respects the difficult task that the agency faces in weighing the rights of commercial speech with the need to protect consumers while ensuring they receive accurate, relevant, and timely information about the health benefits of foods and nutrients, including “novel” nutrients.

¹ Federal Register: Notices. May 16, 2002, Volume 67, Number 95, pages 34942-34944.

The comments contained herein point to two overarching issues:

1. Certain terms set forth by the Federal Food, Drug, and Cosmetic Act of 1938 are out-of-date and need to be clarified.
2. There are few, if any, publicly available consumer research data that answer all of the specific questions posed by FDA in the Federal Register notice dated May 16, 2002.

Definitions of Certain Terms in the FFDCA Need to be Updated

In a governmental effort to protect the public health, Congress enacted two key pieces of legislation—the Food and Drug Act of 1906 and the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA). The FFDCA authorized the U.S. Department of Health and Human Services to protect consumers by developing and enforcing regulations on manufacturers of pharmaceuticals and most foods.

The 64-year-old mandate set forth a very broad definition of food—“articles used for food or drink for man or other animals, chewing gum, and articles used for components of any other such article.”² The definition of a drug,³ however, created the present dilemma with regard to the relationship between food and health because the 1938 statute did not anticipate the advancement of scientific knowledge.

A food-health-disease relationship has been recognized, if not completely understood, since 1742 when James Lind cured scorbatic patients with doses of lemon juice. But it wasn't until 1804 that the British navy ordered lime juice to be a food staple aboard ships undergoing long sea voyages.⁴ These citrus fruits were known to prevent, cure, and treat scurvy—a deadly, nutrient deficiency disease. The curative agent—ascorbic acid or vitamin C—was to be discovered, characterized, and isolated more than a century later.

Other micronutrients found in foods were subsequently discovered and recognized as preventative and curative agents of other nutrient deficiency

² § 201 (f)(1)(C) of the FFDCA [Title 21 United States Code (21 USC) § 321 (f)].

³ “The term ‘drug’ means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the University States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or other components, parts, or accessories.” (§ 201 (g)(1)(B) of the FFDCA [21 USC § 321 (g)(1)(B)] and § 201 (g)(1)(C) of the FFDCA [21 USC § 321 (g)(1)(C)].

⁴ Hornig DH, Moser U, Glatthaar BE. Chapter 22, Ascorbic Acid. In *Modern Nutrition in Health and Disease*, 7th edition. Edited by ME Shils and VR Young. Lea & Febiger, Philadelphia, 1988. pp. 417.

diseases. Another case in point is nicotinic acid or niacin—a B-vitamin. In 1937, just one year before the enactment of the FFDCA, Elvehjem and his colleagues demonstrated that niacin could cure pellagra in dogs.⁵ The U.S. Congress in 1938 did not envision the advances in nutrition science and food technology and production that now blur the bright-line distinction between foods and drugs in preventing disease and promoting health.

The lack of understanding of the link between food and health embodied in the explicit language of the FFDCA prohibiting speech about foods that mitigate, prevent, cure, or treat disease is now a “Gordian knot” for FDA and food manufacturers alike. And while the Nutrition Labeling and Education Act of 1990 (NLEA), Dietary Supplement Health and Education Act of 1994 (DSHEA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) each tried to create some flexibility in conveying important food and health information to the public, these three legislative actions did not untangle the original knot created by the FFDCA. Moreover, the language that making a structure/function claim on the label or in labeling of a food, dietary ingredient, or dietary supplement, does not confer drug status, did not relieve the constraint.⁶

For decades following FFDCA, there was little question that food and nutrients found in food could prevent deadly, classical deficiency diseases, such as scurvy, pellagra, and beriberi. But as the public health tool of epidemiology began to evolve, other important links between diet and complex, chronic diseases of aging were being made. What did not evolve along with the science of nutrition and epidemiology was the law, which remained mired in 1938. The FFDCA did not define the terms “disease” and “mitigate,” which both constrict the language that can be used in commercial speech to educate the public about important diet and health information. While FDA held public hearings to try to define “disease,” the term, as used, remains obscure. And, the concept of *health promotion* is not captured at all.

With the enactment of NLEA, the term “mitigate” became yet another regulatory albatross with regard to making a health claim. Regrettably, FDA further obfuscated the language related to *mitigation* of disease by the use of the

⁵ McCormick DB. Chapter 18—Niacin. In *Modern Nutrition in Health and Disease*, 7th edition. Edited by ME Shils and VR Young. Lea & Febiger, Philadelphia, 1988. pp. 370.

⁶ “A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of this title or sections 403(r)(1)(B) and 403(r)(5)(D) of this title, is made in accordance with the requirements of section 403 (r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.”

phrase “may reduce the risk of...” creating another barrier to lucid communication.

FDA Should Re-Consider *Central Hudson* Case in Restricting Claims Language

With respect to the First Amendment, FDA should re-consider three of the four tests in the *Central Hudson*⁷ case in addressing the definitions of several terms in the FFDCA and the proscriptive language of nutrient content, structure/function, and health claims. These three questions ask:

1. Is the advertising [commercial speech] truthful and not misleading?
2. Do the regulations directly advance the government’s interest?
3. Are the provisions of FDA’s regulation narrowly drawn?

For example, the restrictions on the adjectives used to describe the level of a nutrient in a food such as “excellent source of nutrient x” and the language dictated in pre-approved health claims are not the ‘least restrictive means’ to protect and advance the public health. Consumer research conducted by food manufacturers is more likely to elucidate what consumers do and do not believe about a claim that will or will not persuade them to buy a product. Thus greater flexibility is needed in communicating truthful and non-misleading consumer messages.

FDA’s Regulations Protect, But Do Not Advance Public Health

As noted previously, FFDCA gives FDA ample authority to protect the public health, but it constrains the agency’s objective to advance public health through educational efforts intended by NLEA. The concepts of protection and advancement are nearly mutually exclusive since an effective way to protect something is to deny the request to move forward. Indeed, the mandate to simply provide nutrition information on packaging was implemented effectively. Yet the advancement of knowledge by using truthful and non-misleading claims—nutrient content, health, and structure/function—has been a nettlesome issue. Education (i.e., advancement of knowledge) on complex scientific issues like nutrition and health promotion or disease prevention must have the flexibility and full use of language. To restrict or proscribe language—in spirit, if not in fact—impinges on freedom of commercial speech and defeats the educational goals intended to encourage Americans to consume healthier diets according to energy and nutrient needs.

⁷ *Central Hudson Gas & Electric Corp. v. Public Service Commission of N.Y.*, 447 U.S. 557 (1980). The four tests outlined in *Central Hudson* include: 1) is the advertising truthful and not misleading?, 2) is the government’s interest substantial?, 3) do the regulations directly advance the government’s interest? and 4) are the provisions of the regulation narrowly drawn?

The proscriptive language of health claims and the approval process curtails the timely dissemination of relevant information to consumers. Ippolito and Mathios found that following the 1984 Kellogg/National Cancer Institute campaign, more high-fiber grain products were developed and marketed, and “hard-to-reach” consumers were more knowledgeable about the role of fiber in reducing the risk of cancer.⁸ In 1987, just prior to NLEA, Levy and Stokes noted greater sales of high-fiber cereals, a clear indication of a successful, cutting-edge consumer education campaign.⁹ But recent research by Geiger¹⁰ showed that following enactment of the statute and development of the regulations, fewer health claims were displayed on food packages than before. It appears that the proscriptive language of FDA’s regulations on health claims had a chilling effect on nutrition education campaigns in direct opposition to original intent of the Act. FDA should therefore provide more flexibility for food manufacturers to communicate truthful and non-misleading health information about their products, while advancing consumers’ access to important nutrition and health information in a timely manner.

Little Progress Has Been Made in Consumers’ Use of the Nutrition Label

In 1978, less than half of foods provided nutrient information on the package. But as more research suggested an important link between diet and health, there was greater demand for nutrition information on food packages. Enactment of NLEA in 1990 therefore mandated that virtually all packaged foods display a standardized panel of information on nutrition content of the food. Regulations implementing the Act took effect on May 8, 1994. Three years later, research conducted by FDA showed that 96.5 percent of foods displayed a Nutrition Facts label.¹¹ One objective of NLEA—nutrition labeling—was therefore achieved by the food industry in providing consumers with sufficient information to make informed decisions about their food choices.

Another objective of NLEA was to help consumers improve dietary habits through education. It was presumed that consumers placed significant importance on nutrition when deciding which foods to purchase, and that reading the nutrition label would induce food choices that would lead to a healthier diet.

To understand the driving forces behind consumers’ food purchases, the U.S. Department of Agriculture conducted the Diet and Health Knowledge

⁸ Ippolito PM, Mathios AD. Health claims in food marketing: evidence on knowledge and behavior in the cereal market. *J Public Policy Marketing* 1991; 10: 15-32.

⁹ Levy AS, Stokes RC. Effects of a health promotion advertising campaign on sales of ready-to-eat cereals. *Public Health Rep* 1987; 102: 398-403.

¹⁰ Geiger CJ. Health claims: history, current regulatory status, and consumer research. *J Am Dietetic Assoc* 1998; 98: 1312-1315.

¹¹ Brecher SJ, Bender MM, Wilkening VL, McCabe NM, Anderson EM. Status of nutrition labeling, health claims, and nutrient content claims for processed foods: 1997 Food Label and Package Survey. *J Am Dietetic Assoc* 2000; 100: 1057-1062.

Survey, 1994-96.¹² In this survey, adults were asked about the perceived importance of six characteristics of foods they buy: food safety, nutrition, price, keeping quality, ease of preparation, and taste. The respondents were asked to rank each of the characteristics as “very important,” “somewhat important,” “not too important,” or “not at all important.” Food safety and taste topped the other four characteristics in being “very important” to consumers. Eighty-four and 83 percent of consumers stated that food safety and taste were “very important,” respectively. Nutrition and keeping quality of food were third and fourth in the ranking with 62 and 57 percent of consumers stating these characteristics were “very important.” Price (44 percent) and ease of preparation (38 percent) ranked fifth and sixth as being “very important.” But as income and education increased, fewer consumers stated that price was “very important” in buying food.

Conversely, few consumers disregarded taste as being important to them. For example, only 1.7 and 0.3 percent of adults said that taste was “not too important” or “not at all important,” respectively. Approximately five percent of consumers said that nutrition was “not too important,” but very few (0.9 percent) dismissed nutrition as “not at all important.” Nearly 20 percent of consumers, however, said that price was “not too or not at all important.” Further analysis of this survey may provide better understanding of the trade-offs that consumers make when faced with a decision involving price, taste, and nutrition. For example, a coupon or other price promotion may be more persuasive than a nutrition claim when a consumer of lower income is faced with a decision at the time of purchase.

In October 1994—five months after implementation—FDA noted that about half (52 percent) of consumers used the nutrition label to make food choices.¹³ Between 1993 and 1996, label use increased by 8.5 and 11.3 percent among women and men, respectively.¹⁴ A study published by Neuhouser and her colleagues in 1999 reported that 55 percent of consumers said that they usually or often read the nutrition labels.¹⁵ Thus, while consumers’ initial use of nutrition information was good, there appears to be little progress in getting the general public to read the nutrition label more often.

It should be recognized that some consumers do use the nutrition label. Consumers who use the Nutrition Facts panel tend to be 1) white females, 2) those with higher income and education levels, 3) people who are already eating

¹² Tables 9.1-9.6; <http://www.barc.usda.gov/bhnrc/foodsurvey/pdf/dhks9496.pdf>

¹³ Derby B, Levy AS. *Oral presentation*. “Consumer use of food labels: Where are we going?” American Dietetic Association annual meeting, Orlando, FL, October 19, 1994.

¹⁴ Kristal AR, Levy L, Patterson RE, Li SS, White E. Trends in food label use associated with new nutrition labeling regulations. *Am J Public Health* 1998; 88: 1212-1215.

¹⁵ Neuhouser ML, Kristal AR, Patterson RE. Use of food nutrition labels is associated with lower fat intake. *J Am Dietetic Assoc* 1999; 99: 45-46.

healthfully, and 4) people with an important health concern.¹⁶ For example, a study conducted in four family medicine clinics in southwest Missouri showed that patients who consumed a lower fat diet were more likely to report being influenced by the food label in making their purchasing decisions than were patients who consumed a higher fat diet. In addition, patients with high blood pressure were 63 percent more likely to look for sodium content on the food label than patients with normal or low blood pressure; and patients with high blood cholesterol were more likely to look for saturated fat content. Neither of these groups of patients, however, was more likely than others to look for additional nutrition information on the label.

Analysis of the FDA's Food Label Use and Nutrition Education Survey (FLUNES) showed that the Nutrition Facts panel was used most often to assess the level of a certain characteristic of the food product and to avoid a specific ingredient.¹⁷ This analysis suggested that the nutrition label was not used in making first-time purchases, comparing brands, preparing meals, or deciding how much of the product to eat. Surprisingly, consumers did not use the Nutrition Facts panel to determine the nutritional content of the food, nor was it used to confirm the truth of an advertising or packaging claim.

Newsworthiness of claims is important to consumers, as is a self-determined credibility of the claim for the particular food.¹⁸ A study conducted by FDA summarized its findings as follows:

“A claim that provided information that the respondent did not already know about the product seemed to have a positive effect on attitudes toward that product. A claim that provided no new information, but seemed plausible for the product seemed to have no effect. A claim that provided no new information, but which seemed implausible, produced negative reactions toward the product. The complicated interplay between what consumers already knew about the product, their judgments about the propriety of the product bearing a certain health claim, and the ability of the claim to be compelling, suggested that consumers did not assume that health claims on product labels fulfilled a public health information function. Rather it appeared that they applied critical standards to health claims on food labels analogous to persuasion contexts such as advertising.”

¹⁶ Kreuter MW, Brennan LK, Scharff DP, Lukwago SN. Do nutrition label readers eat healthier diets? Behavioral correlates of adults' use of food labels. *Am J Prev Med* 1997; 13: 277-283.

¹⁷ Brooks KC. The nutrition facts panel: who uses it and how is it used? Practicum for the Master of Public Policy degree, Georgetown University, May 2000.

¹⁸ Levy AS, Derby BM, Roe BE. Consumer impacts of health claims: an experimental study. www.cfsan.fda.gov/~dms/hclm-sum.html.

In other words, consumers were not easily “duped” by health claims on food packages.

Few Consumer Data on the Impact of Claims on Packaging and Advertising
FDA asks: Is there evidence that claims made in advertising should be distinguished from those made on food labels?

There are few, if any, publicly available data that show the relative importance of advertising or packaging claims in enticing product purchases. Proprietary market research data typically show that taste, cost, convenience, and nutrition are important features that consumers consider in making purchases. To our knowledge, there has been no research critically examining (and controlling for) these factors. Other factors, such as coupons, promotions, or other point-of-purchase incentives may override purchase intent instigated by advertising or claims made on the label.

The FDA also asks: is there a basis to believe that consumers approach claims about conventional foods and dietary supplements differently? There appears to be little available data suggesting that consumers view claims differently depending on whether the claims are displayed on a food or a dietary supplement.

Another question that should be asked: are there differences in consumers who take dietary supplements and those who do not? Data from the Third National Health and Nutrition Examination Survey (NHANES III) suggests greater use of dietary supplements among non-Hispanic whites, females, children, and older Americans. Consumers who take dietary supplements also tend to have higher incomes and be better educated than those who do not take them.¹⁹ This suggests that more consumer research should be conducted to understand whether supplement users are harder (or easier) to mislead with claims that “over-promise” a health benefit.

There are no publicly available data to show that consumers discern any meaningful difference between structure/function claims and health claims. Likewise, there are no recent data to suggest that one type of claim or the other has a different effect on purchasing behavior. Therefore, there is little reason to believe that purchases are affected based on the extremely subtle distinction between these two types of claims.

More and Better Qualitative and Quantitative Consumer Research Needed
There is an apparent presumption that structure/function claims are less compelling than health claims and therefore structure/function claims do not

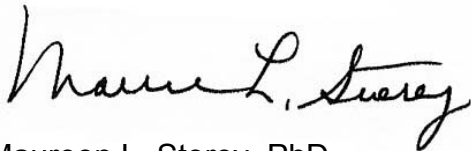
¹⁹ Ervin RB, Wright JD, Kennedy-Stephenson J. Use of dietary supplements in the United States, 1988-1994. Vital Health Stats 1999; 11(244).

require pre-approval by FDA. The indirect allusion to a specific health benefit, such as “helps maintain urinary tract health” versus “reduces the risk of urinary tract infections” by cranberry juice cocktail, probably matters little to a consumer. So while the structure/function claim may be truthful, it is vapid, vague, and more likely to mislead rather than instruct or coerce a sale. FDA should therefore consider that the oblique approach required to make structure/function claims may in fact be more misleading than the direct communication of a benefit from consumption of the food product.

In summary, the Center urges FDA to:

1. Clarify and narrow the definitions of “drug,” “disease,” and “mitigate” in recognition of the effects of foods (including food ingredients and supplements) on disease prevention and health promotion.
2. Commission more and better qualitative and quantitative consumer research to assess:
 - a) whether consumers can distinguish between structure/function and health claims,
 - b) whether one type of claim has a greater or lesser impact on purchase behavior,
 - c) whether consumers’ awareness, beliefs, and behavior are influenced by these claims, and
 - d) whether consumers understand the intended use of product in the context of the claims being made on the label or in labeling and advertising.

Respectfully submitted,



Maureen L. Storey, PhD
Acting Director and Research Associate Professor