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Food Labeling Chaos

The case for reform

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The Center for Science in the Public Interest (CSPI), founded in 1971, is a nonprofit health advocacy organization. CSPI conducts innovative research and advocacy programs in the areas of nutrition, food safety, and alcoholic beverages and provides consumers with current information about their own health and well-being. CSPI is supported by 850,000 subscribers in the United States and Canada to its Nutrition Action Healthletter and by foundation grants.

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Executive Summary

The provision of accurate, easy-to-read, and scientifically valid nutrition and health information on food labels is an essential component of a comprehensive public health strategy to help consumers improve their diets and reduce their risk of diet-related diseases.

However, as Food and Drug Administration (FDA) Commissioner Dr. Margaret Hamburg recognized in a 2009 speech to the National Food Policy Conference, "[T]he public health importance of food labeling as an essential means for informing consumers about proper nutrition . . . has not been substantially addressed since the FDA implemented the Nutrition Labeling and Education Act, more than 16 years ago."

FDA Commissioner Hamburg also noted, "[W]e've seen the emergence of claims that may not provide the full picture of their products' true nutritional value. It will be important to reestablish a science-based approach to protect the public. . . . " Indeed, misleading claims, ranging from promises that a food can "strengthen" your immune system to misleading pictures on the fronts of food labels that misrepresent the type and quantity of fruits and vegetables in a processed food, are out of control and interfere with the consumer's ability to make healthy food choices.

Problems with food labels can be broken down into three basic categories:

- Improving the Nutrition Facts Panel
- Improving ingredient labels
- Stopping false and misleading health-related claims

The FDA and the United States Department of Agriculture (USDA) have recently begun addressing some of those challenges. The FDA has announced it will test consumer reactions to simplified nutrition labels that could be used on the fronts of packages, pressured General Mills to drop exaggerated health claims for Cheerios cereal and stopped the use of industry's Smart Choices program. The USDA has re-proposed rules requiring nutrition labeling on fresh meat and poultry and published an Advance Notice of Proposed Rulemaking in an effort to stop misleading "All Natural" claims on meat and poultry labels. But much more work needs to be done.

Summary of Recommendations

1. Front-of-Package Nutrition Labeling - Key nutrition information should be summarized, using easy-to-comprehend symbols, on the fronts of food packages.

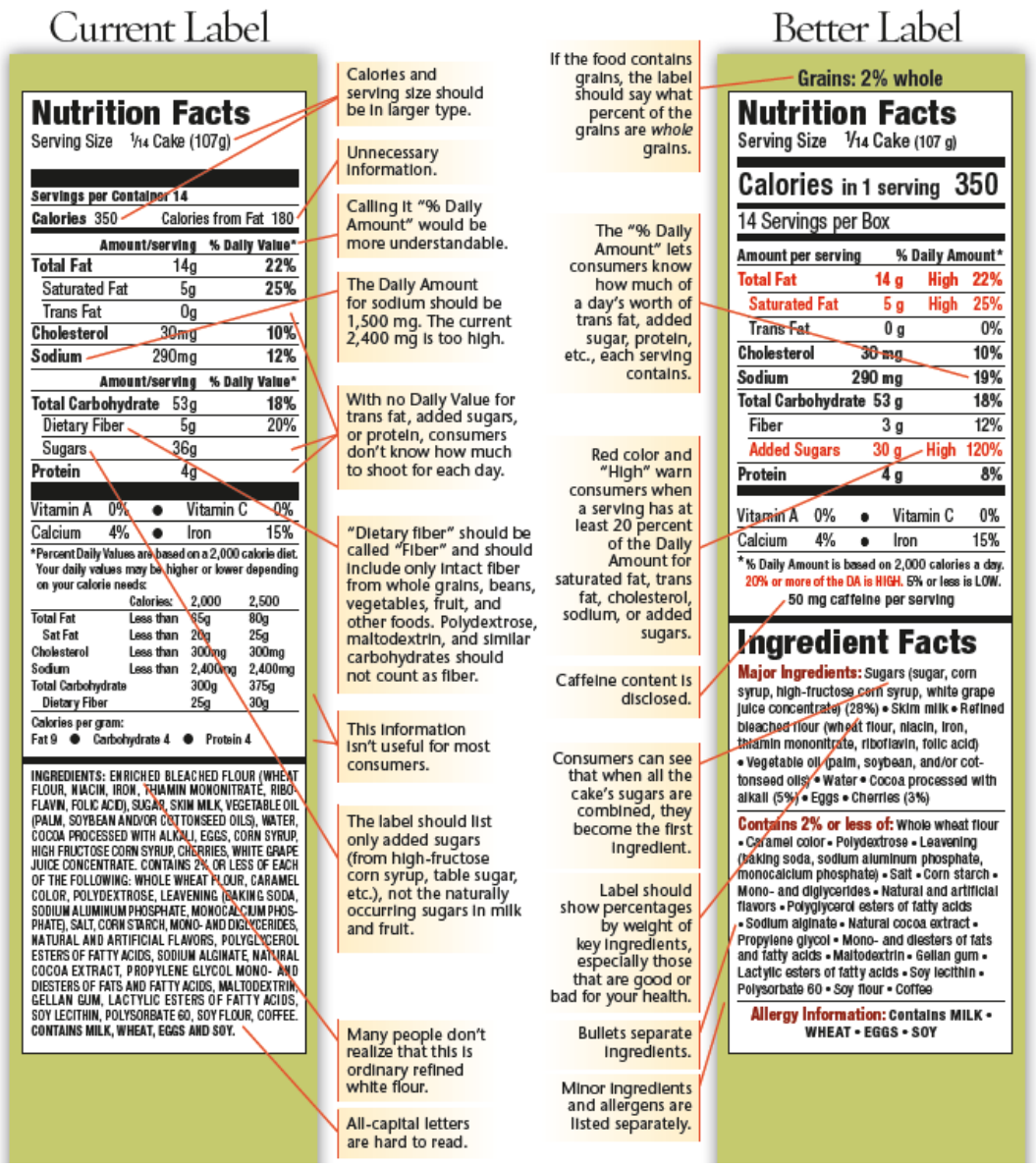
2. Improving the Nutrition Facts Panel - The existing nutrition label needs to be simplified by:

- Deleting extraneous information;
- Providing clearer, more accurate information on calorie, sugars, and fiber content;
- Changing disclosures for "Amount Per Serving," and "Serving Size" to statements like "Amount Per ½ Cup Serving."
- Prohibiting deceptive nutrition disclosures for large single-serving packages;
- Making nutrition labeling mandatory for single-ingredient meat and poultry products.

3. Ingredient Labels - The format of ingredient labels should be modernized by:

- Redesigning the ingredient list so that ingredient information is presented in a format similar to that used for nutrition information;
- Requiring that sources of added sugars be grouped together to give a better indication of total sugar content;
- Requiring that the amounts of key ingredients be disclosed as percentages of the total weight of the product;
- Mandating that caffeine content be disclosed in a conspicuous location on the information panel.

The following side-by-side comparison illustrates some of the changes that need to be made to the Nutrition Facts Panel and the ingredient list.



The mock-up on the right shows changes that are needed.

While the FDA and the USDA have started making greater efforts to reduce the prevalence of misleading health-related claims, the agencies are merely scratching the tip of the iceberg. This mock-up of a food label illustrates some of the misleading claims that need to be addressed.

This illustration shows many of the misleading claims that should be stopped by the FDA.

These problems can be resolved by taking the following steps:

4. **Health-Related Claims:** The FDA and the USDA should issue regulations prohibiting misleading health-related claims on the fronts of packages:

- The agencies should establish a comprehensive regulatory framework for prohibiting misleading claims that a substance in a food can affect the structure or function of a bodily system (i.e., structure/function claims).
- The FDA should cease the practice of exercising its enforcement discretion to permit "qualified health claims" that, by definition, are based on weak scientific evidence.
- Both agencies should prohibit "0 g trans fat" claims on foods that are not also low in saturated fat and cholesterol.
- Both agencies should issue regulations controlling misleading "natural" claims.
- Both agencies should promulgate new rules to stop companies from claiming that a food is made with whole wheat or other whole grains unless the percentage of grains that are whole is prominently disclosed.

Each of these recommendations is more comprehensively discussed at the end of each Part of this report, and at greater length in Part XI.

The Need for Rulemaking

In addition, the FDA and the USDA should develop regulations instead of relying only on case-by-case enforcement actions. While the latter approach may signal to the food industry that the agencies are serious about enforcing the law, binding regulations are much more likely to ensure that companies do not backslide in the future.

A Role for Congress

Many of the actions recommended in this report can and should be taken by the FDA and the USDA under existing legal authority. However, the broad scope and nature of the problem and competing agency priorities demand that Congress exert close oversight, ensure that each agency has sufficient resources and allocated them efficiently, and provide the FDA and the USDA with specific statutory mandates in areas where agency jurisdiction is unclear or motivation is lacking.

The time is ripe for comprehensive, coordinated action. Health experts, consumers, and even some food companies agree that food labeling reform will help consumers improve their diets, reduce the costs of diet-related disease, and provide companies that produce more healthful foods with a level competitive playing field.

Part I

Introduction

Expert Consensus on Food Labeling, Diet, and Health

The provision of accurate, easy-to-read, and scientifically valid nutrition and health information on food labels is an essential component of a comprehensive public health strategy to help consumers improve their diets and reduce their risk of diet-related diseases. Improved food labeling could provide consumers with easy-to-read nutrition and ingredient information that they can use to reduce their risk of the leading causes of death in the United States today, including heart attack, stroke, certain forms of cancer, and diabetes.

Congress recognized the importance of nutrition and health information on food labels when it passed the Nutrition Labeling and Education Act of 1990 (NLEA). The House report accompanying the bill stated:

> The Surgeon General has advised Americans that diets low in fats, low in salt and high in fiber can reduce the risk of chronic diseases such as cancer and heart disease. . . . [S]tatements regarding the level of these nutrients in foods will assist Americans in following the Surgeon General's guidelines.[1]

This statement is supported by numerous public health authorities ranging from the National Academy of Sciences' Institute of Medicine (IOM)[2] to the World Health Organization (WHO).[3]

Nutrition and health information could also play a key role in combating the current obesity epidemic that is plaguing both adults and children. About two-

[1] H.R. Rep. No. 101-538, at 9-10 (1990).

[2] *See* National Academy of Sciences Institute of Medicine, *Nutrition Labeling: Issues and Directions for the 1990s* (1990); National Academy of Sciences Institute of Medicine, *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification* 1-2 (2003), *available at* http://books.nap.edu/openbook.php?record_id=10872&page=1.

[3] World Health Organization, *Global Strategy on Diet, Physical Activity, and Health* (2004).

thirds of American adults are overweight and obese and 18% of American adolescents age 12-19 are overweight.[4] Obesity increases the risk of diet-related disease, and according to the Centers for Disease Control, cost approximately $147 billion dollars last year in health care costs alone.[5] The First Lady of the United States has stated that she intends to help her children learn to read food labels in order to help them maintain healthy weight levels and develop healthy eating patterns that will serve them well into adulthood.[6]

Requirements for Nutrition Facts Labels and Ingredient Lists are Out of Date

As Food and Drug Administration (FDA) Commissioner Dr. Margaret Hamburg recognized recently in a speech to the National Food Policy Conference, "[T]he public health importance of food labeling as an essential means for informing consumers about proper nutrition . . . has not been substantially addressed since the FDA implemented the Nutrition Labeling and Education Act, more than 16 years ago."[7] Indeed, consumer research demonstrates that the majority of Americans do not understand the "% DV fat" disclosure required on Nutrition Facts labels, which is supposed to indicate whether a food is high or low in fat.[8] The current Nutrition Facts label fails to provide any "Daily Value" at all for *trans* fats[9] and added sugars, two nutrients that play a major role in diet-related disease.

Some improvements to the Nutrition Facts Panel (NFP) are relatively straightforward—calories should be listed more prominently, and nutrient content

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[4] Centers for Disease Control, Fast Stats Home Page, Obesity and Overweight, *available at* http://www.cdc.gov/nchs/fastats/overwt.htm (last visited Dec. 11, 2009).

[5] Press Release, Centers for Disease Control, Study Estimates Medical Cost of Obesity May Be As High as $147 Billion Annually. *New Community Recommendations Show Ways to Reduce Burden* (July 27, 2009), *available at* http://www.cdc.gov/media/pressrel/2009/r090727.htm.

[6] Darlene Superville, *Trainer Spills Secrets of Michelle Obama's Arms*, Associated Press, Sept. 7, 2009, *available at* http://today.msnbc.com.

[7] Margaret Hamburg, M.D., Comm'r of Food and Drugs, Keynote Address at the National Food Policy Conference, Washington, D.C. (Sept. 8, 2009), *available at* www.fda.gov/NewsEvents/Speeches.

[8] L. Levy *et. al., How well do consumers understand percentage daily values on food labels?* Am. J. Health Promotion 14:157-60. (2000). "Only 29% correctly selected the definition of % daily value for fat (%DV), as 'percent of the maximum daily recommended amount of fat.'" *Id.*

[9] Providing a DV for trans fat is only an interim solution. *Trans* fat should be banned by the FDA.

should be disclosed for realistic serving sizes.[10] For example, products such as Healthy Choice Minestrone Soup—sold in cups intended both for heating the product in the microwave and for use as a soup bowl—should not be permitted to state that the product contains "about 2 servings." It is highly unlikely that the soup will be consumed by more than one person. The "per serving" information provided on the front of the package should relate to the entire contents of the container. Other improvements may require greater changes regarding how nutrition information is disclosed.[11]

Some countries, such as the United Kingdom, have developed alternatives to traditional nutrition labeling as required in the United States. The key features of these alternatives are to 1) place a modicum of nutrition information on the fronts of packages, and 2) use symbols (such as a keyhole icon on more-healthful foods or red, yellow and green dots on all foods) to indicate a food's overall healthfulness. The European Union has proposed a regulation requiring the amounts of five key nutrients to be disclosed on the fronts of all food packages.[12] In contrast, the FDA has only held a public meeting on the issue and commissioned some consumer research. Congress has appropriated $500,000 for a study by the IOM on the issue[13] and the FDA and Congress may contribute additional funds. The failure to take stronger steps in the United States reduces the full potential that food labeling could play in reducing diet-related disease.

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[10] The FDA's Obesity Working Group recommended that FDA solicit comments on "how to give more prominence to calories on the food label and asked FDA to reexamine its serving size regulations. FDA, *Calories Count: Report of the Working Group on Obesity* 26-28 (Mar. 12, 2004).

[11] A USDA study on consumer use of nutrition labels concluded that "consumers may benefit from a change in the format of nutrition information on labels, particularly one that brings the format more in line with specified USDA dietary guidelines." Jessica E. Todd *et. al.*, USDA 20 (Aug. 2008).

[12] These include energy (calories), fat, saturated fat, carbohydrates with specific reference to sugars and salt content. *Commission Proposal for a Regulation of the European Parliament and of the Council on the Provision of Food Information to Consumers*, at 8, COM (2008) 40 final (Jan. 30, 2008).

[13] Within the total provided for Nutrition, Physical Activity, and Obesity, the bill includes $500,000 for a study by the Institute of Medicine (IOM) that will examine and provide recommendations regarding front-of-package nutrition symbols. These should include, but not be limited to, a review of systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad and the overall merits of front-label nutrition icons, the advantages and disadvantages of various approaches, and the potential benefits of a single, standardized front-label food guidance system regulated by the Food and Drug Administration. Based upon its work, the IOM should recommend one or several of the systems, along with means of maximizing the use and effectiveness of front-label symbols, that it has identified as best at promoting consumers' health.

Omnibus Appropriations Act 2009, Pub L. No. 111-8, Div. F (2009).

In addition to the Nutrition Facts label not being updated for more than one and one-half decades, requirements for ingredient listings on processed foods have not been comprehensively updated since 1938 Ingredients are still allowed to be listed in tiny print, percentages of key ingredients are not generally required to be disclosed (as they are in more than 25 other countries around the world), and allergen information, while subject to new statutory requirements that took effect in 2006, is according to one recent study,[14] still difficult to utilize by the more than 12 million Americans that suffer from food allergies.[15] Statements such as "may contain [name of allergen]" can be overly broad and fail to provide allergy sufferers with useful information. In addition, the quantity of caffeine is not required to be disclosed on foods, including energy drinks that often make health-related claims.

FDA Policies Lead to Marketplace Chaos

The problem is further complicated by inadequate regulation of misleading claims on food labels.

As FDA Commissioner Hamburg has noted, "[W]e've seen the emergence of claims that may not provide the full picture of their products' true nutritional value. It will be important to reestablish a science-based approach to protect the public. . . ."[16]

The 1990 NLEA set up a pre-market approval requirement for health claims (claims that a nutrient in a food can help reduce the risk of a specific disease or health-related condition when consumed from generally healthful foods that form the basis of an overall healthful diet). During the Bush Administration, the Agency essentially adopted a policy of non-enforcement.[17]

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[14] *Allergy study faults labels as ambiguous*, Food Chem. News, Aug. 31, 2009, at 17.

[15] The Food Allergy and Anaphylaxis Network (2009), http://foodallergy.org/page/facts-and-stats (last visited Dec. 15, 2009). Food allergy affects up to 6-8 percent of children four years old or younger and close to 4 percent of adults. U.S. Department of Health and Human Services, National Institute of Allergy and Infectious Disease 1 (2007), *available at* http://www3.niaid.nih.gov/topics/foodAllergy/understanding/quickFacts.htm.

[16] Margaret Hamburg, M.D., Comm'r FDA, Keynote Address at the National Food Policy Conference, Washington, D.C. (Sept. 8, 2009) (*available at* www.fda.gov/NewsEvents/Speeches).

[17] Food Labeling: Health Claims; Dietary Guidance; Advance Notice of Proposed Rule Making, 68 Fed. Reg. 66040-41 (Nov. 25, 2003). FDA noted that July 11, 2003 *Guidance for Industry and FDA: Interim Procedures for Health Claims in the Labeling of Human Food and Human Dietary Supplements* has been implemented on an interim basis. That Guidance permits use of qualified health claims as an exercise of FDA's enforcement discretion. FDA has issued many letters

Further, the NLEA left major categories of other types of health-related claims unregulated, such as those that claim a nutrient in a food can positively affect the structure or function of the body[18] (e.g. that the antioxidants and nutrients in Kellogg's Cocoa Krispies "now helps support your child's immunity" or that the omega-3 in Diamond chopped walnuts can help maintain a healthy heart). Such claims for foods are viewed by the typical consumer as health claims,[19] but are completely unregulated by the FDA. The Agency issued a weak enforcement policy for structure/function claims on dietary supplements (which are subject to a different, weaker statutory scheme), but never established rules for structure/function claims for foods. Such standards should indicate which claims are permissible and set forth requirements for the type of evidence a company needs to substantiate the label claim. In the absence of effective regulation, structure/function claims have become one of the most popular and deceptive forms of claims on food labels today.

The 1990 NLEA also set up a pre-market approval requirement for nutrient content claims (e.g. claims that a food is "low" in fat or "high" in fiber) and required the FDA to define certain commonly used terms at the time such at "lite," "healthy," and "fresh." The regulations implemented by the Act and the FDA have not kept up with the new scientific developments and marketing trends in the food industry. For example, the FDA prohibits claims that a food is "saturated fat free" if a serving contains more than 0.5 grams of *trans* fat, but the Agency has failed to prohibit "0 *Trans* Fat!" claims for foods that are high in saturated fat.

Further, the NLEA ignored an increasingly common category of claims emphasizing the presence of healthful ingredients, such as whole grains, fruits, and vegetables. The amounts of such ingredients are not disclosed on either the Nutrition Facts panel or the ingredient list. Many companies, such as S. B. Thomas, manufacturer of Thomas's Hearty Grains English Muffins imply that their products contain significant quantities of those ingredients by claiming that a product is "made with whole grains." Others like Gerber plaster the front of a package of chewy fruit-flavored "Juice Treats" with pictures of real fruits, when only juice from some of the pictured fruits is actually in the product. This problem can be remedied by requiring on the front of the package or in the ingredient list the percentage by weight of the highlighted ingredient.

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permitting claims based on evidence that does not meet the significant scientific agreement standard.

[18] When the NLEA was passed, structure/function claims were rarely made for foods. But when the Dietary Supplement Health and Education Act of 1994 permitted dietary supplements to carry such claims, structure/function claims proliferated on supplements and, eventually, on conventional food products.

[19] International Food Information Council, *Qualified Health Claims Consumer Research Project Executive Summary* 8 (Mar. 2005).

The FDA has also largely ignored regulating other claims, such as "natural," that some consumers may interpret as indicating a more nutritious or wholesome food product than is actually the case. Thus, while not an explicit health or nutrient content claim, claims such as "natural" are worthy of the Agency's attention as part of a comprehensive program to improve food labeling and help consumers reduce their risk of diet-related disease.

This mock label summarizes the deceptions that consumers often find on food labels as a result of FDA inaction.

Enforcement Declines at the FDA

In general, since 2001, there has been a significant decline in labeling enforcement by the FDA.[20] By 2005, Congress was so concerned that it asked the FDA to report on the types of food labeling violations (other than those relating to

[20] CSPI, *Rebuttal to FDA Report to Congress on Agency Enforcement Actions Regarding Health-Related Claims on Food Labels* (July 18, 2006), *available at* http://cspinet.org/new/pdf/fn5rep.pdf.

safety) that the Agency had uncovered and the actions taken to address them. The Senate Appropriations Committee wanted to ensure that "[F]ood labels can be easily understood and reflect information that is factual" and not misleading.[21] The House of Representatives was concerned that consumers would lose confidence in the trustworthiness of the food label because of inaccuracies in the amount of nutrients declared in the Nutrition Facts Panel, the misuse of terms such as "low calorie" and "healthy," misleading heart health claims, and the use of product names that violate standards of identity.[22]

The FDA's answer to Congress[23] was largely nonresponsive to the Committees' requests. The answer did, however, reveal a lack of commitment on the part of the Agency.[24]

In October 2008, the Congressional watchdog agency, the Government Accountability Office (GAO), gave the FDA failing grades for preventing false and misleading labeling. GAO found that while the number of food firms and products has increased dramatically, the FDA's oversight and enforcement actions "have not kept pace." As a result, the "FDA has little assurance that companies comply with food labeling laws and regulations. . ."[25]

But if the FDA had the will, it could convince companies to obey the law. For example, the Center for Science in the Public Interest (CSPI) stopped numerous misleading labeling claims by leading national food companies. CSPI, working under state consumer protection laws, has secured agreements improving food labeling, marketing, or product formulation with Frito-Lay, Kellogg, KFC, Kraft, Sara Lee, and other companies. The FDA, an agency with approximately 1,000 employees assigned to ensuring that foods are safe and properly labeled, could certainly achieve as many successes as a relatively small nonprofit organization like CSPI.

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[21] S. Rep. No. 109-92, at 153 (2005).

[22] H.R. Rep. No. 109-102, at 83 (2005).

[23] FDA, *Report to Congress on Compliance with Food Label Regulations under the Food and Drug Administration's Purview Senate Report 109-92* (2005); FDA, *Report to Congress on Compliance with Food Label Regulations under the Food and Drug Administration's Purview House Report 109-102* (2005), *available at http://cspinet.org/new/pdf/sen_and_hou_rpt_109-92_food_label_reg..pdf.*

[24] CSPI, *Rebuttal to FDA Report to Congress, supra* note 20.

[25] GAO, Food Labeling: *FDA Needs to Better Leverage Resources, Improve Oversight and Effectively Use Available Data to Help Consumers Select Healthy Foods*, Highlights of GAO-08-597 (Sept. 2008), *available at http://www.gao.gov/new.items/d08597.pdf.*

USDA Policies – Comparisons and Contrasts

The United States Department of Agriculture (USDA) generally follows the same rules for Nutrition Facts labeling and health and nutrient content claims as the FDA.[26] The USDA, however, follows a system of prior label approval—labels of processed foods containing any significant amounts of meat and poultry (such as beef stew or sausage pizza) are approved by USDA officials prior to marketing. The USDA has issued a series of policy memoranda summarizing many of its decisions to approve or disapprove a particular label. This practice has generally resulted in fewer misleading claims on USDA regulated products.

But, there are ways in which the USDA labeling rules are weaker than the FDA's:

- The USDA does not require the amount of *trans* fatty acids per serving to be listed on Nutrition Facts Panels;
- The USDA does not require Nutrition Facts labeling on packages of single ingredient raw meat and poultry (a rule was proposed, but never finalized);[27]
- The USDA allows % lean claims on ground beef, which imply that the product is lower in fat than comparable non-meat foods;
- The USDA allows poultry to be labeled "all natural" even when it has been injected with salty broth.

Consumers do not expect a pepperoni pizza label to be regulated by the US government any differently than a cheese pizza label. The USDA and the FDA should harmonize their regulations and enforcement policies to the greatest extent possible, following a system of "best practices" that draws upon the strength of each agency's approach to a specific labeling issue.

Economic Impact of Past Labeling Reforms

The economic impact of food labeling reforms has been extensively studied. The FDA's major economic impact analysis of its regulations

[26] *See* James T. O'Reilly, *Food and Drug Administration*, ch.24:5 n. 9. (Thomson West 2007).

[27] Nutrition labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products; 66 Fed. Reg. 4969 (proposed Jan. 18, 2001).

implementing the 1990 NLEA concluded that "[E]stimates of the number of discounted life years gained nationwide for the first 20 years after implementation of the act range from a high of nearly 1.2 million to a low of 40,000." According to this study, the value of life years saved by mandatory nutrition labeling ranged from more than $106 billion to $3.6 billion over the same 20-year period based on 1988 dollars. Thus, the FDA concluded that "[R]elatively small changes in nutrient intakes may generate substantial public health benefits."[28] It is not clear (because studies have not been done) what the actual benefits have been.

A later estimate of a modification to the Nutrition Facts Panel in 2006, which required manufacturers to disclose the number of grams of *trans* fatty acids per serving, found that in three years, this single change alone would prevent from 600 to 1,200 cases of coronary heart disease and prevent from 240 to 480 deaths annually. It would also result in total benefits ranging from $4.1 billion to $8.3 billion per year.[29] Those were likely gross underestimates, because the FDA assumed that only a small fraction of *trans* fat would be eliminated; in fact, probably more than half of *trans* fat has been eliminated.

Although the protocols for these two economic impacts analyses were different, they both concluded that changes that provide consumers with certain better and more easily understood nutrition information on food labels would be cost-beneficial. Consumer research has shown that many consumers use the Nutrition Facts Panel and that, while cause-and-effect relationships are difficult to establish, the use of nutrition labeling is associated with healthier diets.[30]

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[28] Gary A. Zarkin, PhD, *et. al, Potential Health Benefits of Nutrition Label Changes,* 83 American Journal of Public Health 717-724 (May 1993).

[29] Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41434, 41488, 41,467 (July 11, 2003).

[30] *See* Sung-Yong Kim, *et. al., The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis*., 25 Journal of Agricultural and Resource Economics 215 (July 2000 (finding that nutrition label users consume fewer calories from fat, less cholesterol and sodium, and more fiber, than non-label users); Alan R. Kristal et al. *Predictors of self-initiated, healthful dietary change,*101 *J Am Diet Assoc.* 762-765 (2000) (finding that the use of food labels is strongly associated with fat reduction); Alan D. Mathios, *The Impact of Mandatory Disclosure Laws of Product Choices: An Analysis of the Salad Dressing Market.* Alan D. Mathios, *J. Law & Econ.*651-677 (2000) (finding that the addition of the NFP to food packages reduced the sale of high fat foods); The American Dietetic Association. *Nutrition Trends Survey 1997*. September 1997 (finding that approximately two-thirds of those reading the NFP reported that they stopped or started buying a food product because of something they read on the label, and 56 percent of consumers said the information on the nutrition label had caused them to switch brands). Some of those studies found associations between reading labels and healthier diets, but could not establish cause and effect.

A Challenge for the Administration and Congress

Many of the actions recommended in this report can and should be taken by the FDA and the USDA under existing legal authority. However, the broad scope and nature of the problem and competing agency priorities demand that Congress exert close oversight, ensure that each agency has sufficient resources and has allocated them efficiently, and provide the FDA and the USDA with specific statutory mandates in areas where agency jurisdiction is unclear or motivation is lacking.

The time is ripe for comprehensive, coordinated action. The public health community, consumers, and even some segments of the food industry agree that food labeling reform will help consumers improve their diets, reduce the costs of diet-related disease, and provide companies who want to produce more healthful foods with a level competitive playing field.

This report suggests how legislators and regulators can confront these challenges by addressing three basic questions:

- How should nutrition information on food labels be improved?
- How should ingredient information be clarified?
- What should be done to prevent misleading health-related claims on food labels?

To answer each of these questions, this report summarizes major health-related issues involving specific food labeling controversies, examines current laws, regulations, and enforcement policies, and outlines recommendations for reform.

Part II

Improving the Nutrition Facts Panel

The Problem

Nutrition information on food labels can play an important role in the battle against obesity and diet-related disease, which are responsible for hundreds of thousands of premature deaths in the United States (U.S.) each year.[1] Almost all foods are required to contain a "Nutrition Facts" Panel (NFP) that discloses nutrition information for key ingredients. One glaring omission is fresh meat and poultry, which are not currently required to be labeled. That matter is currently being addressed by the U.S. Department of Agriculture (USDA).[2]

To reach its full potential, however, the content and format of the Nutrition Facts Panel needs to be modernized. Twenty years ago, Congress drafted The Nutrition Labeling and Education Act of 1990 (NLEA), which established the requirement of the NFP. Now, two thirds of all adults are overweight or obese[3] and, 18% of children age 12-19 are overweight.[4] The current Nutrition Facts label was not specifically designed to help prevent obesity and needs to be revised to help reverse this alarming trend. Information on calories needs to be improved, superfluous information needs to be deleted, serving sizes need to be rationalized, and a Daily Value (DV) for added sugar needs to be established. [5] The Food and Drug Administration (FDA) and the USDA should take the following measures.

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[1] A 2005 Center for Disease Control study estimated that approximately 112,000 deaths are associated with obesity each year in the United States, making obesity the second leading contributor to premature death. See Flegal KM, et al. "Excess Deaths Associated with Underweight, Overweight, and Obesity." *JAMA* 2005, vol. 293, pp. 1861-1867.

[2] See note 39 *infra* and accompanying text.

[3] Trust for America's Health, *F as in Fat 2009* http://healthy Americans/reports/obesity2009 (last visited Dec. 24, 2009).

[4] Centers for Disease Control, Fast Stats Home Page, Overweight Prevalence, *available at* http://www.cdc.gov/nchs/fastats/overwt.htm (accessed Dec. 10, 2009.) Statistics are from 2005-2006. In that period, 15% of children age 6-11 were overweight and 11% of children age 2-5 were overweight. *Id.*

[5] Although the accuracy of the Nutrition Facts Panel is another important issue, it is beyond the scope of this report. The FDA has not conducted a systematic examination of food labels to test for accuracy since

A. Calories per serving should be disclosed more prominently on the Nutrition Facts Panel

The most important declaration on the Nutrition Facts Panel when it comes to obesity prevention is the disclosure of calorie content. Yet, this information is presented in the same size type as other listings on the nutrition label. "Calories" should be listed in larger type and highlighted with a contrasting background.

In addition, the label should integrate the calorie disclosure line with the serving size line. For example, a 12 fl oz can of Coke currently states:

- Serving size 1 can
- Amount per serving
- Calories 140

The revised NFP we recommend would state "140 calories per 1 can serving" all on one or two lines. That disclosure would be simpler for consumers to read and understand.

B. Extraneous information should be eliminated

1. The "calories from fat" line of the NFP should be eliminated

Currently, the FDA's nutrition labeling regulations require that "calories from fat" be listed along side or directly below "calories."[6] (This currently required disclosure should not be confused with "% of calories from fat" which has never been required to be listed on the NFP.)

Deleting "calories from fat" would make more room on the label for a larger disclosure of "calories" per serving**.** The FDA's own Working Group on Obesity recommended that the FDA publish an Advance Notice of Proposed Rulemaking (ANPR) requesting comments on how best to give prominence to calories that would

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1996. *Analysis of 300 Foods with Nutrition Labeling and Education Act (NLEA) Label Requirements, FDA Contract Number: 2233-91-2185.* Some market observers speculate that one out of every four labels is inaccurate. Inaccuracies may include sugar in sugar-free products and fat and sodium content exceeding labeled claims. Mitch Lipka, *Use food labels to know what you're eating? There's a 1 in 4 chance they're wrong*, http://www.walletpop.com/blog/2009/09/22/use-food-labels-to-inow-what-youre-eating (Sept. 22, 2009). CSPI has urged the FDA to periodically conduct systematic tests of the accuracy of the Nutrition Facts Panel. CSPI, *Rebuttal to FDA Report to Congress on Agency Enforcement Actions Regarding Health-Related Claims on Food Labels* (July 18, 2006).

[6] 21. C.F.R. § 101.9(c)(1)(ii).

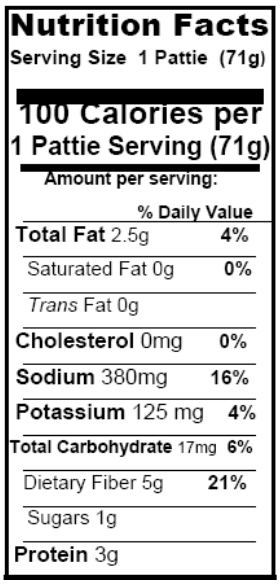
include eliminating "calories from fat." The Working Group stated that the "calories from fat" listing "takes the emphasis away from 'total calories.'" [7]

Current label

Nutrition Facts
Serving Size 1 Pattie (71g)

Amount Per Serving
Calories 100 ~~Calories from Fat 25~~
% Daily Value*
Total Fat 2.5g 4%
Saturated Fat 0g 0%
Trans Fat 0g
Cholesterol 0mg 0%
Sodium 380mg 16%
Potassium 125mg 4%
Total Carbohydrate 17g 6%
Dietary Fiber 5g 21%
Sugars 1g
Protein 3g

Proposed revision



Nutrition Facts
Serving Size 1 Pattie (71g)

100 Calories per 1 Pattie Serving (71g)
Amount per serving:
% Daily Value
Total Fat 2.5g 4%
Saturated Fat 0g 0%
Trans Fat 0g
Cholesterol 0mg 0%
Sodium 380mg 16%
Potassium 125 mg 4%
Total Carbohydrate 17mg 6%
Dietary Fiber 5g 21%
Sugars 1g
Protein 3g

Enlarging the required font size for calories will heighten consumer awareness of its importance.

2. The "footnote" on the Nutrition Facts Panel should be eliminated

Another portion of the NFP that could be deleted to simplify the label is a footnote that includes a table of percent DVs for the macro-nutrients in the product based on both a 2,000 and 2,500 calorie diet.[8] The footnote reflects a 1993 political compromise between the FDA and the USDA. The FDA wanted the % DV to be based on a 2,000 calorie diet, but the USDA wanted % DVs to be based on 2,500 calories. The higher calorie level would make the % DVs for the fat content of meat products appear lower, thereby improving a meat product's apparent nutrient profile.[9] When the two agencies could not agree, the issue ultimately ended up on the desk of President George W. Bush. The FDA ultimately prevailed, but the "footnote" was created as a consolation

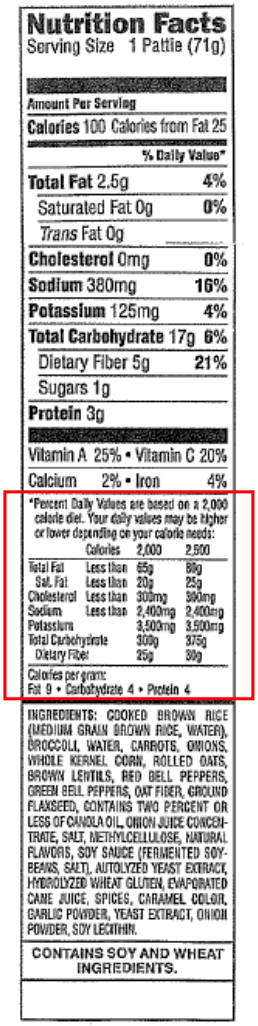
[7] FDA, *Calories Count: Report of the Working Group on Obesity* 20 (2004).

[8] 21 C.F.R. § 101.9(d).

[9] Of course, doing this also lowers the apparent vitamin and mineral content of meat and poultry products.

prize for the USDA – consumers were given the option to use the information in the footnote for a 2,500 calorie per day diet favored by the USDA.

But it is doubtful that many consumers use the "footnote" in this manner. According to results of focus groups conducted by the FDA, the "footnote" may be little used.[10] The footnote should, therefore, be removed, because it is unnecessary and because doing so would make room for more important information.



Nutrition Facts
Serving Size 1 Pattie (71g)

Amount Per Serving
Calories 100 Calories from Fat 25

	% Daily Value*
Total Fat 2.5g	4%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 380mg	16%
Potassium 125mg	4%
Total Carbohydrate 17g	6%
Dietary Fiber 5g	21%
Sugars 1g	
Protein 3g	

Vitamin A 25% • Vitamin C 20%
Calcium 2% • Iron 4%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat. Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

INGREDIENTS: COOKED BROWN RICE (MEDIUM GRAIN BROWN RICE, WATER), BROCCOLI, WATER, CARROTS, ONIONS, WHOLE KERNEL CORN, ROLLED OATS, BROWN LENTILS, RED BELL PEPPERS, GREEN BELL PEPPERS, OAT FIBER, GROUND FLAXSEED, CONTAINS TWO PERCENT OR LESS OF CANOLA OIL, ONION JUICE CONCENTRATE, SALT, METHYLCELLULOSE, NATURAL FLAVORS, SOY SAUCE (FERMENTED SOYBEANS, SALT), AUTOLYZED YEAST EXTRACT, HYDROLYZED WHEAT GLUTEN, EVAPORATED CANE JUICE, SPICES, CARAMEL COLOR, GARLIC POWDER, YEAST EXTRACT, ONION POWDER, SOY LECITHIN.

CONTAINS SOY AND WHEAT INGREDIENTS.

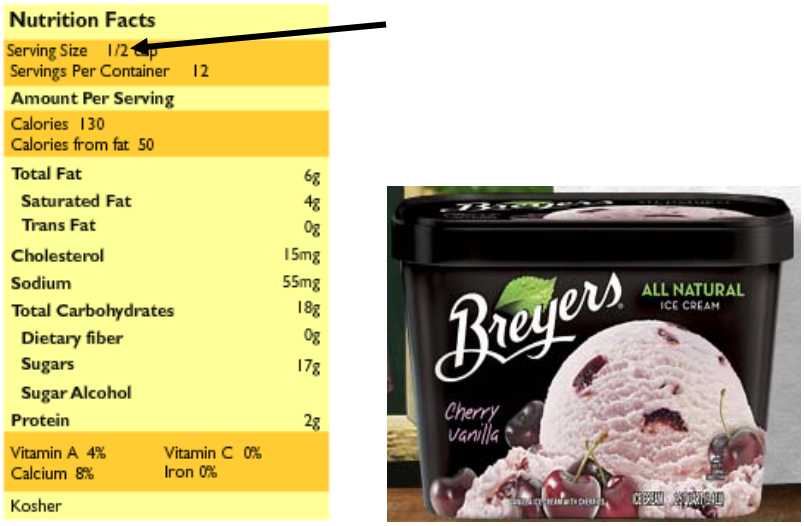
Few consumers use the information contained in the NFP "footnote" according to focus group studies conducted by the FDA.

[10] FDA, *Calories Count: Report of the Working Group on Obesity* 18 (2004).

C. Serving size regulations should be updated

One of the most important changes to the NFP is to rationalize the serving sizes on which all nutrient disclosures and DVs are based. The law requires that the calorie content of a food be disclosed on a per serving basis, which the statute defines as an amount "customarily consumed."[11] The FDA issued regulations setting out serving sizes for 140 food categories in 1993.[12] These serving sizes are referred to as the "Reference Amount Customarily Consumed (RACC)."[13]

Many of those regulations have become outdated; they were based on the 1977-78 and 1987-88 Nationwide Food Consumption Surveys developed by the USDA. Those surveys are now more than 20 years out of date.[14] Newer food consumption data show that consumers are eating larger portion sizes than they did in the 1970s and 1980s. Some consumers typically eat more than the amount the FDA specified in 1993 as a customary serving. For example, the RACC for ice cream is ½ cup. Many consumers eat considerably more than that amount and may not realize that they need to recalculate the calorie information based on the number of servings they actually consume.



Breyer's Cherry Vanilla Ice Cream may seem like a low- calorie treat, however most consumers enjoy more than half a cup of ice cream at a time.

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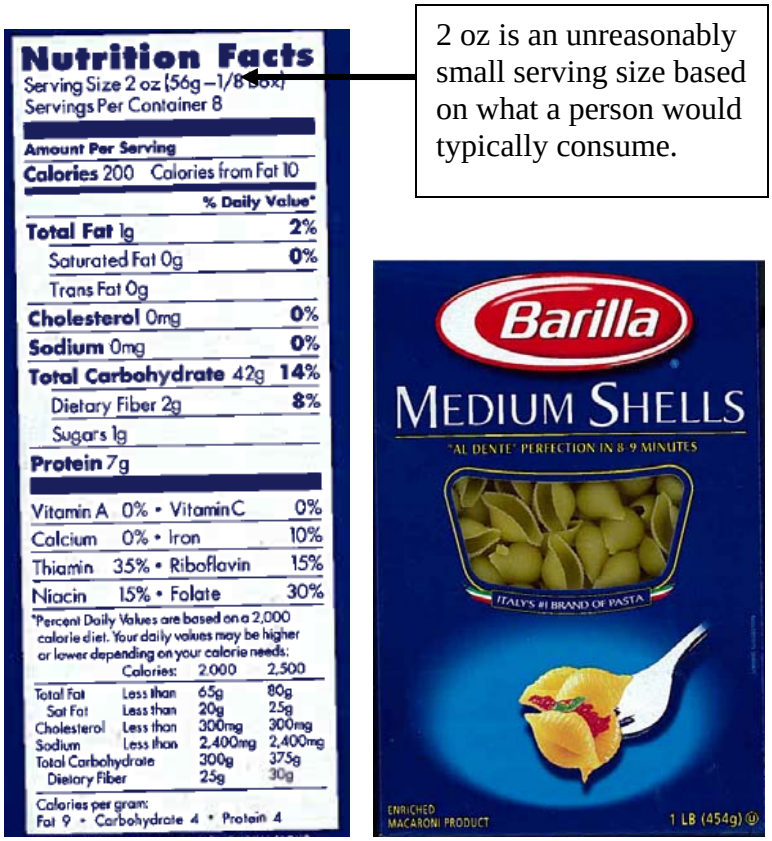
[11] FDCA § 403(q)(1)(A)(i), 21 U.S.C. § 343 (q)(1)(A)(i).

[12] 58 Fed. Reg. 2229 (Jan. 6, 1993).

[13] 21 C.F.R. § 101.9(b)(2).

[14] 70 Fed. Reg. 17,010, 17,011 (Apr. 4. 2005).

Similarly, although pasta has a reference amount of 2 oz. dry weight, which translates into a cup of cooked pasta, many consumers eat at least double that amount during one meal. Thus, a box that is labeled as containing eight servings, may, in fact, be consumed by a typical family of four during a single meal.



Although the serving size for pasta is 2 oz. dry or 1 cup cooked, it is unlikely that a typical family of four would consume only half the box at one sitting.

Deciding whether to update RACCs raises complicated policy issues. If RACC amounts are updated to reflect current consumption, the FDA is afraid that consumers will construe the RACC amount as the amount recommended for consumption.[15] In any event, the FDA should arrive at a solution that is consistent with the NLEA mandate that nutrient content information be based on amounts customarily consumed. Congress's rationale for this requirement was that manufacturers should be required to disclose the amounts of calories, fat, sodium and other nutrients that are *actually* consumed, rather than what consumers should be consuming based on public health recommendations. It was expected that reasonably health-conscious consumers would reduce their

[15] *Id.* at 17,012.

consumption of food items that provided high DVs for saturated fat, sodium, cholesterol, and other undesirable nutrients, if that information was presented clearly and concisely.

D. Regulations should be issued requiring that nutrition information be provided for large single servings

Consumers may be misled when they look at the nutrition information for a product that they assume to be a single serving and do not realize that the nutrition information is based on only a fraction of the product. For example, consumers may buy an individually packaged blueberry muffin that is labeled as containing 200 calories. But that disclosure may be based on the number of calories in only half the muffin. The actual calorie content of the muffins as packaged could be 400 calories. Some consumers may not have purchased the product, or eaten only half, if the calorie content of the product were accurately stated on the label.

Under existing law, only products that are under 200% of the RACC are required to be labeled as single servings. Otherwise, manufacturers have the discretion to choose how many servings to declare.[16] For example, because a soft drink has a RACC of 8 ounces, manufacturers of 20-ounce beverages can legally claim the container has 2.5 servings[17] and disclose calorie, sugar, and other nutrition information for only 8 ounces. Similarly, certain brands of frozen pizzas, baked goods, snacks and other products are labeled as multi-serving products, despite the fact that they are really packaged to be consumed by a single person on one occasion. Many manufacturers prefer listing nutrition information on a RACC basis as opposed to a per package basis (even though consumers are likely to eat the entire package), apparently because doing so makes the calorie content of the product look more modest.

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[16] 21 C.F.R. § 101.9(b)(6). The FDA's rules for serving size are, in the Agency's own words, "very technical." The regulations start from the premise that all products under 200% or more of the RACC are a single serving unless the terms of an exception are met. Manufacturers of products that have more than 200% of the RACC have discretion to label a product as a single serving "if the entire contents of the package can reasonably be consumed at a single eating occasion." *Id. FDA, Letter to Food Manufacturers about Accurate Serving Size Declaration on Food Products*, 2 (Mar. 12, 2004) *available at* http://www.cfsanfda.gov/~dms/fl-ltr4.html.

[17] We note that Coca-Cola, Pepsi, and other beverages list nutrition information for both the RACC and the entire (often a single-serving) bottle.

The label of this 18.5 oz bottle of Fuze Orange Mango Vitalize states 100 calories per serving but is labeled as containing 2 servings. Current FDA regulations permit companies to determine the number of servings in a product when the contents of the container exceed 200% of the RACC (the RACC for beverages is 8 oz). Most consumers, however, would drink the entire 18.5 oz bottle and many may not realize that they have gulped not 100, but 225 calories.

One could reasonably assume that the small packages typically sold in convenience stores, vending machines and snack shops indicate that the nutrition information applies to the entire package. But nutrition information for many such products is based on the misleading premise that each package contains multiple servings.

Given the small package size, consumers are likely to assume that each of these products contains just one serving. But each supposedly contains 2.5 servings.

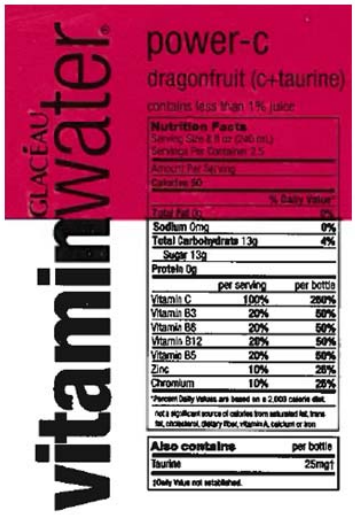
Similarly, Healthy Choice Minestrone soup sold in a microwaveable bowl claims to contain 2 servings, and discloses sodium and other information on the Nutrition Facts Panel for only half of what is clearly a single-serving container. We note that the label does contain a banner stating "This entire package contains 210 calories," but sodium information is presented for only one-half of the container. If the manufacturer provided sodium and other nutrition information for the entire package, the product could no

longer be labeled as "healthy" because the sodium content would be about 800mg, instead of 400mg as declared on the label. FDA regulations require that a food cannot be labeled as "healthy" unless it contains no more than 480 mg of sodium per RACC or per labeled serving.[18]

This product is "healthy" based on FDA official serving sizes, but has too much sodium to qualify for a healthy claim if the entire 14 oz microwave container is consumed.

Some manufacturers have attempted to address the single serving issue by providing nutrition information in two columns – one for the RACC and one for the entire container. An example is Coca-Cola's "Vitaminwater," which is sold in a 20-oz. bottle. The NFP states that it contains 50 calories per serving and has 2.5 servings. Adding dual columns makes the label even more confusing. The bottle is certainly likely to be consumed by one person on a single occasion who will take in 125 calories.

[18] 21 C.F.R. § 101.65(d)(2)(ii)(healthy requirements); FDA, *Food Labeling Guide*, App. B X-4. (Apr. 2008).



The "vitaminwater" label uses a confusing dual column format to disclose nutrition information by both the RACC and the entire (single serving) container.

Makers of large single-serving packages should not be allowed to pretend that those packages really contain multiple servings. A more straight forward way to communicate nutrition information would be to simply disclose nutrient content for the entire container when it is likely to be consumed by one individual at a single eating occasion. The dual-column format is misleading and should be barred.[19]

E. A Daily Value should be established for added sugars, the DV and the amount of added sugars per serving should be disclosed on the NFP, and the term "low sugar" should be defined

In 1999, the Center for Science in the Public Interest (CSPI) and dozens of leading health experts and organizations petitioned the FDA to require that food labels declare how much added sugar is used in soft drinks, ice cream, and other foods, and adopt a Daily Value of 10 teaspoons, about 40 grams for added sugar. That amounts to 160 calories or 8% of total calories. Numerous

[19] FDA regulations permit dual-column labeling only for two or more forms of the same food, e.g., "as purchased," "as prepared," or for two or more groups for which RDIs are established, such as infants and children less than 4 years. 21 C.F.R. § 101.9 (e). That section provides that if dual labeling is used, *all* nutrient information must be provided on a per serving and a per container basis**,** something that the "vitaminwater" label fails to do. *Id.*

health authorities have urged consumers to limit added sugars to 6% to 10% of calories.[20]

Reducing the consumption of added sugars is an essential public health measure. Diets high in added sugars, from such foods as soft drinks, fruit drinks, candy, cakes, and cookies, squeeze healthier foods out of the diet. In some people, diets high in added sugars contribute to obesity. Obesity, in turn, increases the risk of diabetes, heart disease, high blood pressure and other health problems. In addition, frequent consumption of foods rich in added sugars promotes tooth decay.

In one publication called "The Food Guide Pyramid," the USDA advises consumers to try to limit themselves to about 10 teaspoons of added sugars per day (40 grams)[21] based on a 2,000 calorie per day diet. Most recently, the American Heart Association set an upper limit for added sugar intake that is no more than 100 calories per day for most American women and no more than 150 calories for men. [22] To put this in perspective, just one 12-ounce can of Coca-Cola contains 140 calories and has about 10 teaspoons of added sugars.

Further, the U.S. Dietary Guidelines, the Institute of Medicine (IOM), and other health authorities have urged consumers to restrict their intake of sweetened beverages and foods.[23] The American Academy of Pediatrics, the World Health Organization, and other authorities specifically recommend limiting the consumption of added sugars from diluted fruit juices.[24] The failure to disclose added sugars on the Nutrition Facts Panel is a glaring omission. Using current labels, it is difficult or impossible for consumers to determine how

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[20] In 2003, the World Health Organization recommended a limit of less than 10% of energy in the form of "free" sugars (or "extrinsic" sugars, which includes the sugars in fruit juice) WHO-FAO, *Diet, nutrition and the prevention of chronic diseases*, 56 TRS 916 (2003) *available at http://www.who.int/dietphysicalactivity/publications/trs916/summary/en/index.html* (last visited Dec. 24, 2009). The 2005 *Dietary Guidelines for Americans* recommended a limit of 6.4% of calories or 32 grams for a 2000 calorie diet. Dietary Guidelines for Americans, *available at* http://www.health.gov/Dietaryguidelines/dga2005/document/html/AppendixA.htm (last visited Dec. 24, 2009). Appendix A-3.

[21] USDA, Pamphlet, *The Food Guide Pyramid Home and Garden Bulletin No, 252.* (Aug. 1992)(rev'd Oct. 1996 at 17.)

[22] Am. Heart Asso'n, *Dietary Sugars Intake and Cardiovascular Health. A Scientific Statement from the Am. Heart Asso'n,* Circulation (Aug. 24, 2009).

[23] *Dietary Guidelines, supra* note 20 at 38.

[24] Comm. on Nutrition. "The Use and Misuse of Fruit Juice in Pediatrics." Pediatrics. 2001 May;107(5): 1210-1213;. Popkin BM, et al. "A new proposed guidance system for beverage consumption in the United States;"Am J Clin Nutr. 2006 Mar;83(3):529-42. Erratum in: Am J Clin Nutr. 2007 Aug;86(2):525; World Health Organization. "Diet, Nutrition and the Prevention of Chronic Diseases." WHO Technical Report Series No.916. Geneva 2003 http://libdoc.who.int/trs/WHO_TRS_916.pdf.

much sugar has been added to a food such as yogurt, canned fruit, applesauce, or diluted juice drinks.

At least one major food company has intentionally exploited the vacuum caused by the FDA's failure to establish a DV for added sugar. Kellogg, on the label of its Smart Start cereal, cites an IOM report as the basis for telling consumers that they should aim to limit their consumption of added sugars to 25% of calories "to help minimize the consumption of foods with empty calories." Kellogg advises consumers that they can have up to 125 g of added sugar per day.

But, as the president of the IOM has clarified, the report "is not meant to convey a desirable or even acceptable standard intake. . . . Interpretations suggesting that a sugar intake of 25% of total calories is endorsed by the Institute's report are incorrect."[25] Nonetheless, Kellogg continues to use its discredited interpretation of the IOM report.

[25] Letter from Harvey V. Fineberg, M.D., Ph.D., President IOM to Hon. Tommy Thompson, Secretary of HHS (April 15, 2003).

Kellogg misrepresents an IOM study on the label of Smart Start Strawberry Oat Bites Cereal.

Moreover, although the FDA has issued a regulation governing the use of "sugar free," "reduced" and "no added sugars," it has not issued a regulation governing "low sugar."[26] This omission by the FDA has led some companies to label their products as "Low Fat" or "Fat Free" even though the product is not low in sugars and overall caloric content, resulting in what was called the "the Snackwell Syndrome." Some consumers thought they could eat large portions of fat free foods without gaining weight.

In addition, companies have come up with their own terms such as "lightly sweetened," which appears on numerous brands of breakfast cereals and other products. The use of the term "lightly sweetened" may convey the impression that the product is low in sugar. Whether Kellogg's Frosted Mini-Wheats Bite Size is 'lightly sweetened" should be determined by federal rules, not the marketing executives of a manufacturer (see illustration on next page).

[26] 21 C.F.R. § 101.60(c).

Kellogg's Frosted Mini-Wheats Bite Size claim to be "lightly sweetened," but contain 12 grams of sugar per serving or about 20% sugar by weight.

F. Fiber content disclosures should be modified

The FDA should also clarify that the definition of fiber only includes intact fibers from whole grains, beans, vegetables, fruit and other foods. In addition, the term "dietary fiber" on the Nutrition Facts Panel should be changed to "fiber." Currently, fiber is being added to foods such as ice creams, yogurts, juices and drinks so that manufacturers can

brag about their fiber content. But these products do not contain the traditional sources of fiber associated with a variety of health benefits. Instead, they are adding what is known as "isolated fibers," that are mostly purified powders called inulin, polydextrose and maltodextrin. It is unlikely that inulin, polydextrose and maltodextrin lower blood cholesterol or blood sugar. Polydextrose may help with regularity, but inulin and maltodextrim do not. The FDA published an Advance Notice of Proposed Rulemaking addressing this issue and other matters related to the nutrients and DV's listed on the Nutrition Facts panel in November, 2007.[27]

Fiber One claims to have 4 grams of fiber, but most of the fiber comes from nontraditional sources such as chicory root that may not provide all of the traditional health benefits associated with fiber from whole grain foods.

[27] 72 Fed. Reg. 62149, 62166 (Nov. 2, 2007).

Regulatory and Legislative Status

A. Increasing prominence of calories and deleting extraneous information from the NFP

The FDA issued an ANPR on April 4, 2005 seeking comment on whether its labeling regulations should give more prominence to calories.[28] The issue has received little attention since the comment period ended. The FDA has still not even issued a proposed rule. Thus, valuable space on the food label is still occupied by "calories from fat" and a confusing footnote. The space currently utilized for these requirements could be used much more effectively to increase the font size of the calorie declaration. The FDA should make it a priority to review the comments on the ANPR and develop a proposed rule.

B. Rationalizing single size servings and providing nutrition information for large single serving containers

In August 2003, the FDA created the Obesity Working Group to develop an action plan to help address the nation's obesity problem, and the group issued a report in 2004.[29] In response to its recommendations, the FDA issued an ANPR on April 4, 2005, seeking suggestions on ways in which it could make serving size information on the Nutrition Facts Panel easier for consumers to use when deciding which foods and how much of these foods they should eat.[30]

Shortly before that ANPR was issued, the FDA issued a Letter to Food Manufacturers in 2004 attempting to address the problem of supersized, single-serving products being marketed as multi-serving products. The FDA encouraged them to:

> provide the most accurate and useful nutrition information to consumers by taking advantage of the flexibility in current regulations . . . and label food packages as containing a single-serving

[28] 70 Fed. Reg. 7,008 (April 4, 2005).

[29] FDA, *Calories Count: Report of the Working Group on Obesity* (Feb. 2004).

[30] 70 Fed. Reg. 17,010 (Apr. 4, 2005).

if the entire contents of the package can reasonably be consumed at a single-eating occasion."[31]

Makers of large single-serving packages should not be allowed to pretend that those packages really contain multiple servings. The FDA's Letter to Manufacturers does not sanction that practice, but the Agency's request for voluntary action by the industry has been ineffective at stopping deceptive labeling of single serving containers. The FDA should propose a mandatory regulation requiring that nutrition information be disclosed for the entire container if it is likely to be consumed by one person on a single eating occasion. The regulation should also propose prohibiting the use of dual columns on foods packaged in containers likely to be consumed as a single serving.

C. Establishing a DV for added sugars; requiring the disclosure of added sugar content; and defining the term "low sugar"

As discussed above, in 1999, CSPI and dozens of leading health experts and organizations petitioned the FDA to require that food labels declare how much refined sugars are added to soft drinks, ice cream, and other foods and adopt a Daily Value (DV) of 10 teaspoons, about 40 grams.[32]

In 2000, the FDA invited public comment on whether "added sugars" should be included on the food label,[33] but the issue has languished, in part, because of the FDA's unwillingness to press this matter. On August 28, 2008, CSPI sent the FDA updated information on research conducted and expert opinions expressed since its petition was filed. In this update, CSPI stated that:

- The 2005 Dietary Guidelines for Americans notes that someone eating a healthy 2,000 calorie diet (with 29 percent of calories from fat) has room for only 8 teaspoons of added sugar per day.

- Some food industry officials have mischaracterized the IOM as concluding that any level of added sugars under 25 percent of calories is healthful.

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[31] FDA, *Letter to Food Manufacturers about Accurate Serving Size Declaration on Food Products*, 2 (Mar. 12, 2004) *available at* http://www.cfsan.fda.gov/~dms/fl-ltr4.html.

[32] CSPI, *Petition to the FDA to Require Better Sugar Labeling on Foods* (Aug. 3, 1999).

[33] 65 Fed. Reg. 39,414 (June 26, 2000).

- An IOM report on school snacks noted that labeling added sugars on packages would help schools identify foods with less than a given amount of added sugars.

- The Center for Disease Control advised consumers to limit sugar-sweetened beverages.[34]

The FDA's lack of interest in adopting a DV for added sugars was evident at a recent public meeting of international officials. The FDA told attendees that the United States objects to such labeling because of the difficulty in distinguishing between added and naturally occurring sugars for labeling purposes would "present significant enforcement challenges."[35] We do not believe that the FDA's rationale is a sufficient reason to avoid providing consumers with important information. For many foods and beverages (such as soft drinks) that contain only added sugars, the analytical difficulty is irrelevant. For other foods, the FDA could challenge companies that it believes have inaccurate labels to provide information substantiating the labels' accuracy. [36] In any case, the measurement problem could be solved very simply if Congress gave the FDA new authority to inspect company records. Legislation expanding the FDA's authority is pending in the Congress.[37]

D. Revision of reference values and mandatory nutrients

On November 2, 2007, FDA published an Advance Notice of Proposed Rulemaking to revise the Daily Values and list of mandatory nutrients on the Nutrition Facts Panel. The Agency stated that since 1990, new nutrition data and information has emerged including the Institute of Medicine's (IOM) series of reports on the Dietary Reference Intakes for vitamins and other micronutrients, minerals, dietary antioxidants and related compounds, and energy and macronutrients published from 1997 to 2004. In

[34] Center for Disease Control, *Rethink Your Drink* (undated; ca. 2006).

[35] Stephen Clapp, *Codex Labeling Panel to Focus on Anti-Obesity Strategy*, Food Chem. News, Apr. 13, 2009, at 10-11 (quoting US Delegate Barbara Schneeman, who heads FDA's office of Nutrition, Labeling and Dietary Supplements.

[36] In a few cases, the problem might also be addressed by assessing the amount of added sugars by subtracting the naturally occurring sugar known to be in the ingredients used in a product. from the total amount of sugar in the product. Thus, where the level of naturally occurring sugar is known, comparison with the level of sugar in the final product would give some, albeit not the exact, indication of the level of any added sugar. For example, in apple sauce or jam, the level of sugars in the indigenous fruit could be compared with that in the final product.

[37] See, H.R. 2749 § 106 (a). An inspector can "have access to and copy all records relating to. . . whether the food is adulterated or misbranded, or otherwise in violation of this Act . . ." *Id.* The bill has passed the House. Legislation is still pending in the Senate.

addition, the IOM released a 2003 report, *Guiding Principles for Nutrition Labeling and Fortification*, on recommended use of its Daily Reference Intakes in nutrition labeling.

In its ANPR, FDA requested input as to which nutrients should be listed on Nutrition Facts labels, what new reference values should be used to determine percent daily values and which factors should be considered in calculating DVs,[38] as well as several specific issues regarding calories, fats, cholesterol, carbohydrate, protein, dietary fibers, sugar alcohols, sodium, chloride, vitamins and minerals.

Of these topics, two address matters discussed in this report: 1) the addition of added sugars to the Nutrition Facts Panel and 2) the proposed definition of dietary fiber. The IOM recommended three new categories of dietary fiber linked to the physicochemical properties of the fiber, which would have a major effect on how dietary fiber content is calculated for the purpose of nutrition labeling.

The FDA stated that its action was only an ANPR and that the rulemaking process can be expected to require three years or longer.

E. Requiring nutrition labeling of fresh meat and poultry

On January 18, 2001, the USDA published a proposed rule in the *Federal Register* entitled, "Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products."[39] The rule would have extended nutrition labeling requirements to fresh meat and poultry. The Department then let the proposed rule languish for eight years during the Bush Administration.

On December 18, 2009, the proposed rule was given a new life when the USDA announced that it will solicit further public comments. The Department explained that because of the length of time since the publication of the original proposed rule, the USDA is providing the public a new opportunity to comment welcoming comments on relevant issues for which there is new evidence since the proposed rule was originally issued in 2001.

[38] The FDA stated that **"**The IOM report recommended using a population-weighted method of calculating the percent DV, rather than the current population-coverage method. If FDA were to adopt this recommendation, the percent DVs for most nutrients would probably decrease." 72 Fed. Reg. 62149 (Nov. 2, 2007), *available at* http://www.fda.gov/OHRMS/DOCKETS/98fr/07-5440.pdf.

[39] 66 Fed. Reg. 4969 (Jan. 18, 2001).

Recommendations

- The declaration of calories per serving should appear in a larger font, on a contrasting background on the Nutrition Facts Panel. Instead of saying "Amount Per Serving," labels should state "Amount Per ½ Cup Serving."

- Little-used information, such as calories from fat and the NFP "footnote" allowing consumers to convert DVs based on a 2,000-calorie a day diet to a 2,500-calorie a day diet, should be eliminated to simplify the label and create additional space for more important information.

- Products that may reasonably be consumed by one person at a single eating occasion should be considered a single serving and their labels should disclose nutrition information for the entire package. Dual columns that also show nutrition information for the RACC should be prohibited.

- The FDA and the USDA should update certain RACCs in light of current consumption data.

- A Daily Value should be established for added sugars, and the %DV and added sugar content per serving (in terms of teaspoons and grams) should be required on the Nutrition Facts Panel.

- The FDA should also clarify that the definition of fiber only includes intact fibers from whole grains, beans, vegetables, fruit, and other foods.

- The FDA should define "low sugar" and prohibit health claims for products that are not low in sugar, prohibit the use of the term "healthy" on such products, and restrict "fat free" and "low fat" claims on products that are not low in sugar.

- The USDA should adopt the same requirements for foods under its jurisdiction and finalize its proposed rule requiring nutrition labeling on single-ingredient meat and poultry products.

Part III

Standardizing Front-of-Pack Nutrition Labeling

The Problem

The Food and Drug Administration (FDA), consumer groups, and the food industry have all recognized that simply addressing deficiencies in the Nutrition Facts Panel (NFP) does not go far enough in providing consumers with easy-to-use nutrition information. There is a widespread belief that, in addition to improving the NFP, a front-of-pack labeling system using universal symbols should be instituted to further guide consumers, especially those who are less educated, more rushed, or less interested in nutrition, to make healthier choices when shopping for packaged foods.

Some countries, such as the United Kingdom (UK), have developed alternatives to traditional nutrition labeling as required in the United States (US). While 80% of the food products in the UK bear a modicum of nutrition information on the back label,[1] the UK Food Standards Agency (FSA), after extensive consumer research, has developed and urged the use of a front-of-pack nutrition labeling system using red, amber, and green dots (a "traffic light" or "sign-posting" symbol) that permits consumers to tell at a glance whether the amounts of total fat, saturated fat, salt, and sugars are within healthful limits. (A calorie statement is printed adjacent to the "traffic light." Since its introduction in 2006, the system has been voluntary, but several companies, particularly retailers like Sainsbury and Asda supermarkets (owned by the US Walmart chain), have widely adopted the system for their store-brand items. Sainsbury, one of the largest UK retailers, reported that use of the scheme has significantly influenced sales patterns in a positive manner.[2]

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[1] Conversation with Claire Boville, Head of Promotions, Nutrition, Labelling & Dietetic Foods Branch, UK Food Standards Agency, in Washington, D.C. (Dec. 16, 2009).

[2] British Retail Consortium, *British Retailing: A Commitment to Health* 23 (June 2009), *available at* http://www.brc.org.uk/policycontent04.asp?iCat=46&iSubCat=610&sPolicy=Food&sSubPolicy=British+Retailing%3A+A+Commitment+to+Health.

Example of UK "Traffic Light" nutrition labeling system for fronts of food packages

Other countries have taken different courses of action. For instance, Sweden has developed "healthy food" criteria for a variety of food categories. Foods that meet those criteria are permitted to use a keyhole-shaped symbol. Finland has set sodium limits for various categories of foods and requires companies to state "high in sodium" on products containing levels that exceed the specified limit.

The European Union (EU) has proposed a regulation requiring that the amounts of five key nutrients be disclosed on the fronts of all food packages. The European Commission and Parliament are currently debating whether such information should be accompanied by the "Guideline Daily Amount" (GDA) (similar to a Daily Value) for each nutrient or a universal set of symbols as used in the UK.[3]

In the US, manufacturers such as PepsiCo and Kraft developed company systems such as "Smart Spot" or "Sensible Solutions" in an effort to identify "better for you" foods on the front of the package. Eventually, these and other leading food companies recognized that the proliferation of different symbols, each based on different nutrition criteria, was leading only to marketplace confusion.

In the summer of 2009, large food manufacturers joined together to introduce a "Smart Choices Program" that uses a standard check-mark symbol based on uniform nutrition criteria.[4] The logo purportedly "identifies more

[3] These include energy (calories), fat, saturated fat, carbohydrates with specific reference to sugars and salt content. *Comm.Proposal for a Regulation of the European Parliament and of the Council on the Provision of Food Information to Consumers* at 8, COM (2008) 40 final (Jan. 30, 2008).

[4] CSPI initially participated in a consensus conference run by the industry and operated by the Keystone Center. The purpose was to develop a uniform symbol and a uniform set of criteria on which to permit its use. CSPI, however, dropped out of the effort because of certain flaws in the criteria and because CSPI's top priority was to advocate an Institute of Medicine study, involving consumer and other research, to

nutritious choices within specific product categories" and qualifying products also display calorie information per serving on the front of the package.

To qualify for the front label symbol, products must meet the following guidelines.

- Total fat: less than or equal to 35% of calories from fat (for some foods less than 3 g of fat per serving)
- Saturated fat: less than or equal to 10% of calories from saturated fat (for some foods less than 1 g per serving)
- *Trans* fat: less than or equal to 0.5 g per serving ("0" grams as labeled)
- Cholesterol: less than or equal to 60 mg per serving (meat and poultry have higher limits)
- Added sugars: less than or equal to 25% of total calories (except for breakfast cereals, which can be less than or equal to 12 g)
- Sodium: less than or equal to 480 mg (or other amount, depending on product type and serving size) per serving.[5]

However, the Smart Choices program, is using certain weak criteria that are inconsistent with the Dietary Guidelines for Americans. For example, Froot Loops and Cocoa Puffs bear the Smart Choices label, implying that they are healthy foods. Such products are inconsistent with the advice in the US Dietary Guidelines to "choose and

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identify the system that most effectively helped consumers choose the healthiest foods. *See*, Letter from Michael F. Jacobson, Exec. Dir., CSPI to Brad Sperber, The Keystone Center (Oct. 2, 2008).

[5] http://www.smartchoicesprogram.com/nutrition.html.

prepare foods and beverages with little added sugars or caloric sweeteners. . . ."[6] As Congresswoman Rosa DeLauro stated in a letter to FDA Commissioner Dr. Margaret Hamburg, "[i]f Froot Loops and other highly sugary cereals can be considered 'Smart Choices' for children's nutrition, then it is clear the designation is not particularly useful for American families . . . ."[7]

Further, the Smart Choices program criteria do not require that approved cereals and other grain products contain any whole grains. The promotion of cereals and other grain products lacking whole grains is inconsistent with the US Dietary Guidelines, which emphasizes the importance of consuming whole grains and recommends that at least 50% of grains in the diet should be whole.[8] Furthermore, Smart Choices' nutrient criteria may be met through fortification, thereby allowing companies to get the label icon onto non-nutritious products simply by adding inexpensive nutrients. "A basic premise of the Dietary Guidelines is that nutrient needs should be met primarily through consuming foods"[9] To use an extreme example, a snack made of vitamin-fortified sawdust could meet the Smart Choices' criteria.

One of the problems with having numerous rating systems in the marketplace is that they may be inconsistent. The American Heart Association (AHA) licenses its "heart-check" symbol for use on products meeting certain nutrition criteria.[10] The AHA does not consider levels of added sugars or the presence of whole grains –key factors in preventing heart disease and obesity – because it follows 1990-era FDA rules that do not consider the amounts of added sugars or whole grains in determining whether a product can make a

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[6] HHS, USDA, *Dietary Guidelines for Americans 2005* at 36. The Guidelines indicate that healthy diets have room for little added sugar; suggesting, for example, that diets of 1,200 to 1,600 calories, appropriate for many young children, should contain no more than 16 to 20 grams of added sugars per serving. *Id.* at 55. The Guidelines also note that "In some cases, small amounts of sugars added to nutrient dense foods, such as breakfast cereals and reduced-fat milk products, may increase a person's intake of such foods by enhancing the palatability of these products, thus improving nutrient intake without contributing excessive calories." *Id.* at 37.

[7] Letter from Rep. Rosa DeLauro to Margaret Hamburg, MD, Comm. FDA (Sept. 21, 2009), *available at* http://www.house.gov/delauro/.

[8] *Dietary Guidelines*, *supra* note 6 at 24-25.

[9] *Id.*

> Foods contain not only the vitamins and minerals that are often found in supplements, but also hundreds of naturally occurring substances, including carotenoids, flavonoids and isoflavones, and protease inhibitors that may protect against chronic health conditions.

Id. The Guidelines note that supplementation may be appropriate, for example, where certain nutrients may only be present in low amounts in some food or where fortification addresses a documented public health need. *Id.*

[10] http://www.heart.org/presenter.jhtml?identifier=4973.

claim that the product may help prevent the risk of heart disease.[11] Thus, products such as Quaker Instant Oatmeal Cinnamon & Spice qualify for the AHA seal, despite the fact that the product contains 15 grams of sugar per 46-gram serving. That amount of sugar would not meet the Smart Choices criteria, indicating the inconsistency between labeling systems. Similarly, the AHA symbol appears on Uncle Ben's Instant Rice, a refined grain that would not meet the Smart Choices criteria.

Foods can earn the AHA heart check symbol despite being high in sugar or consisting largely of refined grains.

In the last few years, some supermarkets have also developed their own shelf-marking systems for relatively healthful foods. Hannaford Brothers, for example, has established a "Guiding Stars" system for foods in which some products receive zero, one, two, or three stars on a shelf marker next to the item price. Product ratings are calculated based on nutrients per 100 calories.[12] One star indicates a good choice, two stars indicate a better choice, and three stars indicate the healthiest choice. Three-quarters of the products sold receive no stars because they are not especially healthful, as explained in a point-of-sale brochure.[13] But there is no direct correlation between Guiding Stars, the AHA's Heart Check, and other brand-specific program. The Heart Check and other symbols are based on serving sizes and use different criteria.[14]

Meanwhile, a totally different system, NuVal, calculates nutrition ratings between 1 and 100 for all foods. Participating supermarkets put those NuVal ratings on shelf

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[11] 58 Fed. Reg. 2478 (Jan. 6, 1993). Any third party endorsement or reference that meets the definition of a health claim or nutrient content claim must be consistent with the FDA's regulations. *Id.* at 2485. The FDA's list of disqualifying nutrient levels for health claims does not include added sugars or *trans* fat. 21 C.F.R. § 101.14(a)(4). Moreover, the American Heart Association's Heart-Check program has allowed its logo to be used on such foods as Uncle Ben's Instant Rice and Kraft Macaroni and Cheese Baked Cheese Crackers (Parmesan). All are "highly processed" foods or "refined grains." FDA's letter to the sponsors of the Smart Choices program expressed concerns about the use of the Smart Check symbol on such products, *infra* note 24 and accompanying text.

[12] Hannaford Guiding stars – Frequently Asked Questions at 5, *available at* http://www.hannaford.com/Contents/Healthy_Living/Guiding_Stars/faqs.shtml.

[13] Meeting between Lisa Sullivan *et. al.*, Hannaford Foods and CSPI in Washington, DC (Aug. 18, 2006),

[14] *Hannaford, Q & A, supra*, note 12, at 4.

markers. That system may be more or less effective than other systems. Comparative tests have never been conducted.

Along with the Smart Choices symbol, Kellogg continues to print nutritional content and Guideline Daily Amounts (similar to Daily Values) in green colored boxes on the front label of Frosted Flakes and other cereals to indicate levels of calories, total fat, sodium, total sugars, and up to two of the following nutrients: fiber, calcium, potassium, magnesium and vitamins A, C and E. [15]

But Kellogg's front label GDA symbols may be misleading. They all appear in green, (mimicking the UK green traffic light which that government's research found communicated good nutrition to consumers). It is possible that the use of a green symbol for sugar content, even if that number is high, could imply good nutrition to some American consumers especially in the absence of a Daily Value for added sugars. For example, the green boxes on the front of Frosted Flakes cereal disclose that a serving size contains 11 grams of sugar. The placement of this information in a green box suggests that this product contains a healthful level of sugar when, in fact, it is approximately 37% sugar by weight.

[15] http://investor.kelloggs.com/releasedetail.cfm?ReleaseID=264476.

Kellogg's Frosted Flakes illustrates the misleading use of green colored Guideline Daily Amount (similar to a Daily Value) boxes that imply that a product is healthful.

Regulatory and Legislative Status

The legislative history of the NLEA indicates that Congress gave the FDA the option to use "universal symbols to indicate desirable or undesirable levels of particular nutrients."[16] But, the FDA did not formally consider that option until it received a petition from CSPI in November, 2006.[17] In 2007, the Agency held a public meeting on front-label symbols, and the following year the Government Accountability Office (GAO) urged the FDA to collaborate "with other federal

[16] H.R. Rep. 101-538 at 18 (June 13, 1990).

[17] CSPI, Petition for ANPR on the Use of Symbols on the Principal Display Panel to Communicate the Healthfulness of Foods (Nov. 30, 2006).

agencies and stakeholders experienced in nutrition and health issues, to evaluate labeling approaches and options for developing a simplified, empirically valid system that conveys overall nutritional quality to mitigate labels that are misleading to consumers."[18]

In December, 2008, the FDA issued Guidance for Industry on Front-of-Package Symbols, cautioning that some symbols could constitute "nutrient content claims" that characterize the level of a particular nutrient in a food.[19] Nutrient content claims may only be made if the FDA has issued regulations defining their use, and the claims are made in accordance with those definitions.[20] In addition, products that exceed disqualifying levels for certain nutrients require the use of disclosure statements, alerting consumers that one or more nutrients in the food may increase the risk of a disease or health-related condition that is diet related.[21]

In response to GAO's report on the FDA's management of food-labeling issues, Congress included a provision in the Omnibus Appropriations Act of 2009 providing $500,000 for an Institute of Medicine (IOM) study that would examine and provide recommendations to the FDA regarding front-of-label nutrition symbols used by manufacturers, supermarkets, health organizations, and governments in the US and abroad.[22] But IOM will probably need at least $1 million more. The study could take from 18-24 months, once a study committee has been formed.[23] A related research project by the FDA appears to be on a faster track, *infra,* pp. Part III-10.

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[18] GAO, *Food Labeling, FDA Needs to Better Leverage Resources, Improve Oversight and Effectively Use Available Data to Help Consumers Select Healthy Foods,* 44-45 GAO-08-597 (Sept. 2008).

[19] FDA, *Guidance for Industry, Dear Manufacturer Letter Regarding Front-of-Package Symbols* (Dec. 2008, *available at* http://www.cfsan.fda.gov/~dms.flsymgui.html.

[20] FDCA § 403(r)(2)(a)(i), 21 U.S.C. § 343(r)(2)(a)(i).

[21] FDCA § 403(r)(2)(B), 21 U.S.C. § 343(r)(2)(B), 21 C.F.R. § 101.13(h). The label is only required to state "See nutrition information for [fat, sodium, etc.] content." 21 C.F.R. § 101.13(h).

[22] House Appropriations Committee Print, Omnibus Appropriations Act, 2009 (H.R. 1105); Public Law 1121-8, Division F – Department of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2009 at 1398. The FY '10 appropriations bill contains another $500.000 for the IOM study, but at this time, has not passed the full Congress.

[23] Meanwhile, in April 2009, the FDA issued a memorandum summarizing the comments received during the public meeting and indicated areas where there are still information gaps. Memorandum from Vincent De Jesus, Office of Nutrition, Labeling and Dietary Supplements, FDA to Division of Dockets Management, April 21, 2009.

The Smart Choices program has been identified as a potential problem area by the FDA[24] and has been criticized by leading members of Congress.[25] It is also being investigated by state attorneys general. On October 20, 2009, the FDA and the USDA announced that they were attacking the issue by:

- Taking enforcement actions against products with front of pack symbols that are false or misleading or violate current requirements for claims characterizing the level of a nutrient.
- Proposing a regulation that would specify nutrient levels that a serving of a product must contain in order to indicate on the package in any format that it is a better-for-you, or healthier, choice than other foods;
- Undertaking its own consumer research program, and working with the IOM, to determine how consumers use front-of-pack nutrition symbols and which type of symbols communicate nutrition information most effectively;
- Working with manufacturers and retailers to voluntarily adopt the front-of-pack nutrition symbol(s) created by the FDA (regardless, companies would have to follow the FDA nutrition criteria if they chose to use their own symbols);
- Retaining the authority to issue mandatory regulations requiring manufacturers and retailers to use government-mandated front-of-pack nutrition symbols.[26]

In May, 2009, the FSA in the UK completed its most comprehensive study comparing consumer reactions to, and comprehension of, several front-of-pack nutrition labeling schemes, including one utilizing only nutrient-content disclosure and Guide Daily Amounts (GDA's) and one utilizing that Agency's color-coded traffic light nutrition labeling system. The study found that a combination of approaches worked the best, i.e., color-coded traffic lights for key nutrients accompanied by both the words "high," "medium," or "low" and the percent of the GDA per serving.[27] Of course, the formats studied did not include approaches

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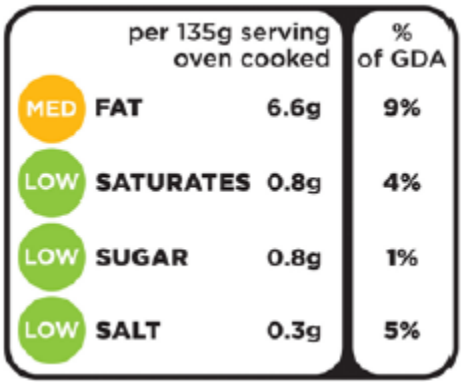
[24] FDA Response to Representative DeLauro (Oct. 19, 2009), *available at* http://www.fda,gov/Food/LabelingNutrition/LabelClaims/ucm187369.htm.; FDA, *Guidance for Industry: Letter Regarding Point of Purchase Food Labeling, available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm187208.htm ; Letter from Michael R. Taylor, Senior Advisor to the Comm. FDA, and Jerold R. Mande, Deputy Under Secretary for Food Safety, USDA, to Sarah Krol, General Manager Smart Choices Program (Aug. 19, 2009).

[25] Press Release, Rep. Rosa DeLauro, *Representative DeLauro Calls for FDA Investigation into "Smart Choices" Labeling* (Sept. 21, 2009), *available at* http://www.house.goc/delauro/.

[26] *FDA Guidance 2009, supra* note 24, at 3.

[27] UK Food Standards Agency, *Comprehension and use of UK nutrition signpost labelling schemes* (May 2009).

similar to NuVal, the Swedish keyhole, or Guiding Stars. Moreover, we recognize that for various reasons British consumers might react differently to particular formats from consumers in the United States. Appropriate consumer research in the United States is vitally important.



This front of pack nutrition label scored the highest in consumer comprehension in an extensive study conducted by the UK Food Standards Agency.

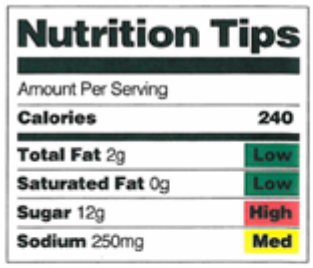
On Dec. 1, 2009, the FDA sought approval from the Office of Management and Budget for two experimental studies addressing consumer understanding and use of a variety of front of package labeling schemes so that FDA can determine which approach is most effective in communicating nutrition information to consumers. Study I will address five labeling conditions: (1) the Smart Choices Program, (2) Guideline Daily Amounts; (3) a scheme similar to the Multiple Traffic Light approach used in the United Kingdom; (4) a control using only the Nutrition Facts label; and (5) a control showing no front of pack information. Study II will test various "Nutrition Tips" schemes showing per serving amounts of calories, total fat, saturated fat, sugar and sodium; interpretative words relating to the Daily Value (DV) (i.e., high, low, etc.) and color coding of the amounts of those nutrients.[28]

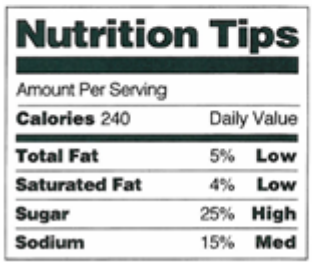
The following are the label formats to be tested by the FDA:

[28] 74 Fed. Reg. 62,786 (Dec. 1, 2009)

FDA Research Options

Option 1





Option 2

Option 3

Option 4

Option 5

Option 6

Option 7

Recommendations

- The FDA and the USDA should promptly take enforcement actions against manufacturers using misleading front-label nutrition symbols developed by private parties and propose regulations detailing nutrient criteria that must be met before such symbols are used on food packaging. Unlike the FDA's current criteria for "healthy," new criteria should include added sugars. That might entail the FDA's adopting a Daily Value for added sugars, perhaps based on the Dietary Guidelines for Americans (Appendix A3).

- The FDA should promptly commence its consumer research program, in conjunction with related work being conducted by the IOM, and identify the most effective front-of-pack nutrition labeling approach (including nutrient criteria, logo, font size, etc.) for empowering consumers to choose healthier foods.

- The FDA and the USDA should then propose regulations for a mandatory new labeling system.

- The FDA and the USDA should prohibit the use of competing front-of-label nutrition labeling schemes.

Part IV

Making Ingredient Labels Easier to Read

The Problem

Manufacturers have been required by law to list all ingredients in order of predominance by weight since 1938.[1] However, the format for disclosure of this essential information has not been modernized – ingredients appear on packages much the way they did more than 70 years ago.

Many ingredient labels are difficult to read. They are often printed in small, condensed type, and many manufacturers use all capital letters that studies show are more difficult to read than upper and lower case letters.[2] Furthermore, many manufacturers use full justification, meaning that the left and right margins of each line of the list are flush. This typesetting practice tends to squish letters and words together, making them even harder to read. And, in what may be an attempt to obfuscate the ingredient list even further, some companies print the list in various colors of ink against ill-contrasting backgrounds or insert the ingredient list in a fold or other area where it will not be visible unless the consumer makes an extra effort to reveal the list or opens the package.

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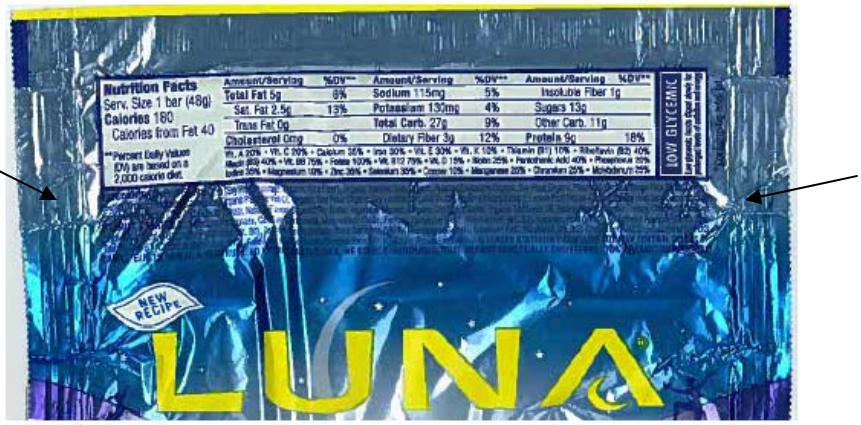
[1] FDCA § 403(i), 21 U.S.C. § 343 (i), 21 C.F.R. § 101.4(a).

[2] Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, *Action Plan for the Provision of Useful Prescription Medicine Information* 55-56 (Dec. 1996); European Comm., *Guidelines on the Readability of the Labelling and Package Leaflet of Medicinal Programs for Human Use*, 7-9 (Rev. 1) (Jan. 12, 2009).

The small type size, condensed and sans serif font, as well as full justification make this list very difficult to read.

The package folds at the arrows, making it very difficult to read the ingredient list.



This ingredient list is even more difficult to read because the manufacturer printed the information on an ill-contrasting background and situated the list so that it is not fully visible until the package is actually opened.

Because the Food and Drug Administration (FDA) has only required eight[3] allergens to be highlighted on food labels, people who are allergic to other ingredients need readable ingredient lists. Also, because ingredients are listed in descending order of predominance, consumers should be able to quickly scan an ingredient list to check the relative position of more and less valuable ingredients.

[3] FDA has since added a ninth allergen to the list, *infra*, note 4. 74 Fed. Reg. 207 (Jan. 5, 2009).

Difficult-to-read ingredient lists are also a problem even for consumers suffering from one of the eight most common food allergies. Under the Food Allergen Labeling and Consumer Protection Act of 2004,[4] allergens may be identified in the ingredient line or in a separate declaration, "Contains _____" in close proximity to the ingredient declaration. But in both cases, the print size need not be more prominent than that of the ingredient declaration.[5] This Act allows allergen declarations to be printed in the same very small type used for the ingredient list. Furthermore, the FDA does not require that the allergen declaration be in bold type – that step remains optional with the manufacturer.[6]

Furthermore, because the FDA does not (yet) require the percentage of whole grains to be disclosed and because the Agency has failed to establish a Daily Value (DV) for added sugars, it is important that consumers be able to quickly refer to the ingredient list to determine the presence and relative amount of such ingredients in a product (e.g., if sugar or high fructose corn syrup is the first ingredient, the product is high in added sugars; if whole wheat flour is somewhere in the middle of the ingredient list, the product probably has only a small amount of whole grains). In addition, because sugar has numerous names that consumers may not identify as a source of added sugar, e.g. lactose, fruit juice concentrates, etc., sugars should be grouped together in the ingredient listing so that consumers get a truer picture of how many sugary ingredients are actually in the product.

Regulatory and Legislative Status

The FDA has not made any efforts to improve the ingredient label since the 1970s. At that time, the FDA held a series of five nationwide hearings and solicited written statements on food labeling.[7]

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[4] Pub. L. No 108-282. After the law was passed, the FDA is requiring a ninth allergen, carmine/cochineal extract, to be disclosed on labels; heretofore, those ingredients have only been listed as "natural coloring."

[5] FDCA § 403(w)(1), 21 U.S.C. § 343(w)(1).

[6] FDA, *Guidance for Industry A Food Labeling Guide* § VI 13 (Apr. 2008), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm; FDA, *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004* (Ed. 4 Final Guidance, Oct. 2006), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059116.htm.

[7] 43 Fed. Reg. 25,296 (June 9, 1978). The FDA published an undated summary of comments entitled *Food Labeling Report on the Analysis of Comments.* Ultimately, the FDA, the FTC, and the USDA jointly announced tentative positions on food labeling. 44 Fed. Reg. 75997 (Dec. 21, 1979). No further action was taken.

Under current FDA regulations, manufacturers are required to use a type size that is at least 1/16th inch in height (based on the lower case "o").[8] This is approximately 4.5 pt. type,[9] which is a tad more than half the size of the typeface that newspapers commonly used around 1996.[10] Newspapers have been increasing font size over the years.[11] Ingredient lists are supposed to be "prominent," "conspicuous," and likely to be "read and understood," but 4.5 pt. type is extremely small and does not meet such requirements in accordance with contemporary standards for readability.[12]

This weak requirement contrasts sharply with more modern FDA rules for the display of information on the Nutrition Facts Panel. For example, all Nutrition Facts Panels must:

- Utilize a single easy-to-read type style
- Use upper and lower case letters
- Use at least 1 pt. leading (i.e., space between two lines of text); in some cases, at least 4 pts of leading are required.
- Letters should never touch
- Most of the required information must be in at least 8 pt. type. Some information must have a minimum 6 pt. type.[13]

Some exceptions for small packages may be necessary, and FDA rules provide options in such situations.[14] But, in some cases, if the FDA deletes extraneous

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[8] 21 C.F.R. §101.2(c); *FDA Guidance on Food Labeling, supra* note 6, at § VI. 3.

[9] An inch equals a point size of 72. One/sixteenth of an inch is approximately 4.5 pts. http://www.unitconversion.org/typography/postscript-points-to-inchs-conversion.html.

[10] *Action Plan, supra* note 2 at 55. More than a decade ago, newspapers were usually printed in 8-point type. *Id.*

[11] *See, e.g., Redesign Owner's Manual* Wash. Post, Oct. 19, 2009 at Special Section 3.

[12] The Federal Food, Drug and Cosmetic Act provides that a food is misbranded:

> If any word, statement or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

FDCA § 403(f) 21 U.S.C. § 343(f)).

[13] 21 C.F.R. § 101.9(d)(1); FDA, *Food Labeling Guide*, *supra* note 6, at § VI. 2-3.

[14] 21 C.F.R. §101.2. The FDA's regulations provide that the ingredient statement (as well as other required statements) may lack the prominence and conspicuousness required by § 403(f) of the FDCA because of

information from the Nutrition Facts Panel, space will be freed up on the package that could be used for ingredient lists printed in larger type and easier-to-read formats.

Here is an example:

Current

INGREDIENTS: ENRICHED FLOUR [WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMINE MONONITRATE (VITAMIN B1), RIBOFLAVIN (VITAMIN B2), FOLIC ACID], VEGETABLE SHORTENING (CONTAINS PARTIALLY HYDROGENATED SOYBEAN AND/OR COTTONSEED OILS), WHOLE WHEAT, CHEDDAR CHEESE (PASTEURIZED CULTURED MILK, SALT ENZYMES), CALCIUM CARBONATE, SALT, WHEY, AUTOLYZED YEAST, BUTTERMILK SOLIDS, LEAVENING (SODIUM ACID PYROPHOSPHATE, SODIUM BICARBONATE, CORNSTARCH), SUGAR, YEAST, LACTIC ACID, ARTIFICIAL COLORS (ANNATTO, YELLOW 5, YELLOW 6), SODIUM PHOSPHATE, SODIUM CASEINATE, ONION PODER, ACETIC ACID, XANTHANGUM, POTASSIUM SORBATE.
CONTAINS: WHEAT, MILK, AND SOY

Proposed

Ingredient Facts

Major Ingredients: Enriched Flour [wheat flour, niacin, reduced iron, thiamine, mononitrate (vitamin B1), riboflavin (vitamin B2), folic acid] • Vegetable shortening [contains partially hydrogenated soybean and/or cottonseed oils] • Whole wheat • Cheddar Cheese (Pasteurized cultured milk, salt, enxymes) • Calcium carbonate • Salt • Whey (milk) • Autolyzed yeast • Buttermilk solids • Leavening (sodium acid polyphosphate, sodium bicarbonate, cornstarch) • Sugar • Yeast • Lactic Acid

Minor Ingredients: Artificial colors (annatto, Yellow 5, Yellow 6) • Sodium phosphate • Sodium caseinate (milk) • Onion powder • Acetic acid • Xanthan gum • Potassium sorbate

Allergy Information: Contains wheat, milk, and soy

The above example of a modernized ingredient list is based on the format requirements for the Nutrition Facts Panel. Both nutrition and ingredient information should be equally easy to read.

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the smallness or the style of type, crowding with other written, printed, or graphic material, and obscuring designs or vignettes. 21 C.F.R. § 101.15.(a)(6)

Recommendations

- The FDA, in consultation with the USDA, should publish a Notice of Proposed Rulemaking in the *Federal Register* with the goal of modernizing the format of the ingredient list.

- Requirements for type size, style, spacing, and leading of ingredient lists should be established based on requirements set forth for the Nutrition Facts Panel.

- The use of all capital letters should be prohibited, and left justification only should be required.

- Eight-point, non-condensed type should be the minimum for print size, except on small packages.

- Sugar sources in the product should be grouped together in the ingredient list so that consumers could readily identify the ingredients that add sugar, get a better sense as to the relative amount of sugar in the product, and not be fooled by healthy-sounding names, such as "fruit juice concentrate."

- Ingredients information should be set off in a box by use of hairlines and should be all black or one color type, printed on a white or other highly contrasting background.

- Once FDA regulations are issued, the USDA should approve only those labels that conform to the new requirements.

Part V

Disclosure of Caffeine Content

The Problem

Caffeine is a psychoactive drug[1] that is present in a variety of foods and beverages. For several reasons, it is important that the amount of caffeine contained in a serving of a food be clearly disclosed on the label in conjunction with other nutrition and ingredient information. CSPI has urged this action for more than a decade.[2]

In 1997, the American Medical Association passed a resolution calling for the disclosure of the amount of caffeine on product labels.[3] The AMA resolution is supported by a series of public health recommendations. In 1981, the FDA warned "Pregnant women should avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly. . . ."[4] The March of Dimes recommends that women who are, or wish to become pregnant, consume no more than 200 milligrams of caffeine per day.[5] Health Canada recommends that women of reproductive age limit their caffeine intake to no more than 300 mg a day "based on possible adverse effects on some factors of reproduction and development."[6]

But without the quantity of caffeine per serving listed on food labels, it is difficult for women who are or are considering becoming pregnant to

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[1] Gilbert, R.M. (1984). Caffeine Consumption. In G.A. Spiller (Ed.), *The Methylxanthine Beverages and Foods: Chemistry, Consumption, and Health Effects* (pp. 185-214). New York: Alan R. Liss.

[2] CSPI first petitioned the FDA for caffeine content disclosures in 1997 as well. Petition for Amendment of Food Labeling Regulations to Require Quantitative Labeling of Caffeine Content and Request for Review of Health Effects of Caffeine (Docket No. 97P-0039) (July 31, 1997).

[3] American Medical Association House of Delegates Resolution 523 (1997) The resolution provides that: " RESOLVED, That the American Medical Association work with the Food and Drug Administration to ensure that when caffeine is added to a product the label reflects this in prominent letters and the amount of caffeine in the product be written on the label." *Id.*

[4] HHS, Public Health Service, FDA, *Caffeine and Pregnancy,* FDA Pub. No. 81-1081 (1981).

[5] http://wwwmarchofdimes.com/professionals/14332_1192.asp.

[6] Health Canada, http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/food-aliment/caffeine-eng.php.

know how much caffeine they are consuming. Although major soft drinks, Lipton Tea, and some energy drinks list caffeine content, many food products do not. Hence, the FDA should promulgate a regulation requiring caffeine content to be listed on the information panel of all foods that contain a significant amount (for example, ≥ 5 milligrams per serving).

These recommendations are well-grounded in scientific research. Too much caffeine may increase the risk of miscarriage and infertility. In one study, among 1,063 pregnant women interviewed by researchers, 24 percent of those who consumed at least 200 mg of caffeine a day suffered miscarriages, compared with 10 percent of those who consumed less than 200 mg.[7] A 1988 study by the National Institutes of Health reported that just one cup of coffee a day could cut the odds in half of becoming pregnant. But later studies indicate that if caffeine affects fertility, it takes at least 300 mg per day.[8]

Caffeine can also cause physical dependence in those who regularly consume it.[9] More than 200 mg of caffeine per day can produce increased anxiety, jitteriness, and upset stomach.[10] Consuming caffeine interferes with adenosine, which is believed to be the brain's natural sleep regulator.[11] Those who abruptly stop consuming caffeine after a long period of use can expect withdrawal symptoms, which include headaches, sleepiness, lethargy, and irritability.[12]

For all of those reasons, caffeine content per serving should be listed on the food label so that consumers can limit their caffeine consumption if they so choose.

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[7] *Am. J. Obstet.* doi:1016/j.ajog.2007.10.803.

[8] http://www.otispregnancy.org/pdf/caffeine.

[9] James, J.E. (1994). Caffeine, health and commercial interest. *Addiction, 89*, 1595-1599.

[10] Griffiths, R.R., & Mumford, G.K. (1995). Caffeine - A drug of abuse? In F. Bloom & DJ. Kupher (Eds.), Psychopharmacology: The Fourth Generation of Progress (pp. 1699-1713). New York: Raven Press Ltd.

[11] Dunwiddie, T.V., & Masino, S.A. (2001, March). The role and regulation of adenosine in the central nervous system. *Annual Review of Neuroscience, 24*, 31-55. doi:10.1146/annurev.neuro.24.1.31

[12] Hughes, J.R. et. al. (1991). Caffeine self-administration, withdrawal, and adverse effects among coffee drinkers. *Archives of General Psychiatry, 48*(7), 611-617; Silverman, K. (1992, October). Withdrawal syndrome after the double-blind cessation of caffeine consumption. *New England Journal of Medicine, 327*(16), 1109-1114; van Dusseldorp, M., & Katan, M. (1990, June). Headache caused by caffeine withdrawal among moderate coffee drinkers switched from ordinary to decaffeinated coffee. *British Medicine Journal, 300*, 1558-1559. doi:10.1136/bmj.300.6739.1558

Over the course of a day, caffeine consumption can add up quickly, far beyond recommended levels. For example, in a single day, a person could consume:

- Three 6 oz cups of Seattle's Best (each containing 65 mg contains a total of 195 mg of caffeine.[13]
- One 20-ounce bottle of Coca Cola contains 57 mg.[14]
- One single serving size container Dannon Coffee Yogurt contains 30 mg.[15]
- Five squares of Hershey's Special Dark Chocolate 31 mg.[16]
- **Total…… . . . . . 313 mg [17]**

This total is above the 200 mg limit set by the March of Dimes and the 300 mg limit set by Health Canada.[18] Thus, it is important that women have a mechanism to determine the amount of caffeine in various foods so that they can limit their caffeine consumption. It is also important for all consumers to know the amount of caffeine they are consuming to avoid possible anxiety, jitteriness, withdrawal symptoms, and upset stomach associated with high caffeine consumption.

It is difficult for consumers to determine which types of foods provide significant amounts of caffeine. Some types of healthful-sounding foods contain surprising amounts of caffeine. For example, Dannon Coffee Yogurt has a 30 mg of caffeine per serving. [19]

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[13] Telephone conversation between Hayley Reynolds, CSPI and Seattle's Best Customer Relations (Nov. 24, 2009).

[14] As listed on label of 20 ounce Coca Cola.

[15] Telephone conversation between Hayley Reynolds, CSPI and Dannon Customer Relations (Nov. 18, 2009).

[16] *See* Note 18 *supra* and accompanying text.

[17] Consumers who have coffee from Starbucks or another coffee shop, may consume far higher levels of caffeine. According to Starbuck's website, each 16 ounce brewed coffee contains 330 mg. of caffeine. www.starbucks.com/retail_beverage_detail.asp (last visited Nov. 18, 2009.

[18] http://wwwmarchofdimes.com/professionals/14332_1148.asp; Health Canada, http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/food-aliment/caffeine-eng.php.

[19] Based on telephone conversation between Hayley Reynolds, CSPI and Dannon Customer Relations on Nov. 18, 2009.

One single serving size container of Dannon Coffee Yogurt contains 30 mg of caffeine, almost as much as a serving of dark chocolate.

Hershey's Special Dark Chocolate fails to disclose that it contains a significant amount of caffeine. A single serving (five squares) contains about 31 mg.[20]

Consumers who eat dark chocolate for its antioxidant content, as promoted on the front of this label, are also getting about 31 mg of caffeine per serving.

[20] http://www.hersheys.com/nutrition/caffeine.asp. The website discloses that 1.45 oz of chocolate contains 31 mg of caffeine.

In other instances, foods like ice cream can contain more caffeine than colas and many other soft drinks.

Starbucks Java Chip Frappuccino ice cream contains Starbucks coffee, giving it 40 -50 mg per half-cup serving,[21] more caffeine than most sodas including Mountain Dew, Coca Cola, and Pepsi.

Another Starbucks product, the bottled Frappuccino, also contains nearly 100 mg of caffeine.

[21] http://www.starbucksicecream.com/#/faqs/ (last visited Nov. 18, 2009). Mountain Dew Contains 36 mg of caffeine per 8-ounce serving. www.pepsiproductfacts.com (last visited Dec. 15, 2009). Pepsi contains 25 mg of caffeine per 8-ounce serving. *Id.* Coca Cola Classic contains 23 mg of caffeine per 8 ounce serving *www*.thecoca-colacompany.com (last visited Nov. 17, 2009).

This vanilla Frappuccino contains 96 mg of caffeine per bottle.

We are not aware of any marketers of coffee, the biggest source of caffeine for most adults, that list caffeine content on labels. Consumers may drink many cups of coffee per day without knowing how much caffeine they are consuming.

A 6 ounce cup of home brewed coffee may have from 59-124 mg depending on the brand.[22]

[22] Most caffeine content information was obtained by CSPI staff in telephone conversations with the companies' customer relations offices on November 24, 2009. Based on a 6 oz. serving,

Since CSPI and others proposed caffeine-content labeling, some major companies, such as Coca-Cola and PepsiCo, have begun listing the amount of caffeine on product labels.

Caffeine content is listed to the side of the Nutrition Facts Panel, underneath the ingredients.

Some companies voluntarily list the amount of caffeine.

But caffeine disclosures need to be standardized in terms of type size and location so that consumers can tell at a glance whether, and how much, caffeine is contained in a food. Some caffeine disclosures, such as the one on Sunkist Orange Soda, are in dense type that appears in all capital letters.

Seattle's' Best contains 65 mg; Maxwell House contains 65-75 mg; Folgers's contains 59 mg; Peet's contains 100 mg. Information pertaining to Starbuck's Pike Place Roast was obtained by extrapolating from the caffeine content information provided by the company's web site for a 16 ounce serving. If a 16 oz. serving contains 330 mg of caffeine, then there are 20.6 mg of caffeine per ounce. A 6 oz serving would, therefore, contain 124 mg of caffeine. http://www.starbucks.com/retail/nutrition_beverage_detail.asp.

Although the label for Sunkist orange soda discloses the amount of caffeine, it is printed in a hard-to-read font. Caffeine labeling needs to be standardized so that consumers can tell at a glance how much caffeine is in a product.

Regulatory and Legislative Status

Caffeine may occur naturally in some ingredients added to foods, e.g. when coffee is added to mocha ice cream; or it may intentionally be added as a separate ingredient in the form of pure caffeine or in the form of caffeine-containing ingredients such as guarana and yerba mate, which are often used in energy drinks. Presently, food labels are merely required to list caffeine in the ingredient list. Although companies are required to list guarana, yerba mate, and other caffeine-containing ingredients, they are not required to disclose that those ingredients contain caffeine.

Serious legal questions are raised by the addition of caffeine to foods beyond carbonated cola drinks. Caffeine has only been recognized by the FDA as Generally Recognized as Safe (GRAS) for use as a food ingredient when it is used in cola-type beverages at up to 200 parts per million (48 mg per 8oz).[23] In the 1980s, while trying to clarify the status of caffeine in soft drinks as Generally Recognized as Safe or subject to a "prior sanction" that would insulate it from regulation as a food additive, the FDA indicated that "at some future date" the

[23] 21 C.F.R § 182.1180.

remaining uses of caffeine would be addressed.[24] But the FDA's Center for Food Safety and Applied Nutrition never resolved the matter.[25]

Since that time, the addition of caffeine to beverages and other foods has exploded. Red Bull was introduced into the United States in 1997 with 80 mg of caffeine per serving. When the FDA failed to require the maker of that product to demonstrate that that level of caffeine was GRAS, the Agency, in essence, opened the floodgates to similar products.

[24] 52 Fed. Reg. 18,923, 18,925 (May 20, 1987).

[25] In contrast, the FDA's Center for Drug Evaluation and Research did take action. In 1988, that division issued a *Final Monograph for Stimulant Drug Products for Over-the-Counter Use* which required a number of warning statements to appear on products containing caffeine as an active ingredient (in amounts that are often found in foods). Two of the warnings are particularly relevant:

> The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heartbeat.

In addition the product must state: "Do not give to children under 12 years of age." 21 C.F.R. § 340.50(c). Such statements are not required to appear on the labels of food products containing similar, or even larger amounts of caffeine.

None of the products pictured above lists the considerable amount of caffeine –160 mg to 280 mg per container.[26]

Whether these uses of caffeine are GRAS[27] is beyond the scope of this report. The FDA might decide to ban some uses. [28] In other cases, the

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[26] Reissig, C., & Griffiths, R. (2009, January). Caffeinated energy drinks—A Growing Problem. *Drug and Alcohol Dependence, 99*, 1-10. doi:10.1016/j.drugalcdep.2008.08.001. Monster has 160 mg (16 oz); Jolt Cola has 280 mg of caffeine (23.5 oz). *Id.* at 3. Stinger has 200 mg of caffeine per 8.4 oz, (telephone conversation between Hayley Reynolds, CSPI and NVE Pharmaceuticals Customer Service Nov. 24, 2009).

[27] In a newly released Draft Guidance on criteria for distinguishing liquid dietary supplements from beverages, the FDA implied that it would be addressing caffeine. FDA expressed concern about the safety of "ingredients that have been present in the food supply for many years that are now being added to beverages and other conventional foods at levels in excess of their traditional use levels or in new beverages or other conventional foods." *Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Consideration Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods* (Draft) (Dec. 2009), 74 Fed. Reg. 63759 (Dec. 4, 2009).

[28] A November 2009 action by the FDA demanding that manufacturers of alcoholic beverages containing caffeine submit their rationale and supporting data for GRAS status to the FDA is a sign that the Agency may enforce its GRAS regulations more strictly. On Nov. 13, 2009, the Agency sent warning letters to 30 manufacturers of caffeinated alcoholic beverages, stating: that it was unaware of any basis for concluding that the use of caffeine in alcoholic beverages is GRAS. FDA, *FDA To Look Into Safety of Caffeinated Alcoholic Beverages Agency Sends Letters to Nearly 30 Manufacturers* (Nov. 13, 2009), *available at* http://www.fda.gov/Food/FoodIngredientsPackaging/ucm190366.htm.

FDA might condition GRAS status on the provision of a cautionary statement. But in all cases, caffeine content should be disclosed.

The FDA stated in 1987:

> [U]nder section 403(a) of the Act (21 U.S.C. § 343(a)), the agency could require warning labels on caffeine-containing nonalcoholic carbonated beverages if it determines that such products present a potential health hazard to consumer. Although the FDA does not believe that a requirement for such a warning label is warranted at this time, such a requirement can be proposed at any time the available data indicate a need for such action.[29]

If the FDA has the authority to require cautionary statements, it most certainly has the authority to require the declaration of caffeine content, a step CSPI has urged for years.[30] Action by the FDA is even more important today given the growth of caffeine-containing food products that have flooded the marketplace.

Other countries have already acted. For example, the European Union requires that products (other than coffee and tea—a huge loophole) containing caffeine in excess of 150 mg/L state on the label "high caffeine content."[31] Australia now requires formulated caffeine beverages to state on the label: "Not suitable for children and caffeine sensitive persons."[32] Australia also requires that manufacturers advise consumers that products containing guarana are a "source of caffeine."[33] Now is the time for the FDA to act and protect consumers in the United States.

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[29] 52 Fed. Reg. 18,923, 18,925 (May 20, 1987).

[30] FDCA §§ 701(a) "the authority to promulgate regulations for the efficient enforcement of this Act. . . .", 403(a), 201(n); 21 U.S.C. §§ 371(a), 343(a), 321(n).

[31] Commission Directive 2002/67/EC, O.J. (L 190/20).

[32] A formulated caffeinated beverage is defined as "a non-alcoholic water-based flavoured beverage which contains caffeine and may contain carbohydrates, amino acids, vitamins and other substances, including other foods, for the purpose of enhancing mental performance." The product must contain between 145 and 320 mg/L of caffeine. Australia New Zealand Food Authority, Standard 2.6.4-Formualted Caffeinated Beverages.

[33] Australia New Zealand Food Standards Code Standard 1.2.3. clause 2.

Recommended Reforms

- Caffeine content per serving should be prominently disclosed on food labels, such as on a separate line between the Nutrition Facts Panel and the ingredient list; above the top of the Nutrition Facts Panel where percentage juice content is declared; or in large, clear type on products (such as cans of coffee) that lack nutrition panels and ingredient lists.

- The terms "guarana" and "yerba mate" (and any other ingredients that are used as a source of caffeine) should be followed by "(a source of caffeine)" in the ingredient list.

- The FDA should require foods containing more than a specified level of caffeine to carry the FDA's advice for pregnant women: "Pregnant women should avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly."

Part VI

Stopping Misleading Structure/Function Claims

In 1990, Congress permitted manufacturers to make health claims for foods that pertained to particular nutrient/disease relationships.[1] An example is: "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."[2]

To prevent abuse, the law requires that the Food and Drug Administration (FDA) approve health claims prior to marketing and allow only those claims that are supported by "significant scientific agreement."[3] That process can take up to 540 days[4] because the law requires that the FDA follow a transparent rulemaking process that allows for the full participation of scientists, consumers, and all other interested parties. The FDA has approved 12 health claims for conventional foods through this process, and another 6 health claims through an abbreviated process established by Congress in 1997. [5]

Food companies have continually sought ways to make health claims more quickly, with less FDA review. This chapter discusses one of the major ways food

[1] Until the Federal Food, Drug and Cosmetic Act was amended in 1990, foods were not permitted to claim that they could prevent a disease. If they tried to do so, they were considered unapproved new drugs. In 1985, the FDA first began experimenting with allowing health claims for conventional foods without requiring pre-market approval. The result was a few truthful claims followed by a flood of products claiming to cure almost every ailment under the sun. After several years of such experimentation, the cover of *Business Week* magazine proclaimed "Can Cornflakes Cure Cancer? Health Claims for Foods are Becoming Ridiculous," Bus.Wk., Oct. 9, 1989.

[2] 21 C.F.R. § 101.75.

[3] Although petitions for health claims are filed by an individual company, any company may make the claim once FDA has issued a regulation granting the petition, so long as eligibility criteria are met.

[4] FDCA § 403 (r)(4)(A), 21 U.S.C. § 343(r)(4)(A).

[5] The food industry obtained a 1997 amendment to the law whereby food companies file a notification with the FDA that they intend to make a health claim based on an authoritative statement of another US government agency or the National Academy of Sciences; the claim becomes lawful if the FDA does not issue a regulation rejecting or modifying the proposed claim within 120 days of receiving the notification. Pub. L. No. 105-115 codified at 21 U.S.C §. 343(r)(3)(C).

companies have tried to achieve that objective, both of which have led to marketplace chaos.

The Problem

The primary approach taken by companies has been to make what are referred to as "structure/function" claims, i.e., claims that a nutrient in a food can benefit the normal structure or functioning of a bodily system without expressly mentioning the role that such nutrient plays in the prevention of any disease. However, the inference is often perfectly clear to the consumer. For example, companies cannot state without prior FDA approval that a nutrient in a food "may help reduce the risk of heart disease," but they can state without FDA approval that the nutrient "helps maintain a healthy heart."

Manufacturers have been permitted to make claims that a food can "affect the structure or any function of the body"[6] since 1938. Until recently, such claims were rare. However, dietary supplement companies were given the right to make such claims by legislation passed by Congress in 1994,[7] and supplement sales soared. That trend was closely observed by the food industry, and over the last several years food manufacturers have increasingly utilized structure/function claims to market conventional foods on the basis of health benefits. In addition to being a successful marketing tool, many companies prefer structure/function claims because in contrast to health claims, the claims can be more succinct and need not be preapproved by the Agency.[8]

Furthermore, structure/function claims do not have to satisfy stringent nutrient-content eligibility requirements that FDA established for health claims. Health claims may not be made if the product exceeds disqualifying levels for total fat, saturated fat, cholesterol, or sodium[9] or, if prior to fortification, the food does not contain at least 10% of the RDI of Vitamin A, Vitamin C, iron, calcium, protein, or fiber.[10] This minimum nutrient requirement, known as the "Jelly Bean" rule, prohibits health claims for soft drinks, chewing gums, bottled waters, and other foods and beverages. For health claims, the nutrient that is the subject of the claim must be present at levels that are at least 20% of the daily value or in amounts specified by FDA.[11] Finally, approved health claims require that claims

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[6] FDCA § 201(g)(1)(C), 21 U.S.C. § 321(g)(1)(C).

[7] Dietary Supplement Health and Education Act, Pub. L. 103-417.

[8] Although petitions for health claims are filed by an individual company, any company may make the claim once FDA has issued a regulation granting the petition, so long as eligibility criteria are met.

[9] 21 C.F.R. § 101.14(a)(4).

[10] 21 C.F.R. § 101.14(e)(6).

[11] 21 C.F.R. § 101.14.(d)(2)(vii).

be phrased in a particular way and indicate that the disease at issue may be caused by a variety of factors and that the product must be consumed as part of a healthy diet. FDA has no such requirements for structure/function claims for foods.

Some companies also favor structure/function claims over more explicit health claims for marketing reasons. A national study of public attitudes and actions toward shopping and eating found that many shoppers favored more succinct and positive-sounding structure/function claims like "supports the immune system" over health claims like "may reduce the risk of cancer."[12]

Health Claim Supported by "Significant Scientific Agreement."

For the most part, food companies using health claims approved by FDA under the "significant scientific agreement" standard meet the requirements of the law. But even the strongest law cannot prevent deception if it is not enforced. In the last decade, FDA generally signaled the food industry that it was stepping back enforcement of food labeling regulations. A few food companies making FDA approved health claims took advantage of that political environment and coupled an approved FDA claim based on significant scientific agreement with exaggerated label statements that violated FDA rules. For example, General Mills' Cheerios, which used an FDA approved health claim about oat bran and heart disease, further claimed on its label that the cereal could "Lower Your Cholesterol 4% in 6 weeks." But on May 9, 2009, FDA sent General Mills a warning letter, signaling industry that the Agency would not let companies stray so far from FDA approved language. That action by FDA was welcomed by consumer organizations.

Through clever wordsmithing, food manufacturers can imply disease prevention, using the softer wording that surveys show many consumers prefer. A

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[12] Linda Gilbert**,** *Marketing Functional Foods: How to Reach Your Target Audience,* AgBioForum 272-290 (Winter 2000).

study by the industry-funded International Food Information Council (IFIC) concluded that:

> Consumers do not perceive a difference among unqualified textual health claims [e.g. those based on "significant scientific agreement"], structure-function claims, and dietary guidance statements with respect to scientific evidence.[13]

A study conducted by the American Association of Retired Persons (AARP) revealed that a majority of the respondents could not distinguish between health claims and structure/function claims. When asked to compare "calcium reduces the risk of osteoporosis" and "calcium builds strong bones**,"** 38% f respondents thought the claims meant the same thing.[14]

Similarly, in 1999 the FDA concluded that consumers in numerous focus group studies conducted by the agency could not tell the difference between structure/function claims and health claims.[15] The FDA's own research demonstrated that:

> [T]here was no indication that participants differentiated at all between structure/function and health claims.[16]

Because consumers cannot distinguish between structure/function claims and health claims for foods, the FDA should apply the same evidentiary and eligibility standards for their use. This has been a longstanding problem that FDA has largely ignored.

In a report discussing, *inter alia*, conventional foods sold as so-called "functional" foods, the GAO recommended that the FDA "develop and implement a strategy for identifying and taking appropriate enforcement actions against companies marketing products with unsupported structure/function claims on their labels."[17] More recently, House and Senate Appropriations Committees have also

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[13] International Food Information Council, *Qualified Health Claims Consumer Research Project*, March 2005 at 12, *available at* http://www.ific.org/research/qualhealthclaimsres.cfm.

[14] Sandra B. Eskin, AARP Public Policy Institute, *Dietary Supplements and Older Consumers* 4 (Dec. 2001).

[15] General Accounting Office, *Food Safety, Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods,"* 23 GAO/RCED-00-156 (July 2000).

[16] *Id. quoting* unnamed report of FDA research conducted in August 1999.

[17] *Id.* at 27. The FDA issued a guidance document setting out substantiation standards for structure/function claims for dietary supplements, but has not taken such action for structure/function claims for foods. As explained, *infra*, p. VI-15, the FDA should not apply substantiation standards for dietary supplement claims to structure/function claims for foods.

urged the FDA to take enforcement action against false or misleading claims to maintain the integrity of the food label and retain consumer confidence in its accuracy.[18]

The FDA has failed to implement those recommendations. Supermarket aisles are filled with structure/function claims boasting about the roles that specific nutrients purportedly play in maintaining good health. Many such claims are unsubstantiated, others impermissibly imply disease prevention, some are simply untrue.

For example, in the fall of 2009, Kellogg's Cocoa Krispies proclaimed that it "now helps support your child's immunity" (a concern of many parents during flu season), because it is fortified with vitamins A, B, C, and E. While a severe deficiency in those vitamins could interfere with the proper functioning of the body's immune system (and any other system), there is no evidence that Cocoa Krispies actually improves a children's immune status or wards off disease. Moreover, the cereal is almost 40% sugar, containing 12 grams per ¾ cup (31 grams) serving.

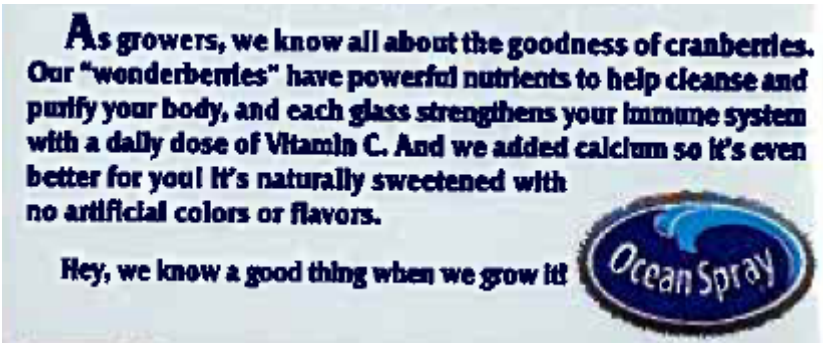
There is no evidence that the product "supports" a child's immune system, although that claim is stated on the front and back of the package label. Moreover, the cereal is about 40% sugar – a quintessential "junk food."

[18] Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, FY 2006, S. Rep. No. 109-92, at 153 (2005), H. Rep. No. 109-102, at 83 (2005).

Kellogg's immunity claim is not only unsubstantiated, it illegally implies disease prevention. The only reason a consumer may be concerned about the strength of their immune system is to ward off disease. A survey conducted by CSPI supports this premise and shows that large numbers of consumers believe that products with "immunity" claims on the label can help prevent disease, including the common cold and the flu.[19] Such claims, therefore, constitute impermissible health claims that have not been authorized by the FDA prior to marketing.

While the FDA has taken no public action, the San Francisco City Attorney objected to the claim. That led Kellogg to announce that it would discontinue the use of immunity claims on its Cocoa Krispies and Rice Krispies cereals.[20]

But numerous other immunity claims for foods still exist, and FDA action is needed. For instance, Ocean Spray recently began a major promotional campaign involving advertising and labeling that claims that cranberry juice can help strengthen your immune system. The label on Ocean Spray Cranberry Juice states that "each glass strengthens your immune system with a daily dose of Vitamin C."



Vitamin C is important for the functioning of the immune system (and every other system). However, consuming Ocean Spray Cranberry Juice Cocktail has no impact on the immune system of healthy persons.

General Mills' Green Giant "immunity blend" frozen vegetables are healthful, but no more likely to improve one's immune system than any other

[19] Online Caravan Advertisements Survey Prepared for CSPI by Opinion Research Corp. (May 21-22, 2009). For example, of the thousand consumers shown advertisements for a juice making an immunity claim, 37% believed that it helps prevent diseases in general. A third of the consumers thought that it helps prevents colds and the flu. *Id.*

[20] Bruce Horovitz, *Kellogg pulls immunity claim from Rice Krispies*, USA Today Nov. 4, 2009, *available at* www.usatoday.com/money/industries/food/2009-11-04-kellogg-immunity_N.htm.

fresh or frozen vegetables. Moreover, the packaging promotes a cancer-related fundraising drive, linking the immunity claim with cancer prevention. The FDA does have an approved health claim stating: "Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors."[21] But General Mills has eschewed that authorized claim for a more proprietary claim that attempts to portray the product as a magic bullet that strengthens the immune system and wards off disease.

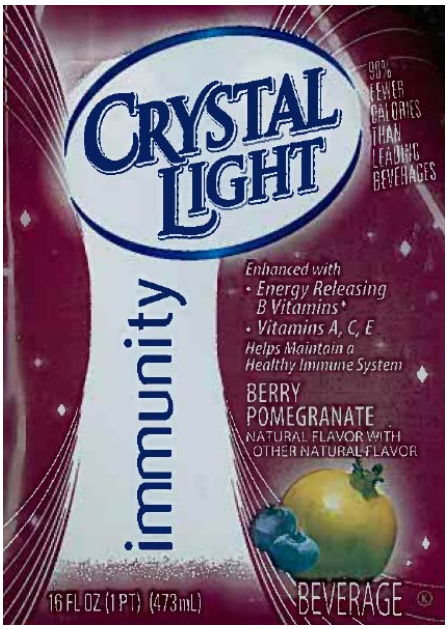
Vegetables are healthful, but General Mills' Green Giant "immunity blend" is no more likely to improve one's immune system than any other fresh or frozen vegetables.

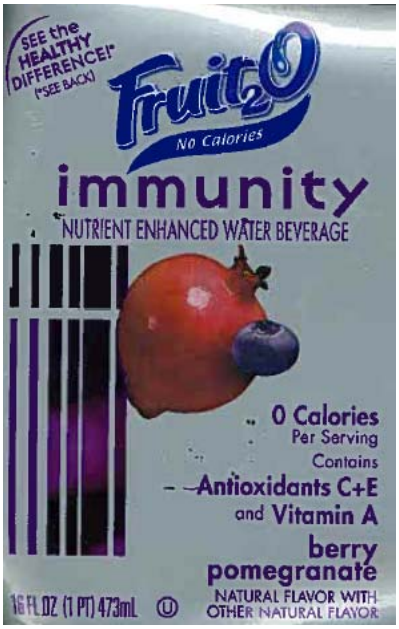
Another example is Nestlé's Carnation Instant Breakfast. The label boasts "Antioxidants to help support the immune system." Again while severe deficiencies in such nutrients can lead to serious health problems, consumption of this product won't ward off disease by strengthening the average consumer's immune system. Such implied claims are false.

[21] 21 C.F.R. § 101.76(e)(1).

The label of Nestlé's Carnation Instant Breakfast misleadingly claims "Antioxidants to help support the immune system."

Kraft Foods' Crystal Light Immunity Diet Beverage claims on its label that its "Vitamins A, C, E Helps [sic] Maintain a Healthy Immune System." Similarly, Kraft Foods' Fruit$_2$O Immunity Nutrient Enhanced Water Beverage claims on the label that it contains vitamin A and antioxidants C and E to "help maintain the immune system."





Kraft admits that neither of these products, by themselves, will benefit the immune system.

In response to a query from CSPI, Kraft said: "We do not expect, or claim, that consumption of *Crystal Light* Immunity and *Fruit$_2$O* Immunity will—in and of itself—significantly impact immune function. Consumed as part of a healthy, balanced diet, however, we believe the added Vitamins C, E and A in these products can supplement consumers' intake of these important nutrients and in so doing 'help maintain a healthy immune system,' as the labels state."[22] But that is not what is implied by the statement on the label.

Anther example of a product making an immunity claim is Fresh Express Baby Spinach. The product is certainly healthful but does not boost the immune system.

[22] Email from Bridget A. MacConnell, Kraft Inc., to CSPI (Sept. 7, 2007).

The label of Fresh Express Baby Spinach claims the product is "loaded with natural phytonutrients that help boost immunity."

The label of Juicy Juice Berry Fruit Juice Beverage claims that it "Helps Support Immunity," [23] and Dannon DanActive Probiotic Dairy Drink states "Helps strengthen your Body's Defenses Immunity." Both are deceptive.

[23] The main trend in the kid's beverage market is beverages that are all natural, that contain ingredients to strengthen the immune system and that are free from ingredients perceived as unhealthy, according to a report published by *New Nutrition Business.* That report apparently claims that immunity is parents' top health concern worldwide and cites Nestlé's findings that mothers identified immunity as the most important benefit for children ages 2-5. Rod Addy, *Kids' beverages target 'all natural,' 'free-from,' 'immunity,'* AP-Food Technology.Com (Sep. 4, 2009), *available at http://www.ap-foodtechnology.com/Industry-drivers/Kids-beverages-target-all-natural-free-from-immunity.*

Both of these products misleadingly imply that they can ward off disease. Such claims are false and misleading.

Companies have made other types of misleading structure/function claims as well. Nestle markets Juicy Juice Fruit Juice Beverage Brain Development with "DHA—A Building Block for Brain Development." An asterisk on the label indicates that the beverage is intended for use "in children under two years old." The label also informs parents that "The human brain triples in volume between birth and two years, so it's never too early to start good nutrition habits," but fails to mention that the American Academy of Pediatrics recommends that children under six months old not be fed juice at all and that children aged 1 to 6 consume no more than 4 to 6 ounces per day in part to reduce the risk of obesity.[24] The fact that the product is packaged in 1-liter bottles is not conducive to limiting serving sizes. Furthermore, a serving of Juicy Juice contains only 16 mg of DHA (as much as ¼ teaspoon of salmon). There is no evidence that this product will facilitate the development of a normal baby's brain.

[24] American Academy of Pediatrics Committee on Nutrition, *The Use and Misuse of Fruit Juice in Pediatrics*, 107 Pediatrics 1210 (May 2001), Reaffirmed 119 Pediatrics 405 (Feb. 2007).

Nestle aims juice drinks with structure/function claims regarding brain development at parents of infants. But even if that baseless claim were true, infants under six months should not be consuming juice at all according to the American Academy of Pediatrics.

Minute Maid Active orange juice makes bogus claims "to help protect healthy joints." The label boasts that a serving contains 750 mg of glucosamine HCl.

Minute Maid claims that this product is designed "to help protect healthy joints." The information panel states: "Glucosamine helps protect cartilage and joints from the stress of normal daily activities."

The form of glucosamine used in this beverage, glucosamine hydrochloride, does not relieve the symptoms of osteoarthritis. The most recent review of the 15 best studies of glucosamine and osteoarthritis concluded that "glucosamine hydrochloride is not effective."[25] In the largest study of glucosamine, funded by the National Institutes of Health, glucosamine hydrochloride did not reduce pain in patients with osteoarthritis of the knee.[26]

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[25] *Arthritis Rheum.* 2007; 56: 2267-77.

[26] *N Engl J Med.* 2006 Feb 23; 354 (8):795-808, *available at* http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3051&itool=AbstractPlus-def&uid=16495392&db=pubmed&url=http://content.nejm.org/cgi/pmidlookup?view=short&pmid=16495392&promo=ONFLNS19.

Regulatory and Legal Status

Structure/function claims for foods are commonplace, but the FDA has no particular standards for regulating them. Unlike dietary supplements, a disclaimer is not required on the label,[27] and the FDA receives no notification of such claims from the manufacturer.[28] Moreover, the FDA has never issued guidance for the level of substantiation food companies[29] need to make such claims and has ignored recommendations from the GAO to do so.[30]

In remedying this problem, the FDA should not merely follow the model it has used to try to regulate structure/function claims on supplement labels. That approach has been shown to be ineffective to protect consumers from misleading claims. Misleading structure/function claims on dietary supplements abound despite those requirements.

Furthermore, surveys have shown that the disclaimer -- "These statements have not been evaluated by the Food and Drug Administration . . .," which appear on dietary supplement labels have been ineffective.[31] Further, the post-market notifications that FDA may receive of structure/function claims for dietary supplements have not permitted the agency to stop misleading claims before they are made.

Moreover, FDA is under no obligation to regulate structure/function claims for foods under the weak scheme it has devised for dietary

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[27] Dietary supplements carrying structure/function claims must prominently state: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." FDCA § 403(r)(6), 21 U.S.C. § 343(r)(6).

[28] *Id.* FDA receives 30 day post-market notification of structure/function claims for dietary supplements, but not for foods. Post-market notification is not an effective way to stop misleading claims before they appear in the marketplace.

[29] In 2000, FDA issued a regulation intended only to prevent supplement manufacturers from making unapproved drug claims under the guise of structure/function claims. 65 Fed. Reg. 1000 (Jan. 6, 2003). Although that regulation applies only to claims on dietary supplements, the FDA said in the Preamble to the final regulation that "[F]or consistency, the agency is likely to interpret the dividing line between structure/function claims and disease claims in a similar manner for conventional foods as for dietary supplements." *Id*. at 1034. Regardless, the regulation, does not address the issue of how much substantiation a food manufacturer needs to render a structure/function claim non-misleading.

[30] The FDA did issue a substantiation standard for structure/function claims for dietary supplements, 74 Fed. Reg. 304 (2009), but that standard does not, and should not apply to foods**,** *infra*, p. VI-15.

[31] Sandra Eskin, American Public Policy Institute, AARP, Dietary Supplements and Older Consumers (2001). This nationwide random digital dial survey of 1,480 personage 50 and over found that "only 41 percent of supplement users report having noticed such a disclaimer." *Id.* at 4.

supplements because Congress has established different regulatory schemes for structure/function claims for foods and dietary supplements. In brief, these two product categories present very different health considerations, and Congress has recognized that structure/function claims for each of them should be regulated in different fashions.[32]

For all those reasons, the FDA should treat structure/function claims for foods just like health claims for foods. Studies show that consumers do not typically distinguish structure/function claims from health claims that require FDA approval and must be supported by "significant scientific agreement."[33] The two types of claims should therefore be regulated in the same manner.

Recommendations

- **The FDA Should Take Enforcement Action Against Specific Deceptively Labeled Products**

Dishonest structure/function claims mislead consumers with regard to serious health matters and threaten the integrity of the food label and of public confidence in food manufacturers and the FDA. Section 403(a)(1) of the Food, Drug, and Cosmetic Act (FDCA) states that "a food shall be deemed to be misbranded if its labeling is false or misleading in any particular." Section 201(n) of the FDCA provides, in pertinent part, that:

> [I]n determining whether the labeling . . . is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . thereof or under such conditions of use as are customary or usual.[34]

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[32] The FDA has recognized this distinction in a variety of contexts. For example, structure/function claims for conventional foods must focus on effects derived from "nutritive value," while supplements may focus on nutritive as well as non-nutritive effect. 62 Fed. Reg. 49,859, 49,860-61 (Sept. 23, 1997).

[33] GAO Report, *supra* note 15 *at* 23 (July 11, 2000).

[34] FDCA § 201(n), 21 U.S.C. § 321(n).

The structure/function claims discussed here mislead consumers both expressly and by implication. We, therefore, urge the FDA to order the companies to promptly remove the dishonest claims from product labels.[35]

- **The FDA Should Issue an Industry-Wide Letter Clarifying the Substantiation Standard for Structure/Function Claims for Foods**

The FDA should warn the food industry of its obligations to comply with the law by issuing an industry letter setting forth the substantiation standard for structure/function claims for foods. The last "Dear Manufacturer" letter the FDA issued on food labeling for foods in January 2007,[36] included a cursory discussion of structure/function claims for foods but failed to specify a substantiation standard for such claims; it simply noted that such claims must be truthful and not misleading. The FDA's failure to specify a substantiation standard has effectively granted food manufacturers carte blanche to make any structure/function claims they want.

- **The FDA should require structure/function claims for foods to meet the same standard as health claims for foods**

Both FDA and food industry studies[37] demonstrate that consumers do not differentiate between structure/function claims and health claims on food labels. To prevent deception, the FDA should subject structure/function claims for conventional foods to the evidentiary standard used for health claims for foods. That standard is "significant scientific agreement."[38]

Applying the same evidentiary standard to health claims and structure/function claims for conventional foods would : 1) preserve order within the food industry, 2) restore integrity to the food label, 3) clarify the limited applicability to foods of FDA's regulations and guidance documents pertaining to dietary supplements, and 4) establish a proactive regulatory policy to ensure that all structure/function claims for foods, not just the most egregious examples named here, are scientifically valid. Such steps are consistent with the First Amendment's commercial free speech doctrine, which accords no protection to misleading commercial claims.

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[35] The courts have upheld government prohibitions on deceptive labeling of foods against First Amendment challenges. *See, e.g., United States v. General Nutrition, Inc.,* 638 F. Supp. 556, 562 (W.D. N.Y. 1986) (upholding FDA prohibition of certain nutritional claims on the product label).

[36] *Dear Manufacturer Letter Regarding Food Labeling* (Jan. 30, 2007), http://www.cfsan.fda.gov/~dms/flguid.html. (last visited June 5, 2009).

[37] *Supra*, notes 13-16 and accompanying text.

[38] FDCA § 403(r)(3)(B), 21 U.S.C. § 343(r)(3)(B).

- **The FDA should not apply its substantiation standards for dietary supplements to structure/function claims for conventional foods**

In its 2000 regulation addressing structure/function claims for dietary supplements,[39] the FDA stated in passing that such claims must be "supported by adequate scientific evidence,"[40] noting that "[I]n response to a request for substantiation for the statement, the agency would expect manufacturers to provide a requester with contrary as well as supporting studies."[41] The FDA later stated in both its *Guidance* document and the *Federal Register* notice announcing its availability that the *Guidance* "does not extend to substantiation issues that may exist in other sections of the Act." [42] Thus the FDA's "Guidance" for substantiating structure/function claims for supplements does not – and, for the reasons explained below, should not – apply to structure/function claims for foods.[43]

In its Guidance document, the FDA said that its substantiation standard for dietary supplements "is consistent with the Federal Trade Commission's standard for *advertising* of supplements and other health related products . . ." (emphasis added) which requires that claims be based on "competent and reliable scientific evidence."[44] But advertising is not the same as labeling. Consumers expect ads to be filled with pitches and exaggerations, but depend on food labels for accurate information about product quality and content.[45]

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[39] *Final Rule on Structure/Function Claims*, *supra* note 29.

[40] As opposed to "significant scientific agreement."

[41] 65 Fed. Reg. at 1032.

[42] FDA, *Guidance for Industry, Substantiation for Dietary Supplement Claims Made under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act*, (Dec. 2008), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm*;* 74 Fed. Reg. 304 (Jan. 5, 2009).

[43] We maintain that the claims discussed here are false and misleading, and constitute misbranding, even if the FDA applied the "competent and reliable scientific evidence" standard. That enforcement approach would still require companies to maintain "competent and reliable" substantiation for their claims including studies that are contrary to, as well as supportive of the claims in question. Clearly, if the FDA requested the companies to provide their substantiation, studies contrary to the claims would greatly outweigh any studies supporting the claims. However, as discussed herein, we believe the FDA should require that structure/function claims for foods meet the same significant scientific agreement standard as health claims for foods.

[44] *Guidance*, *supra, note 42, at 3-4* The availability of the Guidance document was announced on Jan. 5, 2009, shortly before the end of the previous administration. 74 Fed. Reg. 304 (2009).

[45] *Korber Hats v. Federal Trade Commission*, 311 F.2d. 358, 361, (1st Cir. 1962) ("Consumers accept labelling [sic] statements literally while perhaps viewing with a more jaundiced eye the vaunted claim of the advertising media.") *Id.* at 361.

Thus, it would be inappropriate for the FDA to apply the FTC's advertising substantiation standard to food labeling claims. Further, the FTC's approach to supplement advertising claims, while enforced by that agency on numerous occasions over the last decade, has overall been a failure; misleading claims in supplement advertising abound despite repeated attempts by the FTC to stop them. The latest court decision weakened the FTC's "competent and reliable" scientific evidence standard even further.[46] The extension of the FDA's structure/function claims substantiation policy for supplements to conventional foods would merely accelerate the spread of the dishonesty and skullduggery that has plagued the dietary supplement industry to the much larger food industry.[47]

- **The FDA Should Issue a Safe Harbor List of Permissible Structure/Function Claims**

The FDA should facilitate industry compliance with our recommended regulatory approach by establishing a "safe harbor" of permissible claims. Such a list could include claims such as: "Calcium builds strong bones" on foods with at least a specified amount of calcium[48] and that do not exceed the disqualifying levels for nutrients such as saturated fat.[49] The list could also include approved health claims that have been reworded as structure/function claims. This step would help ensure that manufacturers use only those structure/function claims that are scientifically sound.

[46] See *FTC v. Lane Labs*-USA Inc. (Civ. Act. No. 00-cv-3174 (D.NJ) (Aug. 11, 2009). The Federal District Court's holding makes the FTC's advertising substantiation standard even less appropriate for label claims that consumers rely on for dependable information. The Court held that FTC's determination that the defendant did not rely on competent and reliable evidence to support its claims was erroneous when the company "provided credible expert testimony for the claims it made and the substantiation it provided in support of those claims." *Id.*

[47] It is noteworthy that under the FDCA, Congress addressed structure/function claims for foods and dietary supplements in different manners, *compare*, 21 U.S.C. § 201(g)(1)(C) with 21 U.S.C. § 403 (r)(6)(A).

[48] *See* 21 C.F.R. §101.54 (nutrient content claim for "good source").

[49] 21 C.F.R. § 101.14(a)(4). See discussion *supra* pp. VI-2-3.

Part VII

Prohibiting Qualified Health Claims for Foods

The Problem

The second way companies have sought to avoid statutory requirements that health claims for foods be based on "significant scientific agreement" is to persuade the FDA to authorize health claims based on any amount of scientific evidence, so long as the claim is accompanied by a disclaimer that the evidence is uncertain. Such claims are referred to as "qualified health claims."

The Grocery Manufacturers of America had pressured the FDA to follow that approach for foods after the U.S. Court of Appeals decision in *Pearson v. Shalala*.[1] That case held that under the First Amendment the FDA must consider permitting qualified health claims (QHCs) for dietary supplements. From 1999 to 2002, the FDA refused to apply the *Pearson* case to health claims for foods in light of the fact that the Nutrition Labeling and Education Act expressly required that health claims for foods be based on "significant scientific agreement," a requirement justified by volumes of legislative history supporting the need for a strong standard.

In contrast, no such body of legislative history existed for demonstrating that dietary supplement claims needed to be strictly regulated, and Congress did not set out any specific standard in the Act that a court could review. Nonetheless, food industry trade associations continued to pressure the FDA and after the Bush White House appointed a new chief counsel, the Agency's policy was turned on its head. In 2002, by administrative fiat, the FDA simply declared that the Court's holding in *Pearson* did apply to the foods.

The FDA's decision to ignore its statutory mandate and authorize qualified health claims for conventional food was based on an overly broad reading of *Pearson.* First, the FDA was under no legal obligation to apply the Pearson case to the food industry. The Court never considered whether its holding applied to foods, and no food company had sued the Agency over the matter.

[1] Pearson v. Shalala, 164 F.3d 650 (D.C Cir. 1999).

The FDA also circumvents statutory requirements that specify that health claims should only be developed through notice and comment rulemaking. Instead, the FDA merely sends authorization letters to food companies that admit, in essence, that the claims requested by the companies violate the "significant scientific agreement" standard written into the law, but state that the Agency will exercise its prosecutorial discretion and not take enforcement action to halt them. The FDA refers to such health claims as "qualified health claims" because to purportedly protect consumers, the Agency requires that the claims be qualified by a disclosure indicating that the scientific evidence underpinning the claim is uncertain.[2]

That policy decision has led to some rather bizarre FDA-authorized qualified health claims for conventional foods.

An example involving tomatoes and cancer is:

> 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.[3]

An example involving green tea is:

> Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer.[4]

Such claims have been highly criticized by leading health, medical, and consumer organizations.[5] The American Medical Association stated that it opposed qualified health claims because the FDA did not have the legal authority to allow them, that the

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[2] Even assuming that *Pearson* did apply to foods, the Court held that if the FDA had evidence that the disclaimer statements failed to protect consumers, it could hold companies to the "significant scientific agreement" standard. The FDA's own consumer research, in fact, shows that disclaimers fail to protect consumers from being misled. Hence, the Agency is under no obligation to authorize such claims. See *infra*, p. VII-18.

[3] FDA, *Qualified Health Claims: Letter Regarding Tomatoes and Prostate, Ovarian, Gastric and Pancreatic Cancers (American Longevity Petition*) (Docket No. 2004Q-0201)(Nov. 8, 2005), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072767.htm.

[4] FDA, *Letter Responding to Health Claim Petition dated January 27, 2004: Green Tea and Reduced Risk of Cancer Health Claim* (Docket No .2004Q-0083)(June 30, 2005), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072774.htm.

[5] *E.g.*, Mike Mitka, *Food Fight Over Product Label Claims, Critics Say Proposed Changes Will Confuse Consumers*, 290 JAMA 871 (Aug. 20, 2003), *available at* http://jama.ama-assn.org/cgi/reprint/290/7/871.
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new FDA policy would lower scientific standards for label claims, and that such claims would confuse consumers. Opposition was also voiced by the American Public Health Association on, the American Cancer Society, the American College of Preventative Medicine and others.[6]

While few food manufacturers use qualified health claims,[7] perhaps because of the wordy FDA-required disclaimers, the Agency's policy has still caused many problems for consumers. Some companies take advantage of the lax regulatory environment created by the FDA's handling of this matter and choose to make only the positive portion of the qualified claim authorized by the Agency, leaving out the required disclaimer. Others may make the complete claim in small print on labels, but use the FDA's authorization of the qualified health claim as the basis for full-page advertisements or Internet sites that contain statements going far beyond the FDA-authorized language, *infra*, p. 5 Then there are companies that do not use the qualified health claim at all, but bootstrap on the publicity that surrounds an FDA action to authorize such a claim and simply emphasize on labels and in ads the presence of the ingredient that is the subject of the claim, *infra*, VII-pp. 8-12.[8]

At the end of the day, the FDA's policy of authorizing qualified health claims for foods has led not only to problems for consumers, but also diminished respect for the Agency's scientific determinations, once regarded as a "gold standard," both here and abroad.[9]

A. Some companies fail to comply with the specific requirements of FDA authorization letters

The FDA's practice of authorizing qualified health claims by informal communications with food companies has led some manufacturers and trade associations to push the envelope and make only portions of a qualified health claim authorized by the FDA. Although the FDA takes the position that manufacturers must use the exact wording specified by the FDA for a qualified health claim,[10] some

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[6] Letter from Am. Cancer Soc'y *et al.* to Sen. Herb Kohl (Sept. 25, 2007).

[7] Paula Fitzgerald Bone *et al*., *Qualified Health Claims on Package Labels*, 28 J. Pub. Pol'y Mktg. 253 (Fall 2009).

[8] Some of those statements constitute impermissible, unapproved nutrient content claims. *Infra*, pp. VII-9-10.

[9] Discussion between Center for Science in the Public Interest (CSPI) and the DG Sanco officials of the European Commission at the meeting of the Transatlantic Consumer Dialogue, Brussels, Belg. (June 9, 2008).

[10] The FDA routinely states in its letters authorizing qualified health claims that companies must use the exact language specified by the Agency. For example in the FDA's *Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary*

companies simply ignore the Agency. For example, the FDA issued a letter of enforcement discretion permitting a qualified claim that limited evidence suggested that consuming olive oil might reduce the risk of heart disease. The claim states:

> Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.[11]

The company illustrated on the right, Olitalia, does not use the entire claim that the FDA authorized. Instead, the company uses only the part of the FDA authorized claim that is positive, but ignores the FDA wording-requirement that possible health benefits are contingent upon not increasing calories and not substituting olive oil for foods that contain significant amounts of saturated fat.

Heart Disease (Docket No. 2003Q-0401) (September 8, 2004), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072963.htm. The Agency stated:

> Thus, FDA will consider exercising enforcement discretion *for the following qualified health claim:*
> Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and *DHA* omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content]. . . .
> *FDA intends to consider exercising enforcement discretion for the above qualified claim* when all other factors for enforcement discretion identified in Section IV of this letter are met. (emphasis added).

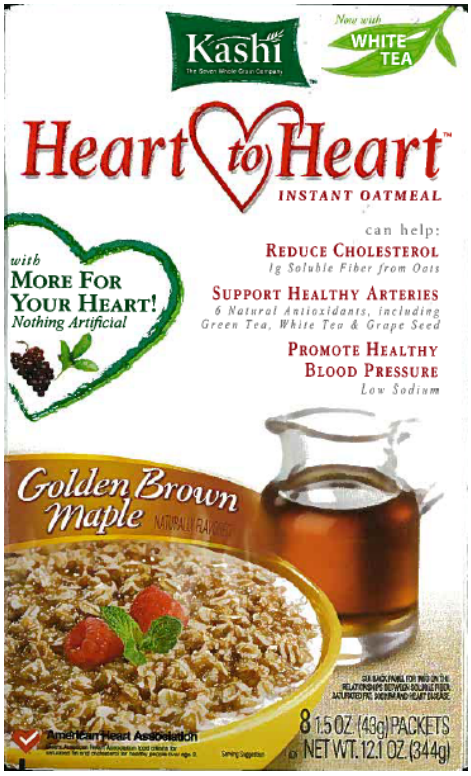
Id. at 25.

[11] FDA, *Letter Responding to Health Claim Petition dated August 28, 2003: Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease* (Docket No. 2003-0559)(Nov. 1, 2004), *available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072963.htm.*

Authorized Language **Incomplete Language**

The product on the left, produced by Filippo Berrio, carries the FDA-authorized language in its entirety. However, the bottle on the right, produced by Olitalia, fails to use the key qualifying language indicating that any health benefits may occur only if the olive oil replaces a similar amount of saturated fat in the diet and overall caloric consumption is not increased.

In another case, a company hypes the presence of green tea, the subject of an FDA qualified health claim for cancer. The product label, however, claims that green tea can purportedly support healthy arteries, a matter not addressed in the FDA authorized claim for this ingredient.



This cereal hypes the presence of green tea to support healthy arteries. However the FDA's QHC for green tea relates to cancer, not heart disease.

In still another example, a company misleadingly embellishes the language authorized by the FDA. In this case, the FDA issued a letter of enforcement discretion permitting Diamond of California to make the following claim on its walnuts:

> Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content.[12]

In its letter announcing that it would not take enforcement action against such a claim, the FDA specifically stated that Diamond could not refer to the alpha-linolenic acid (ALA) omega-3s in the nuts as contributing to any possibility that walnuts could

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[12] FDA, *Qualified Health Claims: Letter of Enforcement Discretion - Walnuts and Coronary Heart Disease* (Docket No 02P-0292) (Mar. 9, 2004), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072910.htm.

reduce the risk of coronary heart disease. The FDA explained that Diamond's request for a qualified health claim did not identify a specific substance in the walnuts responsible for the purported benefits, and the FDA had insufficient information to do so.[13]

After issuing its qualified health claim for walnuts, the FDA authorized a separate qualified health claim for two types of omega-3s -- docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) – that might reduce the risk of coronary heart disease. That FDA action created so much positive publicity about omega-3s that Diamond wanted to brag about omega-3 fatty acids, in addition to the qualified health claim authorized by the FDA specifically for walnuts.[14] Therefore, Diamond brazenly—and misleadingly—prefaced the FDA's authorized qualified claim for walnuts with language about the heart benefits of omega-3s even though such information was not part of the FDA's authorization letter to the company.

Diamond's actions are particularly misleading because ALA,[15] the type of omega-3 fatty acids found in walnuts, was neither included in the FDA's qualified health claim for walnuts nor in the FDA's qualified health claim for omega-3 fatty acids.[16] Nevertheless, Diamond tried to dupe consumers into believing that its walnuts contained the kind of omega-3 fatty acids that the FDA said might provide heart benefits.[17]

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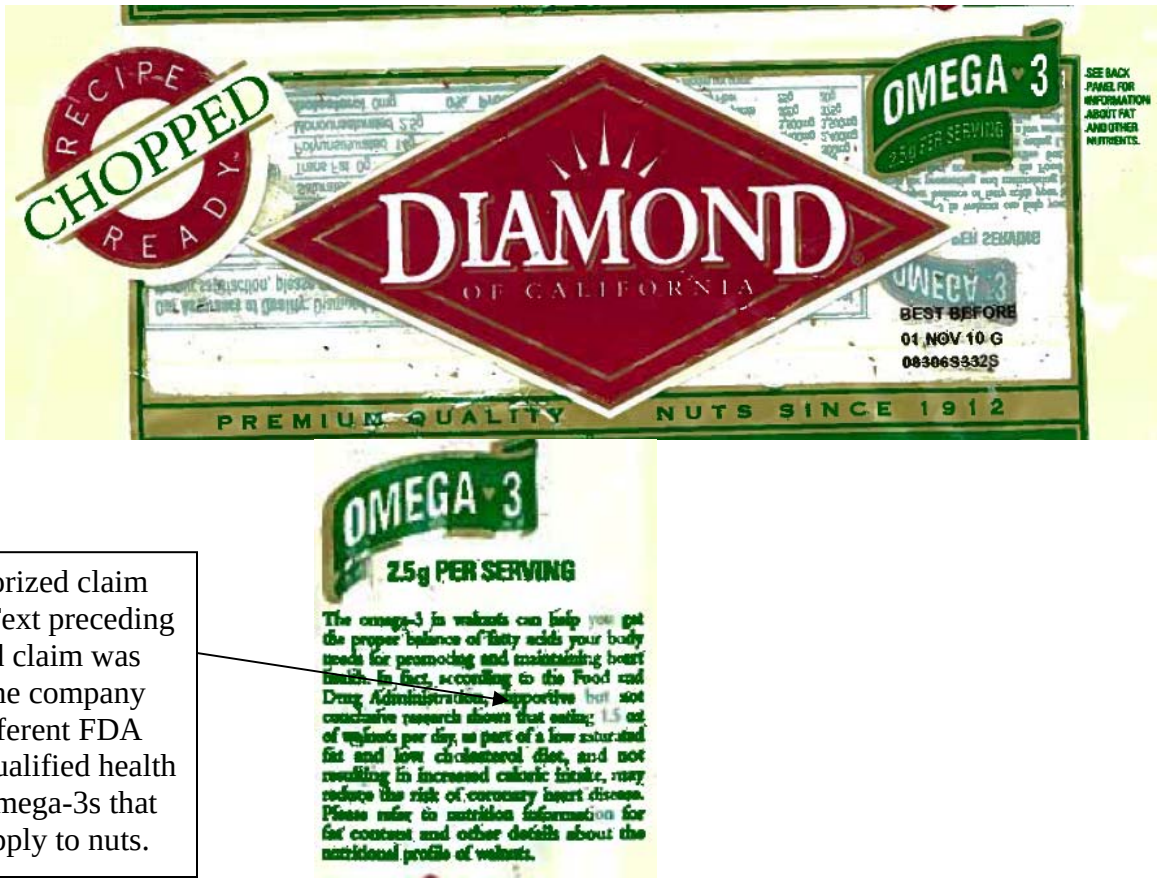
[13] *Id*. at 3.

[14] Food industry trade publications cited the FDA's decision to allow qualified health claims for omega-3s as a reason why the "omega-3 market continues to explode." *Omega 3's: The Supply Side*, Nutraceuticals World, Oct. 2007, at 78. In 2005 alone, omega-3 fatty acids showed up in 120 new food and beverage products. *Foods & Beverages with Omega- 3s's*, Nutraceuticals World, Oct. 2007, at 62.

[15] Although ALA has some benefits, it pales in comparison to the other types of omega-3s that are of aquatic origin, i.e., from fish and algae. Nevertheless, supermarket aisles are filled with cereals, pasta, frozen waffles, and other products containing primarily ALA (from non-aquatic sources such as flax) and implying to reduce the risk of heart disease that is associated with consumption of DHA and EPA omega-3 fatty acids.

[16] FDA, Omega-3 Letter, *supra* note10.

[17] CSPI filed a complaint about the Diamond walnuts with the FDA on Apr. 25, 2007, but no action has been taken, and the product remains on the market with the labeling discussed in our complaint.



FDA authorized claim starts here. Text preceding authorized claim was taken by the company from a different FDA authorized qualified health claim for omega-3s that does not apply to nuts.

Diamond prefaced the QHC authorized by the FDA with language about the benefits of omega-3 in an effort to "end run" the FDA's conclusion that there was insufficient evidence to demonstrate that the health benefits of walnuts are attributable to the food's omega-3 content.

Then there are producers who are ineligible to use a qualified health claim and instead simply highlight the presence of a nutrient that is the subject of a qualified health claim. A prime example is the FDA's authorization of a qualified health claim for EPA and DHA omega-3 fatty acids. The authorization of that qualified health claim, even though it is rarely used on labels, is responsible for much marketplace chaos.

Like Diamond, the egg industry wanted to take advantage of the qualified health claim for omega-3 fatty acids even though eggs were not eligible for such claims. In fact, the FDA specifically denied a petition for a qualified health claim for omega-3 eggs,

because of their high level of cholesterol.[18] To circumvent the FDA's policy, egg producers simply began to include the term omega-3 in a prominent position on egg cartons.[19]

The simple disclosure of omega-3 content (as well as any other nutrient) in terms of milligrams per serving is permissible under the FD&C Act and the FDA policy so long as the disclosure does not imply that the food is high or rich in omega-3s. [20] But some companies place such factual information in large letters, or surround it by graphics that imply the product is rich in omega-3s.

Eating Right Eggs marketed under Safeway's brand use a red sunburst to emphasize the omega-3 content of eggs, but the eggs are high in cholesterol and ineligible to make a qualified health claim, even if only implied, about omega-3 and heart disease.

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[18] FDA, *Eggs with Enhanced Omega-3 Fatty Acid Content and a Balanced 1:1 Ratio of Omega-3/Omega-6 Fatty Acids and Reduced Risk of Heart Disease and Sudden Fatal Heart Attack* (Apr. 5, 2005). http://www.cfsan.fda.gov/~dms/qhceggs.html (last visited Nov. 14, 2009).

[19] The American Egg Board stated at that time that it "is committed to research to increase the omega-3 content of egg and egg products." http://www.aeb.org/Assets/PDF/AmericanEgg Board_Nov.06 PDF. at 1 (last visited June 6, 2007).

[20] 21 C.F.R. § 101.13(i)(3).

Here is another example of this misleading technique used by another major food retailer:

Whole Foods Eggs Boast "OMEGA-3" in large, upper-case letters, implying that the product is rich in omega- 3s.[21] Judging from the numbers on the label, the omega-3s are probably mostly of the less-valuable ALA type.

The authorization of a qualified health claim for omega-3 fatty acids also coincided with the launch of a number of plainly illegal health claims for eggs. The website for Country Hen eggs states that "Omega-3s can also help reduce blood pressure, blood clots, heart disease, arrhythmia and cancer."[22] The FDA has never approved such claims.

[21] FDA, *Guidance for Industry a Food Labeling Guide*, Ch. VIII Claims N. 21 and 22.

[22] http://www.countryhen.com/about.php (last visited Oct. 7, 2009).

Frequently Asked Questions

What are Omega-3's?

What are Omega-3's?

High in OMEGA-3's

Our eggs contain six times the amount of Omega-3's in the normal eggs. Our feed, which we mix in our own mill, contains rich sources of the essential long chain polyunsaturated fatty acid. Omega-3's help reduce blood pressure, blood clots, heart disease, arrhythmia and cancer.

County Hen's website goes far beyond the qualified health claim authorized by the FDA and makes several unauthorized claims. The FDA has expressly stated that eggs, because of their high cholesterol content, must not make claims related to heart disease and has never permitted claims about eggs and cancer.

CSPI filed a formal complaint[23] with the FDA in 2007, in part on the grounds that producers were implicitly claiming that their eggs were rich in omeaga-3s due to the use of large typeface and other techniques used to highlight statements on food labels, but the FDA has taken no enforcement action. [24]

B. The FDA's authorization of qualified health claims for foods has led to misleading claims in advertising and other sources of consumer information.

Some companies do not use the FDA's qualified health claims at all, but use the FDA's authorization of such claims as an excuse to make blatantly misleading advertising and public relations claims that deceive consumers. Each FDA authorization letter, stating it will not take enforcement action against health claims that fail to meet the "significant scientific agreement" standard required by law, signals an "anything goes" regulatory environment that contributes to the dissemination of a variety of nutrition misinformation. The problem is exacerbated by the fact that the Federal Trade Commission (FTC), which regulates food advertising, has no pre-market procedure for reviewing advertising claims. Thus, deceptive claims can only be stopped after the fact, often through a time-consuming process that sometimes involves litigation that can take years to complete.

For example, the FDA's authorization of a preliminary health claim for a reduced heart-disease risk due to certain omega-3 fatty acids helped give "omega-3s" a positive connotation, spurring the use of statements such as "100 mg omega-3s" on products not eligible to make the qualified health claim on labels. Food industry trade publications cited the FDA's decision to allow qualified health claims for omega-3s as a reason for the increased popularity of adding the substance to foods.[25]

Research shows that when consumers become aware that a product contains an ingredient that is the subject of a qualified health claim they are more likely to buy a

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[23] Complaint letter from CSPI regarding eggs products illegally labeled with omega-3 claims (June 21, 2007).

[24] CSPI's complaint also addressed other problems caused by the FDA's authorization of a qualified health claim for omega-3s, including the Agency's failure to permit qualified health claims in the absence of a Daily Value for the nutrient that is the subject of the claim. As a result, consumers have no idea whether they are consuming a significant amount of omega-3s, even on products that the FDA authorized to carry the qualified health claim. *See*, Omega-3 letter, *supra*, note 10."[T]he scientific evidence . . . does not support the establishment of a recommended daily dietary intake level. . . ." *Id.* at 22.

[25] *Omega 3's: The Supply Side*, Nutraceuticals World, Oct. 2007, at 78. According to trade press reports "The rate of product launches continues to outpace other nutrients," and omega-3s are "still at the beginning of a growth curve." Adam Ismail, *Omega's 3s' Potential in Foods*, Nutraceuticals World (June 2009), *available at* http://www.nutraceuticalsworld.com/articles/2009/06/omega-3s-potential.

product containing that ingredient because they are predisposed to associate a health benefit with it. When consumers read claims that implicitly characterize the level of omega-3 fatty acids in the product as being high, they may infer that the food is useful in reducing the risk of heart disease.[26]

The chief of the Consumer Studies Branch of the FDA's Center for Food Safety and Applied Nutrition (CFSAN) summarized the results of research on how consumers are influenced by a relevant content claim for a dietary ingredient specified in a qualified health claim and how this effect, in turn, influences advertising and related marketing efforts:

> Consumers will tend to become more responsive to relevant content claims as they become more familiar with the diet/disease relationship being invoked by the QHC [qualified health claim], but the speed and magnitude of the response is likely contingent on the amount and successfulness of marketing efforts to popularize the diet/disease relationships. As a practical matter, an approved QHC from FDA probably helps these marketing efforts, which is the practical value to the company of getting a QHC.[27]

After the FDA authorized qualified health claims for nuts on July 14, 2003, and walnuts on March 9, 2004, "a tremendous amount of media buzz" was generated. One industry expert explained that "The qualified health claim has given people permission to put nuts back into their diet"[28] and revived an industry that was "somewhat depressed because of nutrition policy about fat."[29] By the summer of 2004, Diamond of California's walnut sales increased 30% over the previous year, according to Nutrition Business Journal.[30] *But even those who don't use the FDA qualified health claim are benefiting and "see good things happening to sales*."[31]

It is no surprise then that companies use the publicity surrounding the FDA's authorization of a qualified health claim, which by definition is based on weak

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[26] E-Mail from Alan S. Levy, Chief, Consumer Studies Branch, CFSAN, FDA to Ilene Ringel Heller, Senior Staff Attorney, CSPI (June 13, 2007, 4:05 PM EDT) (on file with CSPI).

[27] *Id.*

[28] *Health Claims and Branded Ingredients Play Role in Marketing*, Nutrition Business Journal 14 (July/Aug. 2004), *quoting* Sam Cunningham of Cunningham Consulting which specializes in services to the nut industry.

[29] *Id.*

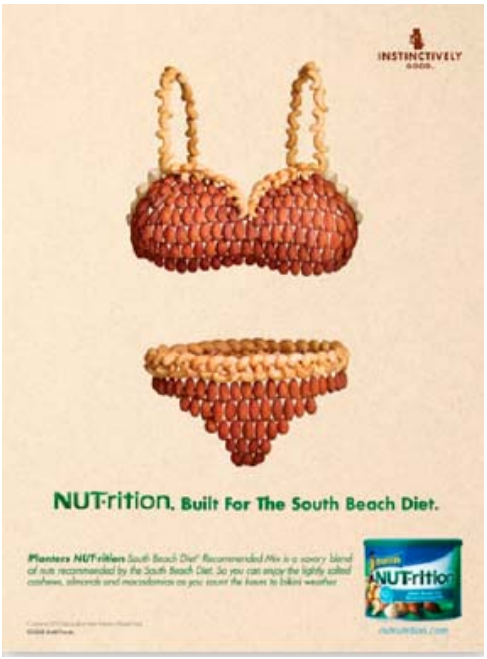
[30] *Id.*

[31] *Id*., *quoting* Cunningham (emphasis added).

scientific evidence, to make misleading claims. Had the FDA not opened the door to qualified health claims, such problems would have been much less likely to occur.[32]

The following examples illustrate this problem:

The FDA's QHCs for nuts recognize that nuts are high in fat and that to be a healthful component of a diet must be consumed only in controlled portions.[33] But ads by some nut marketers obscure that key element of the FDA authorized label claim. This Planter's (Kraft Foods) product has the FDA-authorized qualified health claim on its label, but the advertisement leaves out material information about limiting saturated fat intake.



The FDA qualified health claim does not appear in this ad.

[32] *See*, James E. Tillotson, PhD, MBA, Professor, Tuft's Friedman School of Nutrition Science and Policy, *quoted in Winning the Claim Game—Confused by label claims for health benefits or everything from walnuts to corn oil? Here's how to read the fine print.* Tufts Univ. Health & Nutrition Letter, Aug. 2007, special supplement. "Everybody wants a claim, because it moves product. How valid it is really doesn't seem to matter much . . . .It's kind of a gold badge – if it's on there, people think the product is good . . . .*Id.* at. 1. The standards of proof for the validity of health messages have tobogganed steadily downhill since 1990. You could get a claim for arsenic." *Id*. at *2.*

[33] The FDA's qualified health claim for nuts states that: "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts such as [peanuts, almonds, pistachios, pecans, walnuts or hazelnuts] as part of a diet low in saturated fat and cholesterol may reduce the risk of coronary heart disease. See nutrition information for fat content. *FDA, Qualified Health Claims: Letter of Enforcement Discretion - Nuts and Coronary Heart Disease* (Docket No. 02P-0505 July 14, 2003), *available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072926.htm.*

The following advertisement for almonds also obscures a key element of the FDA's qualified health claim for nuts, e.g. that nuts, when added to the diet, must be part of a healthful diet that is low in saturated fat.

This ad suggests that almonds should be added to steakhouse salad with blue cheese dressing. But adding nuts to a meal that already contains steak and blue cheese dressing simply means adding more saturated fat. Just 1 tablespoon of blue cheese dressing has more than 4 grams of artery-clogging saturated fat.[34]

[34] http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list_nut_edit.pl.

Regulatory and Legal Status

The FDA embarked on an initiative to approve qualified health claims because of food industry pressure to apply *Pearson v. Shalala*,[35] a 1999 decision by the U.S. Court of Appeals for the District of Columbia that only involved dietary supplements, to conventional foods. That court decision required the FDA to determine whether claims for dietary supplements that did not meet the "significant scientific agreement" standard for health claims could be made non-misleading by the addition of a disclaimer explaining the state of the scientific evidence. From 1999 to 2002, the FDA, seeking to prevent the spread of deceptive labeling, maintained that the *Pearson* decision applied only to dietary supplements, not foods.

It is noteworthy that health claims for foods and supplements are subject to different statutory provisions in the Act. Congress specifically spelled out that health claims for foods must be based on "significant scientific agreement" and only permitted such claims after a full notice and comment rulemaking process.[36] That requirement was based on a rich legislative history demonstrating the abuses that occurred in the absence of a strict legal standard.[37]

In contrast, Congress did not examine abuses within the dietary supplement industry and did not set out specific requirements for dietary supplement health claims.[38] Given the two different legislative histories and statutory frameworks for making health claims for foods and supplements, the results of the FDA's consumer research showing that disclaimers are ineffective,[39]and the chaos that has been created in the marketplace since the *Pearson* case, a new court reviewing the issue would likely uphold a FDA

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[35] Pearson, *supra* note 1.

[36] FDCA § 403(r)(3)(B)(i), 21 U.S.C. § 343(r)(3)(B)(i).

[37] *See* H.R. Rep. No. 101-538 (June 13, 1990).

[38] *See* Cong. Rec. S16607 (daily ed. Oct. 24, 1990). Congress did not consider the implications of permitting health claims for dietary supplements. Supplements were added to the NLEA on the Senate floor by the Metzenbaum-Hatch amendment. *Id*. at S 6608(statement of Mr. Metzenbaum). The matter was not raised during the hearing process. The hearings focused solely on food. E.g., *Hearing Before the Senate Comm. on Governmental Affairs on Health and Nutrition Claims in Food Advertising and Labeling***,** 101st Cong. 2d Sess. (No. 101-1224 June 25, 1990), *Hearing Before the House Subc. on Health and the Environment of the Comm. on Energy and Commerce on a Bill to Amend the Federal Food, Drug, and Cosmetic Act to Prescribe Nutrition Labeling for Foods*, 101st Cong. 1st sess.(No. 101-65 Aug. 3, 1989); *Hearing Before a Subcomm. of the House Comm. on Gov't Operations on FDA Proposals to Permit the Use of Disease-Specific Health Claims on Food Labels*, 100th Cong. 1st Sess. Dec. 10, 1987).

[39] Brenda M. Derby, Alan S. Levy, *Working Paper Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Sept. 2005). This is discussed in more detail in notes 47 and accompanying text.

decision to cease exercising its enforcement discretion to permit qualified health claims for foods.

In 2002 and 2003, with the Bush administration fully in place, the FDA changed course and announced in a Guidance Document that the *Pearson* decision applied to food as well as supplements.[40] Under this policy that runs counter to the statute, the FDA issues letters indicating whether it will exercise its enforcement discretion to permit claims that are not legal under the FDCA because they are not supported by significant scientific agreement and have not been promulgated pursuant to notice and comment rulemaking that allows for full input by the general public and scientific community.[41]

CSPI and Public Citizen filed suit against the FDA on the grounds that the Agency set up a new regulatory scheme for qualified health claims that violates the substantive and procedural requirements of the law enacted by Congress in 1990.[42] Those requirements specified that the FDA could only permit health claims for foods if the Agency found through notice and comment rulemaking, the claim was supported by "significant scientific agreement."[43] Just days before a reply to the complaint was due, the FDA issued an Advance Notice of Proposed Rulemaking (ANPR) seeking comments on alternatives for regulating qualified health claims for both supplements and conventional foods.[44] The case was then dismissed on procedural grounds, including, *inter alia,* that the matter was not ripe for judicial review because the FDA had not yet reviewed any qualified health claims under its Guidance.[45]

While the FDA's ANPR has never led to a proposed, let alone final rule, the FDA's statements in the preamble (made prior to any public comment) have become the basis of a *de facto* new law, which was issued via administrative fiat, that is expressly contrary to the requirements for health claims for conventional foods enacted by Congress in 1990. If the FDA sincerely questioned whether the *Pearson* case applied to foods, it should have sought guidance from Congress rather than taking it upon itself to in effect, amend portions of the statue through exercises of enforcement discretion.

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[40] FDA, Guidance for Industry, 67 Fed. Reg. 78,002 (Dec. 20, 2002); FDA, *Guidance for Industry* and *FDA: Interim Evidence-Based Ranking System for Scientific Data,: and Guidance for Industry and FDA: Interim Procedures for Health Claims in the Labeling of Human Food and Human Dietary Supplements.*68 Fed. Reg. 41,387 (July 11, 2003).

[41] Even assuming, *arguendo*, that the FDA correctly applied *Pearson* to qualified health claims for foods, nothing in the holding of that case requires the Agency to abandon notice and comment rulemaking in favor of an information letter authorization process that largely excludes the public and scientific community from providing public comment on proposed claims, as Congress generally intended.

[42] The case was dismissed on procedural grounds.

[43] FDCA § 403(r)(3)(B)(i), 2 USC § 403(r)(B)(i).

[44] 68 Fed. Reg. 29448 (Nov. 25, 2003).

[45] CSPI v. FDA, Civ. Act. No. 03-1962 (D.D.C. July 30, 2004).

Even assuming that the rationale for the *Pearson* decision was applicable to conventional foods, the FDA is not required to follow the disclaimer approach set out in that case. The *Pearson* decision set forth a number of exceptions. The Court stated that if the FDA had empirical evidence demonstrating that consumers would be "bewildered" by the disclaimers and that the disclaimers "would fail to correct for deceptiveness," the Agency would not be obligated to permit qualified health claims.

The Agency is, in fact, in possession of such research. The FDA's own consumer research study completed in 2005 concluded that qualified health claims "failed the key communications test" and that Consumer perceptions of products' health benefits were not diminished by disclaimers indicating greater scientific uncertainty for a claim.[46]

The FDA's conclusions were supported by the FTC. In its official comment to the FDA, the FTC stated that:

- None of the tested disclaimers communicated serious limitations in the scientific evidence.

- Most consumers either overestimated or underestimated the certainty of the science supporting qualified health claims.[47]

In 2006, the FDA announced that a second consumer survey on qualified health claims had been approved by the Office of Management and Budget.[48] Although the study is completed, it has not been released.

In 2007, key health, medical, and consumer groups, including the American Cancer Society, American Diabetes Association, American Heart Association, American College of Preventive Medicine, American Public Health Association, American Medical Association, and others asked Congress to approve language prohibiting the FDA from using FY 2008 appropriations to authorize qualified health claims for foods.

On July 30, 2007, the House of Representatives approved such language, but it was weakened by the Senate. The final congressional language expressed the House and Senate's concern that the "FDA may have exceeded its statutory authority when the Agency decided to begin allowing the use of qualified health claims for conventional foods in 2003." The Committees requested that the Government Accountability Office (GAO), the congressional watchdog agency, conduct an investigation of the FDA's actions and evaluate consumer understanding and the usefulness of qualified health claims. That investigation, to date, has not been formally commenced. Pending

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[46] *Effects of Strength of Science Study*, *supra* note 40.

[47] Comments of the Federal Trade Commission to the FDA in the Matter of Assessing Consumer Perceptions of Health Claims (Docket No. 2005N-0413) (Jan. 17, 2006).

[48] 71 Fed. Reg. 69,134 (Nov. 29, 2006).

completion of the GAO investigation, the Committee urged FDA "not to use funds . . . to review requests for qualified health claims for conventional foods or to issue letters permitting such claims through exercises of enforcement discretion. . . ."[49]

But the FDA ignored Congress. In a June 30, 2008, letter to CSPI and other organizations, FDA Commissioner Andrew C. von Eschenbach, M.D. stated that the FDA would continue work on a petition for reconsideration of a previously authorized qualified health claim and "has no plans to issue a notice or announcement indicating that it will no longer issue letters of enforcement discretion for qualified health claims on conventional foods.[50] Subsequently, in a "midnight" guidance statement issued shortly before President Obama took office in January 2009,[51] the FDA formally announced that it would continue to authorize qualified health claims for supplements and conventional foods.[52] No new petitions have been filed for qualified health claims for conventional foods, although there is a petition pending for qualified health claims for infant formula.[53]

Recommendations

- The FDA should release its second consumer research study on whether the disclaimers in qualified health claims for conventional foods protect consumers from being misled, and, hence, whether the Agency is under any legal obligation under the First Amendment (and the *Pearson* case) to authorize them.

- The FDA should delete language relating to conventional foods from the Bush Administration's January 2009 "midnight" guidance document[54] and specify that, until a court or Congress says otherwise, companies are prohibited from making

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[49] 153 Cong. Rec. H15741 (daily ed. Dec. 17, 2007)(statement of Rep. Obey).

[50] Letter from FDA Comm'r Andrew C. von Eschenbach to Bruce Silverglade, CSPI (June 30, 2008). On August 18, 2008, the FDA refused to modify its prior decision on green tea and a reduced risk of cancer. Letter to Sin Hang Lee, Fleminger, Inc.: *Petition for Reconsideration: Letter Responding to Health Claim Petition Dated January 27, 2004: Green Tea and Reduced Risk of Cancer Health Claim (*Docket No. 2004(Q)-0083 (Aug.19. 2008).

[51] FDA, *Evidence-Based Review System for the Scientific Evaluation of Health Claims* –Final (Jan. 2009).

[52] *Id.* This Guidance replaced the Interim Evidence Based Ranking System for Scientific Data. *Id.* at 26, note 3.

[53] *Petition for Qualified Health Claim for 100% Whey-Protein Partially Hydrolyzed Infant Formula and a Reduced Risk of Atopic Dermatitis in Healthy Infants*, submitted by Nestle Nutrition (Nestle Infant Nutrition/Gerber Product Co.) (May 14, 2009), *available at* http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2009-Q-0301.

[54] *Supra* note 52.

qualified health claims on conventional foods that do not meet the significant scientific agreement standard.

- The FDA should delete language relating to conventional foods from its 2003 ANPR and specify that conventional foods not meeting the significant scientific agreement standard are prohibited from making qualified health claims.

Part VIII

Halting Deceptive "0 *Trans* Fat" Claims

The Problem

The Food and Drug Administration (FDA) recognized in 2003 that about 80% of dietary *trans* fat comes from partially hydrogenated vegetable oils.[1] Artificial *trans* fatty acids are formed when vegetable oils (rarely animal fats) are reacted with hydrogen to increase their melting points, shelf lives, and stability. In the process, some of the unsaturated fatty acids in the oils are converted into saturated and *trans* monounsaturated fatty acids.

Trans fat (naturally occurring or artificial) raises LDL-cholesterol, lowers HDL-cholesterol, and has other physiological effects, making it the most potent type of fatty acid in terms of increasing the risk of coronary heart disease.[2] In July, 2002, the U.S. National Academy of Sciences' Institute of Medicine, at the request of the FDA, reviewed the scientific evidence on *trans* fat and concluded that *trans* fat is at least as harmful to health as saturated fat[3] and increases the risk of heart disease.[4] A 2004 FDA Food Advisory Committee concluded that, gram for gram, *trans* fat is *more harmful* than saturated fat.[5]

The FDA recognized the dangers of *trans* fatty acids and, in 2003, required that *trans* fatty acid content be disclosed on the Nutrition Facts Panel (the rule gave

[1] 68 Fed. Reg. 41,434, 41,470 (July 11, 2003). Calculated from data in Table 1.

[2] Ascherio, AM, Katan MB, Zock PL, *et. al* trans fatty acids and coronary heart disease. New Engl J Med. 1999;340:1994-8.

[3] Food and Nutrition Board of the Institute of Medicine, *Letter Report to the Dietary Reference Intakes for Trans Fatty Acids*, (July 10, 2002) at 34.

[4] *Id.*

[5] Food Chem. News at 27, (May 3, 2004).

companies until January 1, 2006, to change labels).[6] After the FDA required manufacturers to list *trans* fat on the Nutrition Facts Panel, many companies reformulated their products so they could declare "0" on the line of the Nutrition Facts Panel where the *trans* fat content is disclosed. Some companies reformulated their products by replacing partially hydrogenated vegetable oils with more-healthful unsaturated fats. Other companies, however, replaced partially hydrogenated oils with saturated fats, which are almost as unhealthful as *trans* fat.

Moreover, the latter companies sometimes made prominent "0 g *trans* fat" claims on the front of the package label, implying that the product is healthful, when the products actually contained substantial amounts of saturated fat.

The following products illustrate this deceitful marketing technique:

Edy's Dibs Bite Sized Frozen Snacks boast "0 g trans fat!" per serving but contain 16 g of saturated fat (80% of the Daily Value). The FDA limits "cholesterol free" claims to foods with less than 2 g of saturated fat per serving and limits "healthy" claims to foods with less than 1 g of saturated fat,[7] because saturated fats, like trans fats, raise serum cholesterol levels.

[6] 68 Fed. Reg. at 41,433. CSPI has petitioned the FDA to ban artificial *trans* fat completely. CSPI, *Petition for Rulemaking to Revoke the Authority for Industry to Use Partially Hydrogenated Vegetable Oils in Foods* (May 18, 2004).

[7] 21 C.F.R. § 101.62(d).

Nutrition Facts
Serving Size 2 fillets (103g)
Servings Per Container about 5

Amount Per Serving	
Calories 260 Calories from Fat 170	
	% Daily Value*
Total Fat 19g	**29%**
Saturated Fat 4.5g	**23%**
Trans Fat 0g	
Cholesterol 25mg	**8%**
Sodium 680mg	**28%**
Potassium 115mg	**3%**
Total Carbohydrate 15g	**5%**
Dietary Fiber 1g	**4%**
Sugars 3g	
Protein 8g	
Vitamin A 2% • Vitamin C 4%	
Calcium 2% • Iron 4%	

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

INGREDIENTS: POLLOCK, VEGETABLE OIL (COTTONSEED, CANOLA, SOYBEAN, CORN AND/OR RICE BRAN), BEER (WATER, BARLEY MALT, CORN, RICE, HOPS, YEAST), ENRICHED BLEACHED WHEAT FLOUR (FLOUR, NIACIN, IRON, THIAMIN MONONITRATE, RIBOFLAVIN, FOLIC ACID), RICE FLOUR, WATER, MODIFIED CORN STARCH, SUGAR, TAPIOCA DEXTRIN, SALT, LEAVENING (BAKING SODA, SODIUM ALUMINUM PHOSPHATE), YELLOW CORN FLOUR, PALM OIL, DEXTROSE, SOY LECITHIN, XANTHAN GUM, COLORED WITH PAPRIKA AND TURMERIC EXTRACTS, SODIUM TRIPOLYPHOSPHATE (TO RETAIN FISH MOISTURE), WHEY, TBHQ (TO PROTECT FLAVOR), METHYLCELLULOSE, HYDROLYZED WHEAT PROTEIN.
CONTAINS: POLLOCK, WHEAT, SOY, MILK.
DISTRIBUTED BY GORTON'S
GLOUCESTER, MA 01930
©2007 GORTON'S
Best If Used By June 2009

Gorton's Crispy Battered Fish Fillets prominently proclaims "0 grams trans fat" in a sunburst on the front of the package, but contains 4.5 g of saturated fat (23% of the Daily Value), an amount that the FDA considers to be "high."[8]

[8] The FDA considers products containing more than 4 grams of saturated fat per serving to be high in saturated fat and disqualifies such products from making health claims. 21 C.F.R. §101.14(a)(4). In addition, the FDA front-panel disclosure requirements for nutrient content claims are triggered by saturated fat content in excess of 4 grams. 21 C.F.R. § 101.13(h).

Hot Pockets Meatballs and Cheese with Sauce in a Crust emphasizes "0 g Trans Fat per serving," but that serving has 7 grams of saturated fat, 35% of the Daily Value (DV).

"0 g *trans* fat" claims on such products, often printed in large type, surrounded by banners, or followed by exclamation points, imply that the level of unhealthful fats is low and are deceptive in light of the products' saturated fat content.

Regulatory and Legislative Status

When the FDA issued its long-awaited final rule requiring the Nutrition Facts Panel to list the amount of *trans* fatty acids, it withdrew proposed regulations pertaining to nutrient content claims for *trans* fat and qualifying criteria for other claims that relate to it.[9] The FDA proceeded from the premise that because it was premature to develop a DV for *trans* fat, it could not establish a definition for "*trans* fat free," "reduced *trans* fat" and "reduced saturated fat and *trans* fat" nutrient content claims. Further, and inexplicably, the Agency claimed that it could not establish a limit for the permissible

[9] 68 Fed. Reg. at 41,434.

amount of *trans* fat in foods bearing nutrient content claims for saturated fat (as well as disqualifying levels for health claims and disclosure statements for nutrient content claims).

Instead, the Agency took a step backward. It issued an Advanced Notice of Proposed Rulemaking (ANPR), merely soliciting information and data that could be used to establish new nutrient content claims for *trans* fat; qualifying criteria for *trans* fat in existing nutrient content claims for saturated fat, cholesterol, lean and extra lean claims; and health claims that included messages about cholesterol-raising lipids. In addition, it sought comments on disclosure and disqualifying criteria to "help consumers make heart-healthy food choices." Finally, the FDA requested comments on whether it should consider statements about *trans* fat alone or in combination with saturated fat and cholesterol as a footnote to the Nutrition Facts Panel, or as a disclosure statement in conjunction with claims about how to use information about cholesterol-raising lipids to make healthy food choices.[10]

Ironically, the Agency had already prohibited nutrient content claims for "saturated fat free" unless a serving of the food contains less than 0.5 g of saturated fat and less than 0.5 g of *trans* fat per Reference Amounts Customarily Consumed (RACC) and per labeled serving. In contrast, disqualifying levels of *trans* fat are not included in FDA's regulations governing "low in saturated fat" or claims relating to cholesterol.[11] Rather than building on the Agency's precedents for saturated-fat claims, and completing its proposed rules for *trans* fat claims, the FDA said that it merely planned to "continue to evaluate the emerging science and revisit the need for" the proposed rules it had just withdrawn.[12]

Moreover, in the interim, the Agency signaled to the food industry that it would accept an "anything goes" policy. The FDA stated that it would consider requests for the exercise of its enforcement discretion to permit statements about the fat content of a product that are "demonstrably true, balanced, adequately substantiated and not misleading."[13] As of 2006, the FDA had not received any requests from companies for the Agency to exercise its enforcement discretion and permit such claims.[14] Yet, numerous manufacturers began making such claims, some of which were deceptive because the products, while no longer containing *trans* fats, were not low in saturated fat. Such steps by some companies mislead consumers and unfairly disadvantage honest competitors who actually reduced *trans* fats to 0g in their products and replaced them

[10] 68 Fed. Reg. 41507, 41509 (July 11, 2003).

[11] 21 C.F.R. § 101.62.(c) and (d).

[12] 68 Fed. Reg. at 41,509.

[13] *Id.*

[14] Letter from Barbara Schneeman, Dir. Office of Nutritional Products, Labeling, and Dietary Supplements, to Michael Jacobson, Exec. Dir. of CSPI (Apr. 14, 2006).

with more healthful fats. In brief, the FDA's bungling of the issue created marketplace chaos and an unlevel competitive playing field.

On March 14, 2006, the Center For Science in the Public Interest (CSPI) filed a complaint letter with the FDA concerning products that highlight "0 grams of *trans* fat" although they were not low in saturated fat. In an April 14, 2006, response, the FDA concluded that the claims identified by CSPI in its complaint letter (and illustrated in this report) do not characterize the level of *trans* fat, but are merely "factual statement[s]" about the amount or a percent of a nutrient in a product and are permissible under FDA rules codified at 21 CFR 101.13(i)(3).

Nothing could be further from the truth. The "0"*trans* fat claims illustrated here, surrounded by banners, exclamation points, and sunbursts clearly indicate a low level of *trans* fat and imply that the food is heart-healthy. The FDA has grossly mischaracterized these embellished "0" *trans* fat proclamations as mere statements of fact about the amount of a nutrient. The Agency should recognize them for what they are, blatantly deceptive, unapproved implied nutrient content claims.

Furthermore, the exemption that Congress made for simple statements of fact about the amount of a nutrient is limited. Congress instructed the FDA to only "permit statements describing the amount and percentage of nutrients in food *which are not misleading* and are *consistent with the terms defined* in section 403(r)(2)(A)(i)."[15] Statements like "0 trans fat!" are misleading. In addition, they are not consistent with the terms defined in section 403(r)(2)(A)(i). Thus, FDA erred by relying on the narrow exemption set out by Congress to deny CSPI's complaint. [16]

Recommendations

The FDA's conclusion that "0 *trans* fat claims" highlighted by banners, large type, and exclamation points are merely factual statements of the amount of a nutrient is plainly wrong. Rather, such statements clearly constitute implied nutrition claims that have not been approved by the Agency. The FDA should recognize that such claims made on the labels of products that are not low in saturated fat are misleading. To remedy this problem, the FDA should:

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[15] Pub. L. No. 101-535, 21 U.S.C. 343 note (b) regulations (1)(A)(iv), 101 STAT. 2361(emphasis added).

[16] The FDA also erred because Section 403(r)(1) of the Act only exempts statements of nutrient amounts from nutrient content claim requirements if the statement appears in the Nutrition Facts Panel. The legislative history of the Act explains that statements like "0 trans fat" (which appear on the Nutrition Facts Panel) are not exempt from FDA's nutrient content claim requirements if they appear elsewhere on the package of the product." H. Rep. No. 101-538 (101st Cong. 2d Sess.) at 19 (June 13, 1990).

- Review its enforcement policy and promptly issue an industry-wide warning letter stating that products that emphasize "0 *trans* fat" on the front panel when such foods contain per serving more than 5% of the DV for saturated fat (i.e., are not "low" in saturated fat and cholesterol are in violation of the law. Simultaneously, the Agency should send warning letters to manufacturers of products that are making "0g *trans* fat" claims on products that are not low in saturated fat.

- The FDA should propose rules setting forth conditions for making nutrient content (and health) claims for products low in *trans* fats that are based on existing rules for claims for products that are "low saturated fat." Such rules should ban "0" or "no" or "low" *trans* fat claims (and health claims), unless a serving of the food is also low in saturated fat and cholesterol.

- The FDA immediately should revoke the Generally Recognized as Safe (GRAS) status of partially hydrogenated oils, as requested in our 2004 petition. Partially hydrogenated oils are unnecessary, as evidenced by industry's gradual abandonment of them in favor of less-harmful oils. Eliminating the use of partially hydrogenated oil would mitigate the need for all of the activities in which the FDA is currently engaged regarding the labeling of *trans* fat.

Part IX

Misleading Ingredient Claims

The Problem

Health experts have advised consumers to increase their consumption of fruits, vegetables, and whole grains.[1] It is no surprise, therefore, that the supermarket is filled with package labels claiming that a food is "made with" whole grains, fruits, or vegetables, or that emphasize the presence of such healthful ingredients through the use of pictures, banners, or other techniques.

While the law requires companies to comply with specific FDA regulations for claims about *nutrients* such as fats, cholesterol, sodium, fiber, vitamins, and minerals, [2] the law does not cover claims about *ingredients*, such as whole wheat, spinach, broccoli, oranges, or strawberries.

In addition, while the FDA has the authority,[3] the Agency does not generally require companies to disclose the percentage of characterizing ingredients in a food (Congress required in 1990 that the percentage of actual fruit or vegetable juice in diluted juice drinks be disclosed "with appropriate prominence on the information panel" (where Nutrition Facts information appears).[4]

As a result, consumers can easily be deceived by labels that claim "made with whole wheat" or that depict real fruit, implying that the product contains substantial quantities of those ingredients. While ingredients must be listed in order of predominance[5] elsewhere on the label,[6] ingredient lists are sometimes difficult to read, as

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[1] *See* HHS, USDA *Dietary Guidelines for Americans 2005,* at 23-24.

[2] For example, products that contain 10 to 19% of the daily value for a particular vitamin or mineral can claim to be "good" sources of that nutrient. Products that contain 20% or more of the Daily Value for fiber can claim to be an "excellent source" of that substance 21 C.F.R. § 101.54.

[3] 21 C.F.R. § 102.5.

[4] Pub. L. 101-535 NLEA § 7(2); codified at FDCA § 403(i)(2), 21 U.S.C. § 343(i)(2).

[5] 21 C.F.R. § 101.4.

[6] Williams v. Gerber Products Co., 523 F.3d 934 (9th Cir. 2008). "We do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations and provide a shield for liability for the deception." *Id*. at 940.

discussed in greater detail in Part IV. Moreover, it is often not possible to determine the amount of an ingredient in a product simply by noting its position on the ingredient list.

A. Misleading Ingredient Claims for Whole Grains

The Dietary Guidelines for Americans *a*nd the USDA's Food Pyramid recommend that consumers "make half your grains whole."[7] This means that when consumers eat grain foods ranging from bread to pizza, they should try to choose 100% whole grains or products in which at least 50% of the grain content consists of whole grains. Numerous manufacturers try to exploit consumers' interest in eating more whole grain by making claims that misleadingly imply that their products are rich in whole grains when they primarily consist of ordinary refined wheat flour.

For example, the label of Thomas' Hearty Grains English Muffins states "made with whole grains" and "made with the goodness of whole grain." The first (primary) ingredient, however, is "Unbleached enriched wheat flour." While that may sound healthful, it is not whole grain. Whole wheat flour is the third ingredient, indicating that the product contains relatively little. The name of the product," Hearty Grains" and the dark brown color of the wrapper adds to the confusion.

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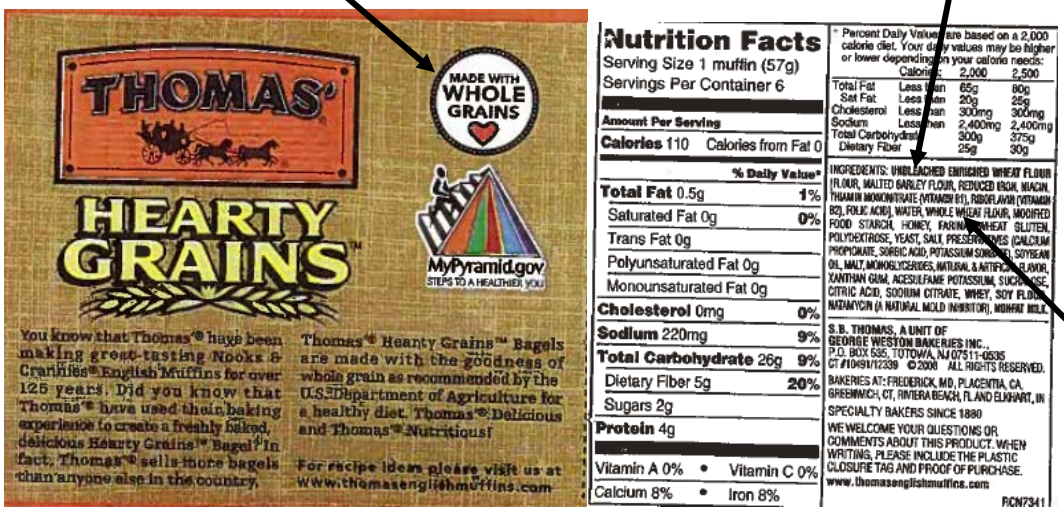
[7] *Dietary Guidelines for Americans*, *supra* note 1 at 36 ("Consuming at least half the recommended grains servings as whole grains is important for all ages, at each calorie level, to meet the fiber recommendation.").

This statement, in conjunction with the heart and the My Pyramid logo, implies that the product contains a significant amount of whole grains.

The first ingredient, listed as "Unbleached enriched wheat flour," sounds healthful but is not whole wheat.

Consumers have to be "label detectives" to find the whole wheat flour in this products' ingredient list.



Although the label says "made with whole grains," the primary ingredient is ordinary white flour. There is more water in the product than whole grain.

Another example is Keebler's Zesta saltine crackers, which proclaims "Made with Whole Wheat." Again, whole wheat flour appears as the third item—just before salt—in the ingredient list. Caramel coloring is used to darken the crackers and simulate the use of whole wheat flour. The label emphasizes the dark color of the crackers because consumers often associate darker-colored baked products with high whole wheat content.[8] The primary ingredient, however, is ordinary refined flour.

[8] *See* FDA, USDA, Eating healthier and feeling better using the Nutrition Facts Label (Aug. 2006) ("Whole grain foods can't always be identified by color. . . .") *Id.*

The label of Zesta saltine crackers proclaims "Made with Whole Wheat" on the front of the box, but the primary ingredient is ordinary flour.

Keebler's Town House Bistro "Multigrain" crackers claim to be made with "hearty ingredients like toasted whole wheat" but are primarily made with ordinary refined wheat flour.

The label of Keebler's Town House Multigrain Crackers boasts on the side of the package that they are made with "toasted whole wheat," but the small print in the ingredient list indicates that the product contains more sugar than whole wheat.

Regulatory and Legislative Status

Some companies have recognized the need for a new regulatory framework. General Mills petitioned the FDA in 2004 to develop definitions for "excellent source," "good source," and "made with" as descriptors for the whole grain content of foods.[9]

[9] Whole Grain Descriptive Claims Citizen Petition Submitted on Behalf of General Mills, Inc. (May 11, 2004 (Docket No. 2004P-0223/CP1).

FDA denied the petition in 2005 on the basis that it needed to assess whether whole grain claims are implied nutrient content claims for fiber and whether such claims should be classified as dietary guidance, nutrient content claims, or health claims before it could reach a decision.[10]

In 2006, the FDA issued a draft guidance permitting companies to disclose whole grain content as the number of grams of whole grains per serving.[11] The Agency said statements such as "10 grams of whole grains" are permissible "factual statements" provided that they are not misleading and do not imply that the food is high in whole grains.[12] FDA's draft guidance discourages companies from making some misleading claims, like "excellent source" of whole grain (on foods that are not excellent sources), but does not address problems such as "made with whole grain" claims that are misleading. Nor does it acknowledge that claims like "Contains 10 grams of whole grain" imply large amounts or high percentages of whole grains and are deceptive for products that contain significant amounts of refined grains.

The USDA's policy is also flawed. The USDA permits statements such as "made with whole wheat," so long as the product contains 8 grams of whole wheat and does not specifically identify the component (e.g. crust, noodles, etc.) that is made with whole wheat. For example, a product such as a pot pie would be permitted to state "made with whole grain" even if the crust was primarily made from refined grains. Like the FDA, the USDA does not acknowledge that such a claim may imply that the amount of whole grains as a percentage of total grains in the product is greater than may actually be case. However, under USDA policy, if a product characterizes the grain in a component, for example, "made with whole grain pie crust,"[13] at least 51% of the grain component must be whole grain and the product must contain a significant amount (8 g) of whole grain as well."[14] Thus, under the USDA's approach, a chicken pot pie with a "whole grain crust" would need to consist of 51% whole grains (and contain a significant amount of whole grains per serving), while a vegetable pot pie under FDA jurisdiction could state

[10] Letter from Margaret O'K Glavin Associate Comm'r for Regulatory Affairs, FDA to Stuart M. Pape, Patton Boggs, LLP Re Docket No. 2004P-0223/CP1) (Nov. 8, 2005).

[11] FDA, *Draft Guidance: Whole Grain Label Statements, Guidance for Industry and FDA Staff* (Feb. 17, 2006), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059088.htm.

[12] FDA cited 21 C. F.R. § 101.13(i)(3) which governs claims about nutrient content.

[13] USDA, *Food Safety and Inspection Service (FSIS) Statement of Interim Policy Guidance, Use of the USDA MyPyramid Reference on Meat and Poultry Labeling and Whole Grains Claims* (Oct. 17, 2005).

[14] USDA indicated that a significant amount of whole grain would be at least a one-half ounce equivalent of whole grain ingredient, i.e., at least 8 grams of dry whole grain ingredient, but that is not the sole criterion for a claim. Whole grains must also comprise at least 51% of the grain content of the product.

the number of grams of whole grain per serving even if the percentage or amount of whole grains were small.[15]

Federal policies that permit disclosures such as "10 grams of whole grain per serving" do not help consumers follow the Dietary Guidelines' advice to "make half your grains whole." That advice encourages consumers to eat a minimum *proportion* of their grains as whole grains. Without knowing how many grams of refined grain are in a food that claims to contain X grams of whole grain, consumers cannot determine whether half or more of the grains are whole.[16]

Disclosures such as "10 grams of whole grain" also make it difficult to compare foods because the total grain content of foods varies so widely. For example, 10 grams of whole grain could be 60% of the grain in a slice of bread, but only about 33% of the grain in a breakfast cereal with a 30-gram serving size or only about 18% of a two-ounce serving of pasta. Even when consumers try to compare one cereal to another, they likely will have trouble sizing up a claim such as "10 grams of whole grain," because 10 grams could comprise 33% of the grain in a breakfast cereal with a 30-gram serving size but just 18 percent of the grain in a breakfast cereal with a 57-gram serving size.

For foods that contain both whole and refined grains, consumers cannot figure out how the whole grain content compares to the refined grain content of the food, though the ingredient label provides some help. Without that information, people trying to consume more whole grains might unwittingly consume excess refined grain in a misguided effort to consume more whole grains.[17]

The Whole Grains Council has developed a "stamp" of approval for products that contain at least 8 grams of whole grain and another for those that are 100% whole grain.[18] But the stamp for products that are less than 100% whole grain may be

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[15] The FDA and the USDA need to coordinate their policies to avoid absurd results. For example, a whole grain pizza crust would be required to be 100% whole grain under the FDA's *Guidance*, but only 51% of the grains would need to be whole for a pepperoni pizza with a whole grain crust that is regulated by the USDA.

[16] The *Dietary Guidelines* also recommends that consumers eat at least 3 servings of whole grains a day. However, that advice was designed to give consumers a rule of thumb regarding the number of servings of whole grains that they should consume. It is less applicable than the advice to "make half your grains whole" because some people consume more – and others fewer – than 6 servings of grain a day. Urging people to consume at least 3 servings of whole grains could mislead people to assume that more is always better. In fact, encouraging people to consume more calories than they should from grains, whole or refined, could promote weight gain.

[17] The FDA's draft *Guidance* also fails to help people follow the *Dietary Guidelines*' advice to consume at least 3 servings of whole grains a day because the disclosures use grams rather than servings. There is no easy way to convert grams into servings because the amount of grain in a serving varies from food to food.

[18] On Jan. 5, 2005, the Whole Grains Council introduced stamps including the words "good source" and "excellent source." Presentation by Cynthia Harriman, Dir. of Food and Nutrition Strategies Oldways & the Whole Grains Council at the Food and Drug Law Institute (Oct. 31, 2006).

misleading because it does not indicate what percentage of the grain in a product is whole. Eight grams might imply that a product is rich in whole grains, but, as noted above, such a product might be only 18% whole grain. Any whole grain disclosure is misleading if it fails to also reveal the refined grain content of the food. FDA should consider that an omission of material fact.

The stamp on the left may be misleading because it does not indicate the percentage of whole grain in the product.

The stamp on the left can also be misleading because the Whole Grains Council permits its logo to be used on products with considerable amounts of saturated or *trans* fat and sugar, such as cookies so long as the products contain 8 grams of whole grain per labeled serving.[19]

In October 2009, The National Academy of Sciences' Institute of Medicine (IOM) released recommendations for school lunches that urged FDA to "take action to require labeling for the whole grain content of food products." IOM explained that "[t]he lack of such labeling is a major barrier to menu planners who are striving to achieve a one-to-one ratio of whole grains to refined grains, as recommended by Dietary Guidelines."[20] The IOM recommended a "temporary criterion for whole-grain-rich foods.[21] One of these criteria is that a serving of a food contain 8g of whole grain. The Whole Wheat Council portrayed that as tantamount to an endorsement of its program.[22]

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[19] Whole Grains Council, *Stamp FAQ* – Manufacturers *available at* http://www.wholegrainscouncil.com/node/31/print.

[20] Virginia A. Stallings et. al., ed., IOM, *School Meals: Building Blocks for Healthy Children.* Recommendation 6, S-1.(2009).

[21] IOM stated that at least *one* of the following conditions must be met:

- the whole grains per serving must be greater than or equal to 8 grams;
- The product bears the FDA-approved health claim for whole grain: "Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol may help reduce the risk of heart disease." The FDA requires that such foods contain 51% whole grain by weight, but does not require that 51% of the of the grain in the product be whole. The two measurements are different.
- Products must list whole grains first in the ingredient list.

But the IOM admitted that such a temporary criterion would likely result in a whole grain intake that is lower than that recommended by the Dietary Guidelines. It said it was not reasonable to set more stringent standards at this time, for a variety of reasons, including the "limited information on product packaging regarding the whole grain content of food products."[23]

Recommendations

Presently**,** consumers have no effective way to determine whether a product can help them "make at least half of their grains whole," because labels do not disclose both whole grain and refined grain content. Ingredient lists are confusing and difficult to read – in many cases, the only way to determine that a product is primarily whole grain is if the label states "100% whole grain" or if the only grain ingredients are whole grains. But FDA regulations allow manufacturers to list ordinary flour, which is often the first ingredient in breads, crackers, muffins, etc., as "Enriched flour (wheat flour)." That declaration may sound very similar to some consumers as a declaration akin to whole wheat.

To prevent deceptive whole-grains claims, the FDA should:

- Withdraw the portions of its 2006 "draft guidance" document dealing with whole grain claims;

- FDA and USDA should propose regulations requiring that the amount of whole grain (as a percentage of total grain) be disclosed conspicuously at the top of the Nutrition Facts Panel;

- FDA and USDA should require that the percentage of whole grains be disclosed prominently in immediate conjunction with any statements mentioning whole grains on the front, back, or side labels of the product.

- Both agencies should issue a new industry-guidance document stating that statements such as "8g of whole wheat per serving" impermissibly imply that a product is rich in whole wheat and are misleading because they fail to disclose the percentage of grains that are whole.

Id. at 7-13, 7-14.

[22] *IOM Calls for Whole Grain Labeling,* The Gourmet Retailer,Oct. 30, 2009, *available at* http://www.gourmetretailer/content_display/news/elece59e59 (last visited Nov. 19, 2009).

[23] *IOM Report, supra* note 20 at 10-18.

B. *Misleading Ingredient Claims for Fruits and Vegetables*

Similar to whole-grain deceptions, some food manufacturers exploit consumers' interest in eating more fruits and vegetables through the use of misleading statements and pictures on product labels. Some labels depicting healthful fruits and vegetables can create the misperception that the product contains more fruits and vegetables than is actually the case.

For example, the label of Gerber Fruit Juice Treats for Preschoolers bears pictures of fresh oranges, raspberries, cherries, peaches, grapes, and pineapple. The product, however, contains no cherry, orange, or pineapple juice, and less than 2% raspberry and apple juice concentrates (although no apples are pictured) and peach juice — and is colored with annatto extract and elderberry juice to help create the impression of greater abundance of actual fruit. The primary ingredients, listed in small print in capital letters, are corn syrup and sugar. The Dietary Guidelines for Americans considers juice concentrates to be a form of added sugars.[24] A single one-ounce serving of the Fruit Juice Treats provides 17 grams of added sugars (approximately 4 teaspoons), almost the maximum amount a 2- to-3-year-old preschooler should have in an entire day.

[24] *Dietary Guidelines supra* note 1 at 38 Table 14. The *Dietary Guidelines* suggest that children 2-3 years old consuming a 1000-calorie diet have no more than 20 g (5 teaspoons) of added sugars. *Id.* at 55.

Gerber Fruit Juice Treats do not contain juice from most of the fruits pictured on the front and back of the package. But they are loaded with added sugars.

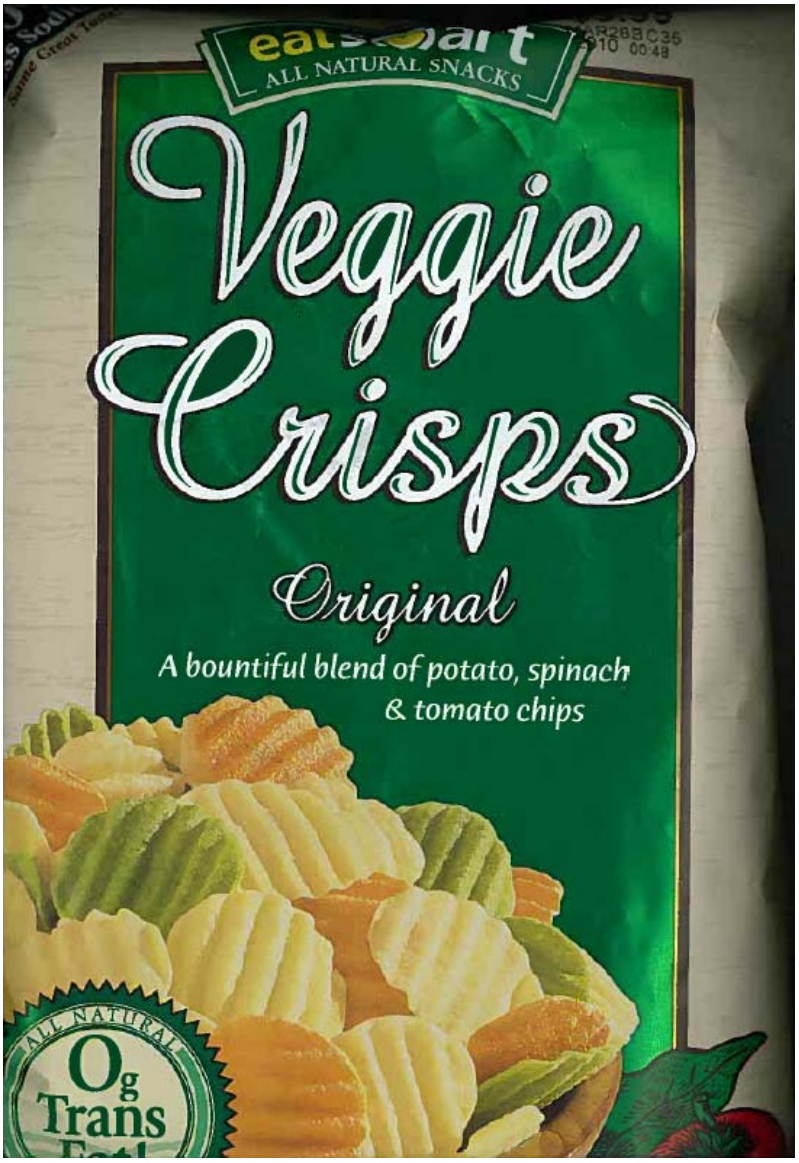
Similarly, Betty Crocker "Strawberry Splash Fruit Gushers" claim on the side label to be "Made with REAL FRUIT." The product however, contains no strawberries at all. The "REAL FRUIT" promoted on the side of the label turns out not to be real strawberries, but pears from concentrate. The product is almost half sugar containing 12 g of sugars per 25 g serving. In addition, the "strawberry" color comes from Red No. 40 dye.

Betty Crocker "Strawberry" Fruit Gushers claim to be "Made with REAL FRUIT" but do not contain any strawberries. Rather, the ingredient panel lists pears from concentrate and lots of refined sugars from a variety of sources.

Some manufacturers also misleadingly portray the amount of vegetables in their products. For instance, Knorr Chicken Broccoli fettuccini noodles contains more salt than dried broccoli despite the fact that the term "broccoli" is highlighted in large letters on a prominent banner on the front label.

The label of Knorr Chicken flavor Broccoli Fettuccini & Broccoli in a Chicken Flavored Sauce gives the impression that broccoli is a major ingredient. The product, however, has more salt than dried broccoli.

Snyder's of Hanover "Eat Smart Veggie Crisps" is described on the front of the package as "A bountiful blend of potato, spinach and tomato chips." The product, however, contains more potassium chloride than spinach and practically none of the vitamins and minerals found in spinach or tomatoes.



The front label of Snyder's of Hanover "Eat Smart Veggie Crisps" misleadingly portrays the product as a healthful potato chip.

The back of the Veggie Crisps label promises that consumers of the product will "enjoy the simple goodness of garden fresh vegetables."

Regulatory and Legislative Status

The FDA has the authority to halt deceptive fruit/vegetable labeling, including the authority to impose percentage-ingredient labeling for fruits, vegetables, and other key ingredients[25] for most foods—but it has failed to do so. The Agency's "common or usual name" regulations require manufacturers to include the percentage of any characterizing ingredient or component when the proportion of that substance "has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case."[26] But few manufacturers follow that general principle, and the FDA has only issued regulations to implement it in three cases.[27]

In contrast, the European Union (EU), Australia, New Zealand and even Thailand have taken much broader measures. Those countries generally require the disclosure of the percentage of key ingredients contained in a particular food.

In the EU, such disclosures are referred to as Quantitative Ingredient Declarations (QUID).[28] The EU's 1997 directive requires QUID "where the ingredient or category of ingredients concerned appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer."[29] For example, the amount of strawberries in "strawberry yogurt" and the amount of vegetables in "spring rolls" must be disclosed.[30]

The following example illustrates the importance of such disclosures for consumers trying to increase their consumption of fruit, vegetables, and other healthful

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[25] Standardized foods such as cheese and flour must comply with FDA content regulations that specify the amount of required ingredients and set forth permissible optional ingredients. E.g., 21 C.F.R. §§ 133.102 137.105.

[26] 21 C.F.R. § 102.5.

[27] The FDA requires that peanut spreads indicate the percentage of peanuts in the spread; olive oil blends indicate the percentage of olive oil; and seafood cocktail include the percentage of seafood ingredients present in the cocktail. 21C.F.R. §§ 102.23, 102.37 and 102.54.

[28] *See* Directive 97/4/EC of the European Parliament and of the Council amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs, art. 1 (Jan. 27, 1997).

[29] *Id.* at art. 7(2)(a).

[30] Ministry of Agriculture, Fisheries and Food, *Draft Guidance Notes*, July 1997, United Kingdom, §§ 13 & 15. The guidance notes are for purposes of providing informal, non-statutory guidance on QUID and should not be taken as an authoritative statement or interpretation of the law.

ingredients. The can of chopped tomatoes actually contains more tomatoes than the can of whole tomatoes. Consumers in the EU are provided that information while consumers of similar products in the US are kept in the dark.

Both products have tomatoes and water as the leading ingredients. An American consumer would have no way of knowing which product contains a higher percentage of tomatoes. In the EU, however, percentage-ingredient labeling reveals that the can of chopped tomatoes actually has more tomatoes (70%) than the can of whole peeled tomatoes (60%).

The EU also requires QUID "where the ingredient or category of ingredients concerned is emphasized on the labeling in words, pictures or graphics."[31] For example, if a package like Gerber Juice Treats features pictures of raspberries on the label, the amount of that ingredient must be disclosed.

In the EU the quantity of an ingredient must be stated "where the ingredient or category of ingredients concerned is essential to characterize a foodstuff and to distinguish it from products with which it might be confused because of its name or appearance."[32]

[31] Directive 97/4/EC at Article 7(2)(b).

[32] Directive 97/4/EC at Article 7(2)(c).

The EU directive requires that the percentages of key ingredients "shall appear either in or immediately next to the name under which the foodstuff is sold or in the list of ingredients in connection with the ingredient or category of ingredients in question."[33]

It should be emphasized that information about the percentage of valuable or characterizing ingredients is not provided by the Nutrition Facts Panel. That panel provides information on *nutrients*, such as calories, sodium, fats, vitamins, and mineral content, but in many cases only a trained dietitian could analyze that data to determine whether one product has substantially more fruits, vegetables, or other healthful ingredients than another. Furthermore, the ingredients panel lists ingredients in order of predominance, but the average consumer (and most nutritionists) cannot translate that order into percentages of ingredients. Thus, percentage-ingredient labeling is necessary to both prevent deception and help consumers choose more healthful foods.

[33] *Id*. at art. 7(5).

Here is another example of the usefulness of QUID requirements:

US.

EU

European consumers can determine that Kellogg's Nutri-Grain Twists "Strawberries & Crème" flavor contains only 5% apples (no strawberries), but consumers of similar Kellogg products, like Nutri-grain Bars, sold in the U.S. are left guessing about the actual amount of fruit (of any type) in the product.

Recommendations

- The FDA should require that the percent by weight of key ingredients that bear on health such as fruits or vegetables be disclosed on the principal display panel in conjunction with any claim or in parentheses after the listing of the relevant ingredient in the ingredient declaration.

- Products stating made with whole grains should disclose what percent of total grains are whole.

- "Key ingredients" should be considered to include those mentioned in the name of the food, or emphasized on the label by words, pictures, or graphics.

- The FDA should coordinate its policy with the USDA so as to include meat or poultry products, including stews and pot pies.

Part X

Controlling Misleading "Natural" Claims

The Problem

The United States market for "natural" foods grew by 10% to $12.9 billion from 2007 to 2008 and "All Natural" was the second-most-common claim on new food products launched in 2008.[1] Products claiming to be natural, particularly those aimed at parents of young children, have a competitive edge in the marketplace, according to recent trade reports.[2]

Some consumers may interpret claims such as "All Natural" or "100% Natural" as indicating a more nutritious or wholesome food product, than is actually the case. Thus, while not an explicit health or nutrient-content claim, "natural" claims are worthy of the Food and Drug Administration's (FDA) and the United States Department of Agriculture's (USDA) attention as part of a comprehensive program to improve food labeling and protect consumers from deceptive marketers.

The FDA and the USDA regulate the term "natural" differently. The USDA has had a formal enforcement policy since 1982 and approves each label individually prior to marketing. Recently, it issued an Advance Notice of Proposed Rulemaking (ANPR) to clarify this complicated issue. The FDA has sent a number of warning letters to companies over the years, but has never issued formal rules on the matter and takes enforcement action only after the fact. Unfortunately, both agencies have allowed deceptive claims to remain in the marketplace.

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[1] Monica Eng, *Organic v. natural a source of confusion in food labeling,* Chi. Trib. July 10, 2009, *available at* www.chicagotribune.com/health/chi-natural-foods-10-jul10,0,834771.story.

[2] According to a recent trade report, *Marketing Kids' Healthy Beverages*: "Across all food categories, the message that a food or food component is naturally and intrinsically healthy is one of the most appealing to consumers . . . ." Report is available from New Nutrition Business at www.new--nutrition.com. Health conscious parents increasingly choose such products for their children. *See,* Mike Stones, *Big growth forecast for US children's healthy drinks market,* food navigator-usa.com (Sept. 24, 2009) quoting Julian Mellentin.

A. FDA

For example, Hunt's, a division of ConAgra Foods, markets its tomato sauce as "100% Natural," despite the fact that it contains added citric acid. As indicated by FDA warning letters, the Agency does not consider citric acid an appropriate ingredient for a food labeled as "All Natural.[3] Further, the product consists of reconstituted tomato paste, instead of whole tomatoes crushed soon after picking.

The claim "packed full of premium vine-ripened tomatoes, in conjunction with the "100% Natural" claim on the front of the label is misleading because the product comes from concentrate.

Hunt's Tomato Sauce claims to be "100% natural" but contains citric acid and is reconstituted [4]

"All Natural" Snapple Tea includes citric acid and is not "natural" under FDA policy. The FDA sent a warning letter in 1992, but the owners of the company today appear to have ignored or are not aware of that warning. The letter stated "The term "all natural" is false or misleading on product containing the added chemical preservatives, ascorbic acid, *or added citric acid*," (emphasis added).[5]

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[3] *See, e.g.*, Warning letter from Henry Fielden, Dist. Dir. Cinn., FDA to Karl A. Hirzel, Hirzel Canning Co. (Aug. 29, 2001). *See also infra*, note X-13.

[4] The Council of Better Business Bureaus National Advertising Division (NAD) found that an earlier version of the claim shown above, "packed full of Hunt's 100% natural vine-ripened tomatoes," should be discontinued because consumers would reasonably take away the impression that the final tomato sauce was made directly from vine-ripened tomatoes, rather than pre-processed tomato puree (i.e., tomato paste and water) as is the case. NAD, Con Agra Foods Hunt's Tomato Sauce, Case No. 4945 (Dec. 8, 2008).

[5] Letter from Edward T. Warner, Dist. Dir. N.Y., FDA to Mr. Leonard March, Chairman of the Board Snapple Natural Beverage Co. (Mar. 9, 1992).

This so-called "All Natural" product contains citric acid.

Products containing citric acid are not "All Natural" according to the FDA.

Some products containing high-fructose corn syrup also claim to be natural. High-fructose corn syrup is made through a complex chemical industrial process in which cornstarch molecules are chemically or enzymatically degraded to glucose and oligosaccharides, and then some of the glucose molecules are converted to fructose. Though glucose and fructose certainly occur in nature, the chemical conversions of cornstarch should not be considered natural.

Thus, Minute Maid "All Natural" Cranberry Apple Juice Cocktail is actually not all natural because it contains high-fructose corn syrup, as well as citric acid.[6]

[6] *See infra* notes X-12-22, and accompanying text for a discussion of the FDA's policy on whether foods containing high fructose corn syrup can be labeled "All Natural."

Minute Maid should not call its beverage all natural: it contains high-fructose corn syrup and citric acid.

Some products should not be called natural because they are artificially colored. For example, Snapple's kiwi strawberry juice drink contains vegetable juice concentrate as a coloring agent. FDA has concluded that the term natural may not be used if a product uses color additives of any type.[7] In this case, a consumer would reasonably assume that the color of the drink comes from its strawberry and kiwi ingredients, not added coloring. The drink also contains citric acid, another violation of FDA policy, assuming that that additive is factory-made.

[7] For example, when beet juice is used to color pink lemonade, it is a color additive, and the product cannot be labeled as "all natural." 21 C.F.R. §70.3(f).

The product is called "All Natural" but it is colored with vegetable juice concentrate and contains citric acid.

Other products may not expressly state "All Natural," but imply that they are natural when they are not. Minute Maid Premium Original 100% Pure Squeezed Orange Juice boasts in large type on the side of the label that it has "natural orange goodness," "natural goodness," and is "naturally delicious." Only in small print on the front does the company admit that the juice is made "From Concentrate."[8]

[8] Natural Claims can be implied less directly as well. Consumers, for example, may assume that a shelf of fresh fruit or vegetables in the produce section of the supermarket is all natural, but often the produce is coated with waxes to prevent moisture loss during shipment and storage or treated with fungicides. The FDA has previously recognized this issue, and requires disclosures, but the policy rarely appears to be enforced. FDA, *Produce Safety, Safe Handling of Raw Produce and Fresh-Squeezed Fruit and Vegetable Juices* 11, *available at* http://www.fda.gov/food/resourcesforyou/consumers/ucm114299.htm (last visited Dec. 4, 2009).

Minute Maid Premium Original 100% Pure Squeezed Orange Juice discloses in small print on the front of the package that it is made "from concentrate" but loads the side label with claims of "natural goodness."

B. USDA

While the USDA has defined the term "natural,"[9] it has made case-by-case exceptions to its general policy resulting in various problems. For example, the use of the term "natural" on poultry products sometimes has been used in a misleading manner. Hormel's "Natural Choice 100% Natural Deli Turkey" lists the following ingredients: turkey breast meat, water, salt, turbinado sugar, carageenan (from seaweed), baking soda, natural flavoring and lactic acid starter culture (not from milk)." That kind of highly processed product barely resembles the natural turkey that a consumer would cook and slice at home.

Although this product claims to be "100% Natural" and minimally processed, in fact, it contains ingredients, such as carrageenan (extracted from seaweed), baking soda, and lactic acid starter culture, not normally found in roast turkey prepared at home.

[9] USDA generally considers a product to be natural if (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 C.F.R. §101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed. Food Safety and Inspection Service, USDA, *Food Standards & Labeling Policy Book* (Aug. 2005).

The USDA also permits other poultry and meat products to be labeled "100% or All Natural" even if they contain added chicken or beef broth which can raise the water and sodium content of the product to decidedly unnatural levels. So-called "enhanced" poultry or beef products are flavored with a watery and usually salty marinade or injection and should not be considered "100% Natural." The added water content deceptively inflates the weight of the product and can lead consumers to pay a premium for water.[10] Further, the added sodium makes the product less healthful than truly natural poultry, because excess sodium increases blood pressure and the risk of heart attack or stroke.[11]

Some products, such as Tyson's 100% All Natural Chicken Wing Sections, contain up to 12% chicken broth, or, as the label states "up to 12% Natural Chicken Broth."

[10] Current USDA policy permits the net weight of poultry to include "solutions that are added to the meat or poultry, or into which the meat or poultry is placed for flavoring, seasoning and tenderizing. . . " Letter from Robert C. Post, Ph.D. Director, Labeling and Consumer Protection Staff, USDA to Steven B. Steinborn, Hogan & Hartson LLP (Mar. 24, 2006).

[11] USDA, HHS, *Dietary Guidelines for Americans 2005* at Ch. 8 , *available at http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter8.htm.*

USDA permitted Tyson to label this product "100% All Natural" even though it contains up to 12% chicken broth which increases the sodium content of the food and inflates the net weight. Other brands have as much as 15% added broth.

Safeway brand boneless/skinless chicken thighs and breasts have 330 mg of sodium per/100g and Shady Brook Farms young turkey breast with broth contains 304 mg of sodium per 100g. Both products contain up to 15% added broth.

Regulatory and Legislative Status

A. FDA

Although use of the term "natural" has been a hot topic since the 1970s, FDA has never issued a comprehensive definition of the term for processed foods. Its longstanding policy is that:

> [N]atural means that nothing artificial (including artificial flavors) or synthetic (including all color additives regardless of source) has been included in or has been added to a food that would not normally be expected to be in the food. Additionally, . . .we do not restrict the use of the term "natural" except on products that contain added color, synthetic substances and flavors as provided for in Title 21 of the Code of Federal Regulations (CFR), section 101.22.[12]

Over the years, FDA has issued warning letters declaring that use of the term "all natural" is inappropriate if the product contains citric acid, calcium chloride, ascorbic acid, or potassium sorbate.[13] In addition, a 1940 letter from FDA to a food producer indicates that at least at that time the term should not be used "for canned grapefruit juice subjected to the usual heat treatment." The Agency indicated that "this term should be reserved for fresh juice or juice which has been kept without intervention of any process of heat treatment."[14]

Over the years, the FDA has considered adopting a more comprehensive policy regarding the regulation of "natural" claims, but never moved forward:[15]

- In 1991, FDA requested comments on how natural should be defined.[16]
- In 1993, FDA concluded that "if the term 'natural' is adequately defined, the ambiguity surrounding use of this

[12] Letter from Geraldine A. June, Supervisor Product Evaluation and Labeling Team, Food Labeling and Standards Staff, Office of Nutrition, Labeling and Dietary Supplements, FDA, to Audrae Erickson, President, Corn Refiners Assoc. (July 3, 2008).

[13] E.g., Warning Letter to Hirzel Canning Co., *supra* note 3 (Chopped tomato products not natural because products contain calcium chloride and citric acid); Warning letter from Robert L. Hart, Acting Dist. Dir. N.Y., FDA to Richard Classey, Oak Tree Dairy Farm (Aug. 16, 2001)(Oaktree All Natural Lemonade misbranded because it contains potassium sorbate; All Natural Oaktree Real Brewed Ice Tea misbranded because it contains citric acid); Warning letter to Thomas E. Nieman, Federal Foods, Inc. from John Feldman, District Director Minneapolis Dist. FDA (Aug. 12, 1994) (Cat food misbranded because ascorbic acid is not natural. Citric acid is a chemical preservative).

[14] FDA, TC-142—March 7, 1940, *reprinted in* Kleinfeld, Dunn and Kaplan, *Federal Food, Drug and Cosmetic Act* 624 (1978).

[15] In contrast, the government of Canada has developed a comprehensive policy on natural claims for both labelling and advertising. *See* Health Canada's Guide to Food Labelling and Advertising which offers numerous examples of processes that disqualify a food from making a "natural" claim. http://www.inspection.gc.ca/english/fssa/labeti/guide/ch4ae.shtml (last visited Dec. 9, 2009).

[16] 56 Fed. Reg. 60421, 60466-67 (Nov. 27, 1991).

term that results in misleading claims could be abated."[17] Nevertheless, because of the complexity of the issue, resource limitations, and other Agency priorities, the FDA did not undertake a rulemaking at that time.[18]

- In 2004, FDA rejected a petition asking FDA to clarify the use of the term "100% Natural" because of concerns that manufacturers were using "big letters" to promote products as 100% natural when those products contained artificial partially hydrogenated oils associated with cardiovascular disease. In denying that petition, FDA said that the petitioner did not provide any information that FDA had not already reviewed in 1993.[19]
- "Natural" claims are not even an enforcement priority during establishment inspections.[20]

FDA recently added confusion to the use of the term "natural" with respect to high-fructose corn syrup. In a 2008 letter to the Corn Refiners Association, FDA stated that a product containing high-fructose corn syrup may be labeled natural when "none of the fixing agent (glutaraldehyde) would come in contact with the high dextrose equivalent corn starch hydrolysate."[21] But FDA confused matters when it also stated that the Agency would make determinations on a case-by-case basis, as opposed to adopting a consistent, uniform policy. The FDA said:

> Consistent with our policy on the use of the term "natural," we have stated in the past that the determination of whether an ingredient would qualify for use of the term "natural" is done on a case-by-case basis. Further, ingredients with the same common or usual name may be formulated in different ways, where a food containing the ingredient formulated one way may qualify for the use of the term "natural" and another food containing the ingredient with the

[17] 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

[18] *Id.*

[19] Letter from Margaret O'K Glavin, Associate Comm'r for Regulatory Affairs, FDA to Antonio Zamora (Dec. 14, 2005).

[20] Letter from John B. Foret, Dir. Div. of Compliance and Enforcement, Office of Nutritional Products, Labeling and Dietary Supplements, FDA to Michael F. Jacobson, Ph.D (regarding the use of the claim natural on the labels of Ben and Jerry products containing artificial flavorings and other man-made ingredients) (Sept. 19, 2002). Letter responded to a complaint filed by CSPI with FDA on July 30, 2002.

[21] Letter to Corn Refiners Assoc., *supra* note 12; Laura Crowley, *HFCS is natural, says FDA in a letter,* Foodnavigator-usa.com/content/view/print/144787.

same common or usual name, which has been formulated in a different way may not be eligible for the use of the term "natural."[22]

B. USDA

Since 1982, USDA, which regulates meat and poultry products, has limited "natural" labeling to those foods that contain no artificial ingredients and are minimally processed.[23] Recently, however, USDA issued an Advance Notice of Proposed Rulemaking to assist the Department in defining the conditions under which it would permit meat and poultry products to be labeled as natural.[24] This latest action follows the submission of a petition by Hormel Foods on Oct. 9, 2006, requesting that the Department institute rulemaking to establish a codified definition for natural. In particular, Hormel seeks a regulation that would prohibit exceptions for specific chemical preservatives and synthetic ingredients. A public hearing was held on the petition in December 2006.

In its ANPR, USDA explained that:

> The comments indicated there is an overall lack of consensus on both the general or common understanding of what the claim "natural" means to the industry and to the public and on the approach that FSIS should take to address issues associated with the use of "natural" on claims on the labels of meat and poultry products.[25]

Recommended Reforms

The FDA should:

- Issue a letter to industry summarizing the contents of past warning letters that had concerned the use of the word

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[22] *Id.*

[23] USDA, Food Safety and Inspection Service, Labeling Policy Memo 55 (1982), superseded by Food Standards Labeling Policy Book (Aug. 2005).

[24] 74 Fed. Reg. 46,951 (Sept. 14, 2009). The USDA should also address other controversies raised by terms such as "Naturally Raised." Defining such terms could help consumers choose meat and poultry products that were produced with animal welfare in mind. This issue, however, is beyond the scope of this report.

[25] *Id.* at 46,952.

"natural" and state that the Agency will be taking similar enforcement actions.

- Prohibit the use of the term "natural" on products that include high-fructose corn syrup, regardless of whether glutaraldehyde was used as the fixing agent.

- Restrict "natural" claims to foods that do not contain artificial ingredients and are minimally processed (and that are not deceptive for any other reason). The latter term, "minimally processed," is admittedly difficult to define, but government needs to provide a uniform standard that consumers can rely on.

The USDA should:

- Finalize regulations under its recent Advance Notice of Proposed Rulemaking concerning the term "natural." The Department should propose rules to prevent "natural" claims on poultry or beef that has been flavored by a watery and salty marinade or injections. In addition, USDA should require much more prominent labeling of the added-water content of those products.

- Determine that high-fructose corn syrup is not a natural ingredient and that products containing it may not be labeled natural.

Part XI

Compilation of Recommendations

• Improving the Nutrition Facts Panel

- The declaration of calories per serving should appear in a larger font, on a contrasting background on the Nutrition Facts Panel (NFP). Instead of saying "Amount Per Serving," labels should state "Amount Per ½ Cup Serving."

- Little-used information, such as calories from fat and the NFP "footnote" allowing consumers to convert Daily Values (DVs) based on a 2,000-calorie a day diet to a 2,500-calorie a day diet, should be eliminated to simplify the label and create additional space for more important information.

- Products that may reasonably be consumed by one person at a single eating occasion should be considered a single serving and their labels should disclose nutrition information for the entire package. Dual columns that also show nutrition information for the Reference Amount Customarily Consumed (RACC) should be prohibited.

- The Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) should update certain RACCs in light of current consumption data.

- A Daily Value should be established for added sugars, and the %DV and added sugar content per serving (in terms of teaspoons and grams) should be required on the Nutrition Facts Panel.

- The FDA should also clarify that the definition of fiber only includes intact fibers from whole grains, beans, vegetables, fruit, and other foods.

- The FDA should define "low sugar" and prohibit health claims for products that are not low in sugar, prohibit the use of the term "healthy" on such products, and restrict "fat free" and "low fat" claims on products that are not low in sugar.

- The USDA should adopt the same requirements for foods under its jurisdiction and finalize its proposed rule requiring nutrition labeling on single-ingredient meat and poultry products.

• Front of Package Nutrition Labeling

- The FDA and the USDA should promptly take enforcement actions against manufacturers using misleading front-label nutrition symbols developed by private parties and propose regulations detailing nutrient criteria that must be met before such symbols are used on food packaging. Unlike the FDA's current criteria for "healthy," new criteria should include added sugars. That might entail the FDA's adopting a Daily Value for added sugars, perhaps based on the Dietary Guidelines for Americans (Appendix A3).

- The FDA should promptly commence its consumer research program, in conjunction with related work being conducted by the Institue of Medicine (IOM), and identify the most effective front-of-pack nutrition labeling approach (including nutrient criteria, logo, font size, etc.) for empowering consumers to choose healthier foods.

- The FDA and the USDA should then propose regulations for a mandatory new labeling system.

- The FDA and the USDA should prohibit the use of competing front-of-label nutrition labeling schemes.

• Making Ingredient Labels Easier to Read

- The FDA, in consultation with the USDA, should publish a Notice of Proposed Rulemaking in the *Federal Register* with the goal of modernizing the format of the ingredient list.

- Requirements for type size, style, spacing, and leading of ingredient lists should be established based on requirements set forth for the Nutrition Facts Panel.

- The use of all capital letters should be prohibited, and left justification only should be required.

- Eight-point, non-condensed type should be the minimum for print size, except on small packages.

- Sugar sources in the product should be grouped together in the ingredient list so that consumers could readily identify the ingredients that add sugar, get a better sense as to the relative amount of sugar in the product, and not be fooled by healthy-sounding names, such as "fruit juice concentrate."

- Ingredients information should be set off in a box by use of hairlines and should be all black or one color type, printed on a white or other highly contrasting background.

- Once FDA regulations are issued, the USDA should approve only those labels that conform to the new requirements.

• Disclosing Caffeine Content

- Caffeine content per serving should be prominently disclosed on food labels, such as on a separate line between the Nutrition Facts Panel and the ingredient list; above the top of the Nutrition Facts Panel where percentage juice content is declared; or in large, clear type on products (such as cans of coffee) that lack nutrition panels and ingredient lists.

- The terms "guarana" and "yerba mate" (and any other ingredients that are used as a source of caffeine) should be followed by "(a source of caffeine)" in the ingredient list.

- The FDA should require foods containing more than a specified level of caffeine to carry the FDA's advice for pregnant women: "Pregnant women should avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly."

• Stopping Misleading Structure/Function Claims

• The FDA Should Take Enforcement Actions Against Specific Deceptively Labeled Products

Dishonest structure/function claims mislead consumers with regard to serious health matters and threaten the integrity of the food label and of public confidence in food manufacturers and the FDA. Section 403(a)(1) of the Food, Drug, and Cosmetic Act (FDCA) states that "a food shall be deemed to be misbranded if its labeling is false or misleading in any particular." Section 201(n) provides for the disclosure of material facts in light of representations made on the label. Both provisions provide the FDA with ample authority to act.

• The FDA Should Issue an Industry-Wide Letter Clarifying the Substantiation Standard for Structure/Function Claims for Foods

The last "Dear Manufacturer" letter the FDA issued on food labeling (in January 2007,[1]) included a cursory discussion of structure/function claims, but failed to specify a substantiation standard for such claims; it simply noted that such claims must be truthful and not misleading. The FDA's failure to specify a substantiation standard has effectively granted food manufacturers carte blanche for structure/function claims.

• The FDA Should Require Structure/Function Claims for Foods to Meet the Same Standard as Health Claims

Both the FDA and food industry studies demonstrate that consumers do not differentiate between structure/function claims and health claims on food labels. To prevent deception, the FDA should, therefore, subject structure/function claims to the same evidentiary standard used for health claims. That standard is "significant scientific agreement." Such steps are consistent with the First Amendment's commercial free-speech doctrine, which accords no protection to misleading commercial claims.

• The FDA Should Not Apply Its Substantiation Standards for Dietary Supplements to Structure/Function Claims for Conventional Foods

The FDA stated in both its Guidance document and the *Federal Register* notice announcing its availability that the Guidance "does not extend to substantiation issues that may exist in other sections of the Act." Thus the FDA's "Guidance" for substantiating structure/function claims for supplements does not – and, for the reasons explained in this report should not – apply to structure/function claims for foods.

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[1] *Dear Manufacturer Letter Regarding Food Labeling* (Jan. 30, 2007), http://www.cfsan.fda.gov/~dms/flguid.html. (last visited June 5, 2009).

The extension of the FDA's structure/function claims substantiation policy for supplements to conventional foods would merely accelerate the spread of the dishonesty and skullduggery that has plagued the dietary supplement industry to the much larger food industry.

- **The FDA Should Issue a Safe Harbor List of Structure/Function Claims**

The FDA should facilitate industry compliance with our recommended regulatory approach by establishing a "safe harbor" of permissible claims.

• Prohibiting Qualified Health Claims for Foods

- The FDA should release its second consumer research study on whether the disclaimers in qualified health claims for conventional foods protect consumers from being misled, and, hence, whether the Agency is under any legal obligation under the First Amendment (and the *Pearson* case on dietary supplements) to authorize them.

- The FDA should delete language relating to conventional foods from the Bush Administration's January 2009 "midnight" guidance document and specify that, until a court or Congress says otherwise, companies are prohibited from making qualified health claims on conventional foods that do not meet the significant scientific agreement standard.

- The FDA should delete language relating to conventional foods from its 2003 Advance Notice of Proposed Rulemaking and specify that conventional foods not meeting the significant scientific agreement standard are prohibited from making qualified health claims.

• Halting Misleading 0 g Trans Fat Claims

- The FDA should review its enforcement policy and promptly issue an industry-wide warning letter stating that products that emphasize "0 *trans* fat" on the front panel when such foods contain per serving more than 5% of the DV for saturated fat (i.e., are not "low" in saturated fat and cholesterol) are in violation of the law. Simultaneously, the Agency should send warning letters to manufacturers of products that are making "0 g *trans* fat" claims on products that are not low in saturated fat.

- The FDA should propose rules setting forth conditions for making nutrient content (and health) claims for products low in *trans* fats that are based on

existing rules for claims for products that are "low saturated fat." Such rules should ban "0" or "no" or "low" *trans* fat claims (and health claims), unless a serving of the food is also low in saturated fat and cholesterol.

- The FDA immediately should revoke the Generally Recognized as Safe (GRAS) status of partially hydrogenated oils, as requested in the 2004 petition submitted by the Center for Science in the Public Interest (CSPI). Partially hydrogenated oils are unnecessary, as evidenced by the industry's gradual abandonment of them in favor of less-harmful oils. Eliminating the use of partially hydrogenated oil would mitigate the need for all of the activities in which the FDA is currently engaged regarding the labeling of *trans* fat.

• Stopping Misleading Made With Whole Grains and Fruits and Vegetables Claims

- The FDA should require that the percent by weight of key ingredients that bear on health, such as fruits or vegetables, be disclosed on the principal display panel in conjunction with any claim or in parentheses after the listing of the relevant ingredient in the ingredient declaration.

- Products stating "made with whole grains" should disclose what percentage of total grains are whole.

- "Key ingredients" should be considered to include those mentioned in the name of the food, or emphasized on the label by words, pictures, or graphics.

- The FDA should coordinate its policy with the USDA so as to include meat or poultry products, including stews and pot pies.

• Controlling "Natural" Claims

The FDA should:

- Issue a letter to industry summarizing the contents of past Warning Letters that had concerned the use of the word "natural" and state that the Agency will be taking similar enforcement actions.

- Prohibit the use of the term "natural" on products that include high-fructose corn syrup, regardless of whether glutaraldehyde was used as the fixing agent.

- Restrict "natural" claims to foods that do not contain artificial ingredients and are minimally processed (and that are not deceptive for any other reason). The latter term, "minimally processed," is admittedly difficult to define, but government needs to provide a uniform standard that consumers can rely on.

The USDA should:

- Finalize regulations under its recent Advance Notice of Proposed Rulemaking concerning the term "natural." The Department should propose rules to prevent "natural" claims on poultry or beef that has been flavored by a watery and salty marinade or injections. In addition, the USDA should require much more prominent labeling of the added-water content of those products.

- Determine that high-fructose corn syrup is not a natural ingredient and that products containing it may not be labeled natural.