

Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority

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INTRODUCTION



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Since 2011, consumer advocacy groups and plaintiffs have filed more than 150 food labeling class action lawsuits against food and beverage companies. According to a recent study, the number of these consumer protection class actions brought in federal court climbed from 19 cases in 2008 to more than 102 in 2012.¹ The majority of these cases have been filed in the U.S. District Court for the Northern District of California, now referred to as the “Food Court.” This surge in lawsuit filings has led some legal commentators to suggest that “food is replacing tobacco as the new regulatory and class action target.”² This “unprecedented surge”³ of deceptive labeling and advertising lawsuits against the makers of products such as Naked Juice, Fruit Roll-Ups, Bear Naked Granola, and Wesson Oil, reveals a trend of regulation by litigation—that is, a turning over of food labeling issues to the courts in light of a lax regulatory system. Although the Food and Drug Administration (FDA) is charged with regulating food labeling, plaintiffs’ attorneys are seeking to fill a void in the FDA’s regulatory authority and enforcement of food labeling laws. This paper provides an overview of the recent food labeling litigation and explores the reasons for this flood of litigation. However, this paper does not evaluate the merits of the lawsuits. Although none of these food labeling lawsuits have yet been adjudicated, the litigation has exposed problems with the FDA’s regulatory oversight of food labeling. The lawsuits represent attempts by consumer groups and plaintiffs’ attorneys to influence marketing behavior of food companies—a task more properly undertaken by the FDA.

Recognizing that consumers have the right to expect that the information on food labels is accurate and not misleading, the FDA has assured consumers, in a message on its website, that it “has your back.” To that end, “as resources permit,” FDA

monitors food products to ensure that the labels are truthful and not misleading. If a product is not properly labeled, the agency claims that it takes appropriate action. However, as this paper will demonstrate, the FDA lacks the resources and regulatory authority to effectively monitor false and misleading labeling practices. Such practices, which are the target of the food labeling lawsuits, have resulted in consumer confusion and an uneven playing field in the marketplace. In light of these issues facing consumers and food producers, this paper offers the following recommendations to address the issues highlighted by the recent labeling lawsuits:

- The FDA should define misleading terms such as “natural” to achieve uniformity and consistency for consumers and food manufacturers. The issue of whether genetically modified ingredients are “natural” is at the core of many recent food labeling class-action suits. The agency should address the controversial genetically modified organism (GMO) labeling issue to prevent the state-by-state patchwork of laws that is beginning to develop.
- The FDA should address the misleading nature of health and nutrition claims on foods and revise its regulations accordingly. Research conducted by the FDA and other groups proves that consumers are confused about these claims, particularly structure/function claims which do not require the FDA’s pre-approval or authorization. However, the FDA has not increased its enforcement efforts, nor has it provided clear guidance to manufacturers about the level of scientific support required to assert such claims. The “significant scientific agreement” standard should be required for each type of claim included on food labels.
- The FDA should increase its monitoring and enforcement of labeling practices by coordinating efforts with the FTC, developing a comprehensive food labeling monitoring system, and instructing inspectors on how to identify potentially misleading claims.

OVERVIEW OF THE FDA'S AUTHORITY

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety and proper labeling of all domestic and imported food except meat, poultry, and processed eggs, which are regulated by the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS). Eighty percent (80%) of the U.S. food supply, including fresh fruits and vegetables, dairy, baked products, and seafood, which equates to \$417 billion worth of domestic food and \$49 billion worth of imported foods,⁴ is regulated by the FDA. In addition to protecting our nation’s food supply, the FDA is also

charged with overseeing human and veterinary drugs, vaccines, medical devices, cosmetics, dietary supplements, and tobacco products. The FDA's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for food and cosmetic products. Within CFSAN, the Office of Nutrition, Labeling, and Dietary Supplements publishes regulations and guidance regarding food labeling requirements. FDA's Office of Regulatory Affairs (ORA), in cooperation with state agencies, conducts food safety inspections. Although food safety is the primary focus of an inspection of a food facility, inspectors are also directed to review the labels of at least three food products of any manufacturer or processor during every food safety inspection. The FDA also follows up on complaints from groups or individuals who believe that they have identified misbranded food.

The Federal Food, Drug, and Cosmetic Act ("FDCA") of 1938 grants the FDA the power to "promulgate food definitions and standards of food quality."⁵ This power includes the regulation of nutritional labeling if a manufacturer makes nutritional or health claims about a food product, such as "low fat" or "high in fiber." In response to growing concern about inconsistent and unclear terms on food labels used to describe nutrient content, Congress enacted the Nutrition and Labeling Education Act (NLEA)⁶ in 1990, which amended the FDCA for nearly all food products within the FDA's jurisdiction to regulate health claims on food packaging, standardize nutrient content claims, and require that more detailed nutritional information be included on product labels.⁷

The FTC and the FDA have overlapping jurisdiction to regulate the advertising and labeling of foods. Section 403(a) of the FDCA prohibits the "misbranding" of food which includes labeling that "is false or misleading in any particular."⁸ Section 5 of the Federal Trade Commission Act (FTC Act) prohibits "unfair or deceptive acts or practices," and Sections 12 and 15 of the FTC Act prohibit "any false advertisement" of food products that is "misleading in a material respect."⁹ This shared jurisdiction over labeling and advertising of food products operates pursuant to a longstanding Memorandum of Understanding between the agencies.¹⁰ Under this agreement, the FDA exercises primary responsibility for regulating food labeling, while the FTC assumes primary responsibility for ensuring that advertising of food products is truthful and not misleading.

Although the FDA is responsible for enforcing labeling regulations, it lacks the enforcement authority to effectively deter food companies from making misleading claims. When the FDA determines that a manufacturer has violated a labeling regulation, the agency's principal enforcement tool is to issue a Warning Letter to notify the manufacturer. These Letters are issued to achieve voluntary compliance and to establish prior notice. In general, the FDA may exercise enforcement strategies such as recall, seizure, injunction, administrative detention, civil money penalties or criminal prosecution.¹¹ However, these other measures are reserved for violations other than the misbranding violations at issue in the recent food labeling

lawsuits. The FDA may enforce compliance with a recall order or impose civil monetary fines when adulteration or misbranding of food “will cause serious adverse health consequences of death,”¹² such as when a label is missing allergen information.¹³ The FDA may condemn and seize misbranded foods only after the company receives proper notice and the opportunity to respond and the FDA has “probable cause to believe . . . that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.”¹⁴ Injunctions or criminal prosecutions are rarely used for food misbranding because the FDCA expressly provides that these enforcement actions should not be initiated for “minor violations” when the “public interest” may be adequately served by a written warning.¹⁵ Thus, the FDA primarily seeks voluntary compliance from food companies when food products are misleading or mislabeled. As the food labeling lawsuits demonstrate, these Warning Letters provide little incentive or threat for companies to avoid or discontinue use of misleading claims on food labels.

The FDA’s Regulation of Health and Nutrition Claims

Pursuant to its statutory authority under NLEA, the FDA promulgated regulations regarding permissible nutrient content and health claims on food labels. FDA regulations permit three categories of health and nutrition claims on food packaging: health and qualified health claims, nutrient content claims, and structure/function claims. Each type of claim is subject to different rules.

A health claim expressly or implicitly, through the use of statements, symbols, or vignettes, “characterizes the relationship of any substance to a disease or health-related condition.”¹⁶ Health claims must be reviewed and evaluated by the FDA prior to use.¹⁷ Health claims are limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. The FDA authorizes unqualified health claims on product labels only if the substance/disease relationship described by the health claim is supported by “significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims.” This is referred to as the Significant Scientific Agreement (SSA) standard.¹⁸ To use an SSA claim, the product must meet detailed regulatory requirements and must not exceed disqualifying levels of total fat, saturated fat, cholesterol and sodium¹⁹ or, if prior to fortification, the food does not contain at least ten percent (10%) of the Reference Daily Intake of Vitamin A, Vitamin C, iron, calcium, protein, or fiber.²⁰ 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. The nutrient, such as fiber, that is the subject of the health claim must be present at levels that are at least twenty percent (20%) of the Daily Value (DV) or in amounts specified by FDA.²¹ Finally, approved health claims require that claims be phrased in a particular way, indicating 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. For

example, a permissible health claim on an oatmeal label would state that: “three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per serving.”

Prior to 2002, the FDA rejected health claims that did not meet the SSA standard. However, in response to litigation that raised First Amendment challenges to this standard, the FDA has permitted qualified health claims on foods. When the evidence for a substance/disease relationship is credible but does not meet the SSA standard, FDA issues a Letter of Enforcement Discretion to the food manufacturer petitioning for use of the health claim. This Letter indicates that the FDA would not object to the use of the health claim, provided that the claim is “qualified” by a disclaimer or other language expressly stated in the Letter to characterize the strengths and limitations of the claim’s scientific support. Such qualification is intended to address the claim’s potentially misleading nature. An example of a qualified health claim for green tea states, “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.” Because of the awkward wording of qualified health claims, many food manufacturers disfavor their use.

A nutrient content claim, which is the claim most frequently used on food products, directly or implicitly characterizes the level of a nutrient in the food, using terms such as, “low,” “high,” “free,” “reduced” or “light.”²² The FDA has established specific standards and definitions for each nutrient content claim that may be used, such as “low fat” or “high in fiber.” Even the ubiquitous term “healthy” has a very specific meaning for use on food labels under the FDA’s regulations. The term “healthy” may be used only if a food is low in fat, contains limited amounts of cholesterol, and if it is a single-item food, it provides at least ten percent (10%) of the DV per serving of at least one of these: vitamins A or C, iron, calcium, protein and fiber.²³ Unlike the strictly defined and regulated health and nutrient content claims, the FDA does not authorize or pre-approve structure/function claims, nor has it indicated the level of scientific support needed to prevent false or misleading information for such a claim.²⁴ Structure/function claims describe the effect that a substance has on the structure or function of the body, but they do not make reference to a disease. An example of such a claim is: “calcium builds strong bones.” The FDA does not require food manufacturers to substantiate structure/function claims, nor does the FDA mandate the use of disclaimers when these claims are used.

THE RISE IN CLAIMS MADE ON FOOD LABELS: SHIFTING CONSUMER PREFERENCES

As the American obesity “epidemic”²⁵ has become one of the most pressing public health issues, consumers have been increasingly demanding healthier food products. While the

Center for Disease Control (CDC) reports that more than one-third of U.S. adults (35.7%) are obese,²⁶ a 2013 Healthy Eating Consumer Trend Report shows that sixty-four percent (64%) of consumers (an increase from fifty-seven percent (57%) in 2010) agree on the importance of healthy eating and nutrition.²⁷ Consumer demand for healthier food has led to an increase in organic food sales from approximately \$11 billion in 2004 to an estimated \$27 billion in 2012.²⁸ Over the past decade, consumer demand for locally produced foods has also grown dramatically. A USDA Rural Development Service Report refers to the availability and demand for locally produced products as “unprecedented in recent history.” Consumer demand for these products has led to the growth of local farmers’ markets and Community Supported Agriculture (CSAs).²⁹ In the past decade, the number of farmers’ markets has increased from 1,755 in 1994 to 8,144 in 2013. Between 2012 and 2013, there was a 3.6 percent increase.³⁰

In light of this new focus on local, fresh, and healthy food, processed food manufacturers have introduced onto supermarket shelves hundreds of processed foods claiming, to be “natural,” “wholesome,” “simple” or “pure.” These efforts to create more apparently healthful processed foods have paid off. For example, in the United States, consumers have spent more than \$40 billion on food labeled “natural” over the past year, and 51% of Americans search for “all natural” products when shopping.³¹ Foods labeled as “natural” accounted for about ten percent (10%) of all grocery sales in 2013, while organic food and products made up about five percent (5%) of all grocery sales that year, according to a report by the Organic Consumers Association.³² A 2013 study by the USDA’s Economic Research Service found that from 2001 to 2010, health and nutrition claims became an increasingly important feature of labeling on new products. For example in 2009, sales of products with claims related to fat, sodium, and calories accounted for \$73 billion in sales or twelve percent (12%) of food sales for at-home consumption.³³

The “American obesity paradox”—the simultaneous increase in obesity rate and demand for healthful foods— may be explained by the so-called “health-halo” claims made on foods.³⁴ The theory is that people tend to overestimate the healthfulness of a food based on one perceived attribute of the food, such as “organic,” “natural,” or containing “whole grains.” With claims such as “natural” on processed foods, consumers feel better about eating these convenience foods even though they may in fact be anything but “natural.” Judging a food as more healthful, may lead people to eat more of that food. This is certainly a positive phenomenon for food producers, but one has had a deleterious effect on consumers’ waistlines. Feeding consumers’ demand for “natural,” “pure,” and “healthful” products has led to the widespread use of these claims, many of which are confusing or misleading, on a wide variety of products. As FDA Commissioner Hamburg noted in 2010, “[W]ith consumers’ growing interest in eating healthy, we’ve seen the emergence of eye-catching claims and symbols on the front of food packages that may not provide the full picture of their products’ true nutritional value.”³⁵ Although the FDA has established regulations for permissible health and nutrition claims, it

has been unable to keep pace with the influx of new products labeled with novel, unregulated, and allegedly misleading claims.

It is against this backdrop of increased consumer demand for healthy foods, a surge in the number of health, nutrition, and other claims, such as “natural,” on food products, and limited oversight by the FDA, that consumer advocacy groups turned to the courts to address deceptive food labeling practices.

A BRIEF HISTORY OF FOOD LABELING LITIGATION

As claims on food labels were used more frequently, the FDA's oversight of claims was declining.³⁶ In 2004, the nonprofit consumer advocacy group Center for Science in the Public Interest (CSPI) established its litigation department “to fill the void left by the inactive government agencies by using state and federal courts to help correct corporate misbehavior.”³⁷ In light of the government's inaction, CSPI's policing efforts uncovered hundreds of food labeling violations. During the next several years, CSPI achieved several significant victories by suing or threatening to sue food and beverage manufacturers for allegedly deceptive labeling practices. For example, in 2005, CSPI reached a settlement after threatening to sue Aunt Jemima's corporate parent, Pinnacle Foods, for the misleading labeling of “blueberry” waffles that contained no actual blueberries. The “artificially flavored blueberry bits” in the waffles were made from ingredients such as sugar, dextrose, partially hydrogenated soybean oil, soy protein concentrate, and food dyes such as Blue 2 Lake and Red 40 Lake. Pinnacle Foods agreed to more clearly indicate that the product is “artificially flavored” and that the “blueberries” are imitation.

CSPI achieved similar success when it convinced General Mills to indicate on its package that its Super Moist Carrot Cake Mix contains only carrot-flavored bits, Quaker Oats to revise labels to inform consumers that several of its instant oatmeal and grits did not contain any real fruit, real butter, or real meats, as the labels implied, and Sara Lee agreed to change its labels to clarify that its “Soft & Smooth Made With Whole Grain White Bread” contains only thirty percent (30%) whole grains rather than claiming the product is nutritionally equivalent to one hundred percent (100%) whole wheat bread. After suing Kraft for deceptive labeling of Capri Sun drinks as “natural,” although they were sweetened with high-fructose corn syrup (HFCS), Kraft agreed to discontinue use of the claim. Similarly, CSPI's threat of litigation halted Cadbury-Schweppes' labeling of 7UP containing high-fructose corn syrup as “All Natural.”

By 2005, Congress was so concerned by the prevalence of labeling violations that it asked the FDA to report on the types of food labeling violations, other than those relating to safety, that the agency had uncovered and the actions taken to address them. The Senate Appropriations Committee wanted to prevent misleading claims and ensure that “food labels can be easily understood and reflect information that is factual” and not misleading.³⁸ The House of

Representatives was concerned about the loss of consumer confidence in food labels because of misleading claims such as “healthy” and inaccuracies in the amount of nutrients stated in the Nutrition Facts Panel.³⁹

In October 2008, the GAO criticized the FDA for failing to keep pace with the growing number of food companies and producers. Although the number of food producers had grown significantly, the number of inspections, Warning Letters, and enforcement actions to address labeling violations decreased or had remained steady.⁴⁰ As CSPI noted, “[g]iven the number of violations identified by CSPI, state officials, aggrieved competitors and consumers, the small number of Warning Letters issued by the Agency is an indication that the FDA has all but abdicated its responsibility to police inaccurate nutrition statements and misleading health-related claims on food labels.”⁴¹ The GAO cited specific failures such as the lack of reliable data on the number of labels that were actually reviewed during facility inspections, decline in number of inspections and label reviews, and failure to track labeling violations or ensure that complete information about problems is promptly posted to the Web to inform the public.⁴² Therefore, the GAO concluded that “FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those prohibiting false or misleading labeling.”⁴³

In light of flagrant labeling violations abounding in the marketplace and pressure from CSPI and Congress, in 2009 the FDA announced that reliable nutrition labeling of food products was a top priority for the agency. In October 2009, the FDA issued a “Dear Industry” letter, noting its concern with the number and variety of potentially false or misleading claims, including nutrient content claims not expressly permitted by the FDA.⁴⁴ In this letter, the FDA urged food manufacturers to examine their product labels and comply with the FDCA. The letter, which was merely a “nonbinding recommendation,” did not have much impact on the industry. CSPI’s 2010 Food Labeling Chaos Report identified a variety of food labeling problems creating consumer confusion and criticized several companies for violations that were unnoticed by the FDA. As CSPI noted in its Report, although the FDA was beginning to address labeling violations, it was “merely scraping the tip of the iceberg.”⁴⁵ Following the Report’s publication in January 2010, two months later in March, FDA Commissioner Margaret Hamburg issued an open letter to the food industry, again urging all manufacturers to review their labels for FDA compliance and reiterating the agency’s commitment to ensuring the truthfulness of food labels.⁴⁶ As part of a food labeling enforcement initiative, the FDA issued 17 Warning Letters on a single day to food manufacturers for FDCA violations such as making unauthorized health claims and nutrient content claims, failing to meet the well-established standard for foods labeled as “healthy,” and making unauthorized claims on products for infants and children less than two years of age. Despite this showing of authority, misleading labels continued to proliferate in the marketplace.

In July 2010, Michael R. Taylor, the FDA's deputy commissioner for foods, identified some challenges facing the FDA in its oversight of food labeling violations:

We will no doubt issue more letters on labeling violations, but I do not see us eradicating questionable claims . . . through a letter writing campaign or other means any time soon. We have no pre-market review authority over such claims, and, under prevailing legal doctrines concerning “commercial free speech,” the evidentiary requirements placed on FDA to prove that such claims are misleading are significant and costly to meet. Moreover, meeting them requires tapping the same team of nutritionists, labeling experts, and lawyers who are working on our other nutrition initiatives.

We're also conscious of the cleverness of marketing folks, who, once we prove today's claim is misleading, can readily come up with another one tomorrow. Going after them one-by-one with the legal and resource restraints we work under is a little like playing Whac-a-Mole, with one hand tied behind your back.⁴⁷

These statements admitting the FDA's defeat in a battle for truthful food labeling, was discouraging for consumers and honest food manufacturers, but promising for plaintiffs' attorneys.

In the absence of FDA's oversight, consumer and public health groups have been policing the marketplace for misleading and deceptive labeling practices. The settlements CSPI achieved with several large food manufacturers proved that lawsuits could be successful in changing corporate behavior. Plaintiffs' lawyers, many of whom had litigated the tobacco cases,⁴⁸ recognized an area of the law ripe for litigation. The Dannon \$45 million settlement in 2010 demonstrated that the lawsuits could also prove lucrative. Dannon's settlement of a class action alleging it made false claims about the digestive benefits of Activia probiotic yogurt was arguably the first major victory against a food company.⁴⁹ Therefore, this case may have sparked the first wave of food labeling lawsuits alleging misleading health claims. Plaintiffs have also achieved more recent successes— in 2013 plaintiffs won a \$9 million settlement with PepsiCo over claims that Naked Juice products were deceptively advertised and labeled as “all natural” and “non-GMO” when its products actually contained processed and synthetic ingredients and ingredients from genetically modified crops.⁵⁰ General Mills agreed to pay plaintiffs \$8.5 million to settle claims that Yoplait Yo-Plus made false claims about its yogurt having digestive health benefits.⁵¹ Kellogg's settled a lawsuit for \$4 million in which plaintiffs claimed that it falsely advertised that its Frosted Mini-Wheats cereal as improving kids' attentiveness, memory and other cognitive functions to a degree not supported by competent clinical evidence⁵² and cereal maker Barbara's Bakery also paid \$4 million to settle claims that the company mislabeled its cereal and snack products as “all natural” when they actually contain genetically modified ingredients.⁵³

Enforcement actions by the FDA and FTC also inspired consumer class action lawsuits alleging violations of state consumer protection laws. For example, on May 5, 2009, the FDA issued a Warning Letter to General Mills for making unauthorized health claims on Cheerios. In its letter, the FDA explained that Cheerios' claims such as "you can Lower Your Cholesterol 4% in 6 weeks" indicate that Cheerios is intended for use in lowering cholesterol, and therefore in "preventing, mitigating, and treating" hypercholesterolemia and coronary heart disease. Because of this intended use, under the FDCA Cheerios would be considered a drug which may not be legally marketed without undergoing a formal drug approval process.⁵⁴ Soon after the Warning Letter was issued, several class action lawsuits, later consolidated into one multi-district suit at the New Jersey District Court, were filed. The lawsuits, which were ultimately dismissed, alleged that General Mills made false claims which induced the plaintiffs to purchase the cereal as a way to lower cholesterol.⁵⁵ Another example of a piggybacking class action was brought against Alexia Foods after the FDA issued a Warning Letter in 2011 to Alexia Foods regarding its improper use of a "natural" claim. The FDA indicated that the "natural" claim on Alexia's Roasted Red Potatoes & Baby Portabella Mushrooms was false and misleading and therefore constituted misbranding because the product contained disodium dihydrogen pyrophosphate, a synthetic chemical preservative.⁵⁶ In May 2012, a class action lawsuit alleging that a variety of Alexia's frozen potato products were falsely labeled as "all-natural" piggybacked on this Warning Letter.⁵⁷ The case was settled for \$3.2 million in July 2013.⁵⁸

OVERVIEW OF LABELING LAWSUITS

The lawsuits against food and beverage companies generally fall into two categories: claims that are legal or unregulated, but are nevertheless allegedly misleading, and claims that violate state laws equivalent to the FDCA and the FDA's regulations. Most of the recent lawsuits involve claims such as "all natural," "nutritious," or "healthful" that are permitted or not regulated by the FDA, but are nonetheless misleading. Lawsuits challenging these types of claims have frequently involved a variety of products such as cookies, granola, smoothie kits, canned tomatoes, ice cream, and cooking spray, containing ingredients like high fructose corn syrup, alkalized cocoa, ascorbic acid, and GMOs. Other recent lawsuits involve alleged misbranding violations that are covered by FDA regulations and policies, and the equivalent state law, such as health and "nutrient content" claims. Other lawsuits reveal food fraud occurring in the market. For example, in one lawsuit plaintiffs claim that a "grape seed oil" product is falsely labeled because it allegedly contains less than 25% grape seed oil.⁵⁹ Another similar lawsuit alleges that defendant's olive oil is falsely labelled "100% Pure Olive Oil," because it actually contains "olive-pomace oil," "olive-residue oil," or "pomace."⁶⁰

Neither the FDCA nor the FTC Act provides for a private right of action.⁶¹ In other words, although the FDA and FTC may enforce the requirements of their respective statutes and regulations, private litigants cannot bring a private cause of action or class action against a company that relies solely on a violation of the FDCA or the FTC Act. Although the NLEA

includes an express preemption requirement which prohibits a state from establishing food laws that are not identical to the requirements of the FDCA,⁶² states may permit causes of action based on violations of state laws that mirror the federal requirements. California's Sherman Law, for example, expressly adopts the federal labeling requirements of the FDCA and NLEA, such as the prohibition of "false or misleading" labeling.⁶³

Therefore, the food labeling lawsuits have been predicated upon violations of state statutes on false advertising, unfair trade practices, consumer protection, fraud, and breach of warranty.⁶⁴ Most of the food labeling lawsuits filed in California allege violations of the Unfair Competition Law ("UCL")⁶⁵ predicated on violations of the False Advertising Law ("FAL")⁶⁶ or the Consumer Legal Remedies Act ("CLRA").⁶⁷ The UCL, FAL, and CLRA are California consumer protection statutes which prohibit deceptive practices and misleading advertising.⁶⁸ Violations of the Sherman Law are unlawful business practices under §17200 of the UCL. These lawsuits are generally based upon the allegation that certain information on the packaging of the food products was false or misleading and that consumers reasonably relied on that information to their detriment.⁶⁹

A. "Natural" Litigation

The majority of food labeling lawsuits, at least 100 filed since 2011,⁷⁰ have alleged the misleading use of the "natural" claim. Confusion and ambiguity regarding the term's meaning can largely be attributed to the FDA's reluctance to establish an enforceable standard for the claim.

1. The FDA's Natural Policy

Although the FDA has seemed to recognize the importance of formally defining this term and has recognized that an adequate definition could prevent consumer confusion,⁷¹ the agency nevertheless has declined to adopt a formal definition. In 1991, it adopted an "informal policy," which states that "natural" means merely that "nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there."⁷² The policy carries only the weight of an advisory opinion, and it does not establish a legal requirement.⁷³

In 1993, when it initiated rulemaking to implement the NLEA, the FDA invited comments on a potential rule regarding the definition of "natural."⁷⁴ After receiving a variety of suggestions, from banning use of the term, to allowing free use of the term, the FDA recognized that "use of the term 'natural' on [a] food label is of considerable interest to consumers and industry. . . ." ⁷⁵ However, it concluded that "[n]one of the comments provided FDA with a specific direction to follow for developing a definition" for the use of the word "natural."⁷⁶

After reviewing and considering the comments, the agency continues to believe that if the term "natural" is adequately defined, the ambiguity surrounding use of this

term that results in misleading claims could be abated. However, as the comments reflect, there are many facets to this issue that the agency will have to carefully consider if it undertakes a rulemaking to define the term “natural.”⁷⁷

The FDA concluded, “[b]ecause of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for ‘natural’ at this time.”⁷⁸ Instead, the FDA has maintained its informal policy and has announced that its determination of whether an ingredient would qualify for use of the term “natural” on a case-by-case basis, rather than adopting a consistent, uniform policy.

On its Web site, the FDA has provided consumers the following explanation of the meaning of “natural” food labels:

From a food science perspective, it is difficult to define a food product that is “natural” because the food has probably been processed and is no longer the product of the earth. That said, the FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.⁷⁹

Because the FDA has refused to provide a definitive and enforceable standard for use of the term “natural,” the issue of what constitutes a “natural” ingredient is now before judges in the dozens of lawsuits alleging deceptive use of the term. However, the FDA’s repeated reluctance to establish a definition or enforceable standard for the term was recently challenged by several judges who decided that the FDA, not the courts, should decide this issue. The order in *Cox v. Gruma Corporation*, referred the issue of GMOs and labeling of “natural” foods to the FDA for the first time.⁸⁰ In providing the FDA with an opportunity to address the question, the court recognized that “[t]he FDA has regulatory authority over food labeling,” the FDCA “establishes a uniform federal scheme of food regulation to ensure that food is labeled in a manner that does not mislead consumers,” and food labeling “requires the FDA’s expertise and uniformity in administration.”⁸¹

The court agreed with the plaintiff’s position that there is “a gaping hole in the current regulatory landscape for ‘natural’ claims and GMOs.”⁸² Although the FDA has not addressed the question of whether foods containing GMO or bioengineered ingredients may be labeled “natural,” or whether those ingredients would be considered “artificial or synthetic,” the court concluded that the FDA is charged with resolving the issue. It thus referred to the FDA “the question of whether and under what circumstances food products containing ingredients produced using bioengineered seed may or may not be labeled ‘Natural’ or ‘All Natural’ or ‘100% Natural.’”⁸³ Otherwise, the court reasoned, it “would risk ‘usurp[ing] the FDA’s interpretive authority[,]’ and ‘undermining, through private litigation, the FDA’s considered judgments.’”⁸⁴

On January 6, 2014, the FDA responded to the court and declined the opportunity to address the issue.⁸⁵ In a letter from Leslie Kux, the FDA's Assistant Commissioner for Policy, the FDA cited several reasons for its refusal to define "natural."⁸⁶ First, it noted that amending its "natural" policy would likely involve "a public process, such as issuing a regulation or formal guidance," rather than an *ad hoc* decision made "in the context of litigation between private parties."⁸⁷ Acknowledging the complexity of the issue and the competing interests of various stakeholders, Ms. Kux stated that "it would be prudent and consistent with FDA's commitment to the principles of openness and transparency to engage the public on this issue."⁸⁸ The letter also noted that defining "natural" would require coordination and cooperation with the USDA and other agencies.⁸⁹ Reconsidering its "natural" policy would entail a consideration of scientific evidence, consumer preferences and beliefs, food production and processing methods, and First Amendment issues.⁹⁰ Finally, the FDA again noted its lack of resources and identified other priorities, such as regulations implementing the Food Safety Modernization Act of 2011 and nutrition labeling regulations.⁹¹

Although the FDA has refused to formally define the term "natural," it has sent a number of Warning Letters to companies who have violated the informal policy.⁹² For example, on April 3, 2012, the FDA issued an import alert against an Israeli "berry juice," citing, among other things, its claim of "natural" despite the inclusion of sulfur dioxide. In the letter, the FDA explained that although it "has not established a regulatory definition for the term natural[,] . . . the Agency has a long-standing policy that restricts the use of the term natural when a product is formulated with added color, synthetic substances, and flavors . . . that would not normally be expected to be in the food." Because the product contains "sulfur dioxide, which is listed in the ingredient statement as a preservative, . . . the product name can not [sic] include the term Natural."⁹³ As the following discussion of the "natural" lawsuits demonstrates, these Warning Letters have had little effect on curbing misleading use of "natural" claims.

2. "Natural" Lawsuits

The "natural" lawsuits generally target four categories of products: products containing artificial preservatives, products processed with chemicals or containing other unnatural ingredients, products containing HFCS, and products containing genetically modified organisms (GMOs).

Examples of lawsuits filed against companies whose products are labeled "natural" but contain artificial ingredients and preservatives include:

- Consolidated complaints against Kashi and Kellogg's alleged that these companies cultivated a wholesome and healthful image by promoting their products as "all natural" or containing "nothing artificial," when the products contained substances like ascorbic acid, calcium pantothenate, calcium

phosphates, potassium carbonate, pyridoxine hydrochloride, sodium acid pyrophosphate, sodium phosphates, tocopherols, and/or xanthum gum.⁹⁴

- Class-action lawsuits have been filed against Ben & Jerry's Homemade, Inc., on behalf of consumers who purchased Ben & Jerry's "all natural" ice cream products containing alkalized cocoa.⁹⁵ According to the Complaint, alkalized cocoa is "a non-natural processed ingredient" containing "potassium carbonate, a man made, synthetic ingredient."
- A lawsuit against Bear Naked, Inc., alleged that the company's products labeled "100% Pure & Natural" actually contain synthetic ingredients such as potassium carbonate, glycerin, and lecithin.⁹⁶
- South Beach Beverage Co. and PepsiCo, were sued by plaintiffs alleging that the companies market their SoBe beverages as "all natural" when they do not contain juice from any of the fruits described in their names and contain substances created by chemical processing, including ascorbic acid, cyanocobalamin, calcium pantothenate, niacinamide, and pyridoxine hydrochloride.⁹⁷
- Most recently, Whole Foods Market was accused of falsely advertising baked goods such as banana muffins, chocolate chip cookies and apple pie as being "all natural," even though they contain synthetic chemical ingredients such as sodium acid pyrophosphate and other synthetic ingredients such as maltodextrin.⁹⁸

Since 2007, class actions have been filed against the makers of AriZona beverages,⁹⁹ Snapple Beverage Corp.,¹⁰⁰ ConAgra Healthy Choice pasta sauces,¹⁰¹ and General Mills Nature Valley products¹⁰² for advertising their products as "100% Natural" when they contained HFCS. The Complaints allege that HFCS is "a highly processed sugar substitute that does not exist in nature."¹⁰³

The most recent wave of lawsuits has been filed against companies whose products contain GMOs and are advertised as "all natural." Although the FDA does not recognize any meaningful difference between GMOs and foods developed by traditional plant breeding and therefore does not require labeling of GMOs,¹⁰⁴ these lawsuits allege that GMOs are inherently unnatural. To support this allegation, several of the lawsuits cite to Monsanto's own definition of GMOs, as "[p]lants or animals that have had their genetic makeup altered to exhibit traits that are not naturally theirs. In general, genes are taken (copied) from one organism that shows a desired trait and transferred into the genetic code of another organism."¹⁰⁵ Examples of lawsuits include:

- Class-action lawsuits have been filed against General Mills, alleging the company engaged in a widespread marketing campaign to mislead consumers about the nature of the ingredients in its Kix cereals.¹⁰⁶ The lawsuit alleges that General Mills is able to command a premium for its cereals by deceiving customers into believing they are made with “All Natural Corn,” when the corn used in the cereals is actually derived from genetically modified plants.
- Lawsuits against Frito-Lay and PepsiCo claim that the companies’ Tostitos and SunChips products were not “made with all natural ingredients” because the corn and oils used to make them were made from genetically modified plants.¹⁰⁷
- ConAgra Foods was sued for including genetically modified corn and soy in the Wesson line of cooking oils which are labeled as “all-natural.”¹⁰⁸
- A lawsuit against Pepperidge Farm, Inc., alleged that the company misleads consumers by labeling its Cheddar Goldfish crackers “natural,” because they contain GMOs.¹⁰⁹

B. Misleading Claims Not Regulated by the FDA

Similar to the “natural” claims cases, plaintiffs have also filed lawsuits alleging misleading use of a variety of claims that are permitted, but not regulated by the FDA, such as “nutritious” and “wholesome.” For example:

- Plaintiffs alleged that Unilever falsely marketed its I Can’t Believe It’s Not Butter, Shedd’s Spread Country Crock, Brummel & Brown, and Imperial margarines as “nutritious,” “cholesterol free,” and “natural,” despite containing artificial trans fat.¹¹⁰ Plaintiffs also argued that Unilever made implied health claims by including the name of the popular health and nutrition website WebMD on the product’s label, suggesting that the product is nutritious and recommended by “MDs” when in fact there is a strong medical consensus against consuming any product containing artificial trans fat.
- Plaintiffs alleged that Kraft falsely markets Ritz Crackers, Original Premium Saltine Crackers, Ginger Snaps, and Teddy Grahams as healthful and “wholesome” despite containing trans fat, which is “highly toxic to human health.”¹¹¹
- In a lawsuit against Nutella, which settled in January 2012 for \$3 million,¹¹² plaintiffs alleged that consumers were misled by the claim that the spread is “an example of a tasty yet balanced breakfast.” This claim was allegedly deceptive

because it omits that the “balanced breakfast” is derived from the other foods or drinks which are depicted on the label, and Nutella contains high levels of saturated fat and over fifty-five percent (55%) processed sugar.¹¹³

- In a lawsuit against Quaker Oats, plaintiffs argued that claims such “wholesome,” “help your family fuel their busy days,” “quality,” “goodness in every bowl,” “will help you feel your best,” “All the Nutrition of a Bowl of Instant Oatmeal!,” and “Helps Reduce Cholesterol,” on labels of Quaker Oats’ Go Bars, Instant Quaker Oatmeal, and Quaker Chewy Bars are misleading because they include the unhealthy ingredient, partially hydrogenated oils (“PHOs”). In a recent settlement, although it disclaims any wrongdoing, Quaker agreed to remove PHOs from its products by the end of 2015 and will thereafter label any products containing trace amounts of PHOs as containing “dietarily insignificant amount of trans fat.”¹¹⁴
- Plaintiffs alleged that Tropicana falsely claimed that its “not-from-concentrate” orange juice is “100% pure” and “natural” orange juice; however, the product is “pasteurized, deaerated, stripped of flavor and aroma, stored for long periods of time before available to the public, and colored and flavored before being packaged.”¹¹⁵
- Plaintiffs brought suit against Hain Celestial Group Inc. alleging that the defendant’s “Unpasteurized,” “100% Raw,” and “Raw and Organic” labels on its BluePrint Juice and BluePrint Cleanse drinks mislead consumers because the high-pressure processing (HPP) with which the products are treated destroys “vital” enzymes and nutrients thus breaching “the fundamental principles underlying the raw food movement, consumers’ expectations and industry standards.”¹¹⁶ The FDA has not provided guidance regarding the labeling of an HPP-treated product.
- More than 50 lawsuits have been filed since 2012¹¹⁷ against food producers such as Chobani,¹¹⁸ Lifeway Foods,¹¹⁹ and Blue Diamond,¹²⁰ and Trader Joe’s¹²¹ for failing to list “sugar” or “dried cane syrup” in the ingredient section, but instead, referring to the ingredient as “evaporated cane juice” (ECJ) claims. Plaintiffs assert that these products are misbranded because the term is misleading and in violation of the FDA’s standard of identity regulations.

In 2009, the FDA issued “Draft Guidance” and sent Warning Letters advising companies that the agency considers the term ECJ to be false and misleading under the FDCA because it fails to reveal the basic nature of the food and its properties (i.e., that the ingredients are sugars

or syrups). The Draft ECJ Guidance, which contains nonbinding recommendations and do not establish legally enforceable responsibilities, also states that because “juice” is defined as liquid coming from a fruit or vegetable, and sugar cane is not considered a “vegetable” in the sense that a consumer considers eating vegetables as part of her diet, the term “evaporated cane juice” should not be considered “juice” as that term is defined in the regulations. Despite the Warning Letters and Guidance, the term is frequently used on a variety of products. Because the FDA did not reach a final decision on the common or usual name for this ingredient, the FDA announced on March 5, 2014 that it is reopening the comment period to request further comments, data, and information about the basic nature and characterizing properties of the ingredient sometimes declared as “evaporated cane juice,” how this ingredient is produced, and how it compares with other sweeteners.¹²²

C. Unsubstantiated Health and Nutrition Claims

Although the FDA's regulations require pre-approval of health claims made on foods and beverages, alleged violations of these regulations has provided fodder for food labeling litigation. One type of frequently alleged claim concerns misleading statements about the health benefits of the product.

- For example, CSPI sued Coca-Cola and Nestlé in 2007 for making fraudulent claims in marketing and labeling Enviga, an artificially sweetened green tea soft drink. Labeled “the calorie burner” on cans, Enviga was marketed as a weight-loss aid, with claims that it had “negative calories” and that it could “keep those extra calories from building up.” CSPI alleged that claims were made without prior substantiation and no evidence that most consumers would realize any calorie-burning benefit.¹²³ Following the filing of this lawsuit, approximately 28 state attorneys general investigated the claims and ultimately settled for \$650,000. Coca-Cola and Nestlé also agreed to add disclosures to Enviga, and any similarly formulated product, to disclaim any weight loss benefits and note that weight loss is only possible through diet and exercise.
- CSPI served as co-counsel to sue Coca-Cola over allegedly deceptive and unsubstantiated claims on its Vitaminwater line of beverages, which are labeled with words evoking health, such as “defense,” “rescue,” “energy,” and “endurance.” The beverages also claim to reduce the risk of chronic disease, reduce the risk of eye disease, promote healthy joints, and support optimal immune function. CSPI alleges that these claims are deceptive because the drinks contain a substantial amount of sugar and despite the full names of the drinks, such as “endurance peach mango” and “focus kiwi strawberry,” Vitaminwater contains between zero and one percent juice.¹²⁴

- Plaintiffs alleged false docosahexaenoic acid (DHA) brain health claims for Dean Foods' Horizon Organic Milk. Plaintiffs argued that DHA-fortified milk products do not support brain health in children or adults and Dean Foods also does not have competent and reliable scientific evidence to support its brain health representation. Although the company modified its radio, television, print and online advertisements following an FTC investigation of the "DHA Omega-3 Supports Brain Health" claim, Dean Foods has not changed product labels and packaging.¹²⁵
- CSPI has recently sent a demand letter to Smart Balance, Inc., identifying deceptive and illegal labeling and marketing practices of Smart Balance Blended Butter Sticks, whose labels claim in big print to "help block cholesterol." CSPI argues that the statement is an illegal disease-prevention claim as well as an illegal health claim. By marketing the sticks as preventing or treating hypercholesterolemia, CSPI alleges that under the FDCA, the products should be considered unapproved new drugs. While there is an FDA-approved health claim for some foods that do have plant sterol esters, CSPI claims that Smart Balance's Blended Butter Sticks do not contain enough of those sterols or certain beneficial nutrients, and have too much unhealthful saturated fat, to qualify. In its letter, CSPI invited Smart Balance to resolve the deceptive practices before it seeks legal action.¹²⁶

D. Unauthorized Nutrient Content Claims

Recent lawsuits have also challenged food manufacturers' use of nutrient content claims. Although the FDA has issued Warning Letters for violation of its nutrient content claim regulations, those Letters have had little to no effect on other manufacturers making similar claims. For example, on July 15, 2011 the FDA sent a Warning Letter to Natural Guidance, LLC informing the company that its claims regarding the benefits of Omega-3s in curing "Child depression, Breast, Colon, and Prostate Cancer," violated the FDCA because these disease treating claims can only be made on drugs.¹²⁷ The FDA also determined that the company made several unauthorized Omega-3 and antioxidant claims which did not meet the requirements for those type of claim as prescribed in the regulations. For example, the claim "30% More Antioxidants than Blueberries" on its Whole Food Bars failed to include the names of the nutrients that are the subject of the claim nor did they provide the names of the nutrients with recognized antioxidant activity in accordance with FDA's regulations.

A 2012 lawsuit against Bumble Bee alleged that similarly improper Omega-3 claims were made, which makes the products drugs under the FDCA, therefore requiring pre-approval by the FDA.¹²⁸ The plaintiffs also asserted that Bumble Bee made illegal nutrient content claims because FDA regulations prohibit claims that the product is a "good source" or "excellent

source” of a nutrient unless the nutrient has an established DV. Bumble Bee products labeled “Rich in Natural Omega-3” or “Excellent Source of Omega-3” are allegedly misbranded because, among other reasons, Omega-3 does not have an established DV.

The FDA has also sent several Warning Letters to companies regarding the unauthorized use of the nutrient content claim “no sugar added.”¹²⁹ However, these letters have not deterred other companies from violating the same regulations. In a lawsuit filed this January 2014, plaintiffs alleged that Nestle’s Eskimo Pies products are misbranded because the claim “no sugar added” on the products’ labels failed to meet the regulatory requirements. In particular, the FDA requires that unless an exception applies, “no sugar added” claims may be made only if two additional statements are included on a label: 1) that the product is not a “low calorie” or “calorie reduced” and 2) a statement that directs the consumer’s attention to the nutrition panel for more information on sugar and calorie content. Plaintiffs asserted that these requirements were not met, thereby constituting a violation of federal and state law.¹³⁰

Although in 2010 the FDA warned Beech-Nut Nutrition Corporation that Beech-Nut that claims on its baby and toddler foods were unauthorized nutrient content claims,¹³¹ competitor Gerber was sued in 2012 for making similar claims.¹³² The plaintiff alleged that Gerber, which reportedly controls between 70 and 80 percent of the baby food market in the United States, makes nutrient content claims such as “healthy” on virtually all Gerber food products, despite the fact that the FDA does not allow nutrient content claims on foods for children under age two. Plaintiffs also alleged that many of Gerber’s products that are labeled with a “No Added Sugar” or “No Added Refined Sugar” nutrient content claim contain sufficiently high levels of calories that FDA’s regulations requires that the claims be accompanied by a disclosure statement warning of the higher caloric level of the products.¹³³ Because Gerber does not place a disclosure statement on food products requiring a disclosure statement, the plaintiff asserts that Gerber’s product labels violate federal and state laws.¹³⁴

These recent lawsuits reveal that consumers and food manufacturers require the FDA’s guidance regarding unregulated common labeling claims such as “natural,” and the FDA’s enforcement of flagrant labeling violations.

CLOSING THE GAPS IN REGULATORY ENFORCEMENT

The FDA must address, not avoid, key food labeling controversies that have been exposed by the food labeling lawsuits. The following is a list of recommendations for FDA regulatory reform.

1. The FDA should define misleading terms such as “natural” to achieve uniformity and consistency for consumers and food manufacturers.

Consumers' inherent lack of knowledge about food ingredients, food technology, food ingredient terminology, and marketing claims places them at a disadvantage when trying to evaluate the “naturalness” of a product or ingredient. Therefore, consumers should be able to rely on the FDA to provide food manufacturers with clear regulations about how the term “natural” may be used. The FDA's 1993 policy addressing “added color, artificial flavors or synthetic substances” fails to resolve issues regarding HFCS, enriched flour, modified starch, partially hydrogenated vegetable oils, organic solvents such as hexane, genetically engineered ingredients, and pesticides. As the FDA has recognized, its longstanding policies on “natural” claims have been challenged by advances in food processing and in packaging methods. As manufacturers continue to develop new ingredients and methods of processing foods, determining whether a food is “natural” will become even more complex.¹³⁵ It is within the FDA's purview to address the question of what constitutes a “natural” ingredient, so that the term may be used consistently by manufacturers.

GM ingredients are at the heart of many of the “natural” class-action labeling suits against food manufacturers. Although the FDA does not recognize any meaningful difference between GMOs and foods developed traditionally, the lawsuits allege that GMOs are unnatural. The FDA should provide more definitive guidance to food producers and it should revisit its non-binding 2001 draft guidance on voluntary GMO labeling.¹³⁶ The FDA has stated that it is currently reviewing its regulation of GMOs and its position on labeling; however there is no indication that the agency is actively undertaking this pressing task.¹³⁷

GMO labeling is a controversial issue that demands that FDA's expertise and attention. Otherwise, federal judges or state legislatures will be making determinations about the naturalness of GMOs in regards to food labels. In the absence of clear guidance from the FDA, the issue of whether food containing GMOs may be labeled “natural” has been addressed by several state legislatures in bills requiring the labeling of GMO foods. On April 23, 2014, Vermont became the first state to require labeling of all foods containing genetically engineered ingredients. Connecticut and Maine have also enacted such laws, but the labeling laws in both states are contingent upon several requirements. Labeling laws have also been proposed in twenty-six states. For example, GMO labeling bills proposed in Indiana¹³⁸ and Massachusetts¹³⁹ would prohibit GMO foods from being labeled as “natural.” According to Connecticut's new law, “ ‘natural food’ . . . has not been treated with preservatives, antibiotics, synthetic additives, artificial flavoring or artificial coloring” “has not been processed in a manner that makes such food significantly less nutritive;” and “has not been genetically-engineered.”¹⁴⁰ A food that is processed “by extracting, purifying, heating, fermenting, concentrating, dehydrating, cooling or freezing shall not, of itself, prevent the designation of such food as ‘natural food.’ ”¹⁴¹ California's defeated Genetically Engineered Foods Labeling

ballot initiative, Proposition 37,¹⁴² also prohibited the labeling of foods containing GMOs as “natural,” but its standard went further and could be interpreted as prohibiting the labeling or advertising any processed food as “natural.”¹⁴³ This definition of “natural” would have conflicted with the standard in Connecticut. “Processed food” was defined to mean “any food other than a raw agricultural commodity, and includes any food produced from a raw agricultural commodity that has been subject to processing such as canning, smoking, pressing, cooking, freezing, dehydration, fermentation, or milling.”¹⁴⁴ Such a strict standard for “natural” would prohibit smoked almonds or frozen vegetables, for example, from being labeled as “natural.”

These state attempts to define “natural” exemplify the inconsistencies that will result if the FDA leaves this issue to be addressed by courts or legislatures. As the Food Marketing Institute recently announced, a national uniform standard for non-GMO food products is required to avoid “inconsistent and confusing pitfalls of a state-by-state patchwork of GMO labeling system.”¹⁴⁵ Despite the costs and challenges, the FDA has the statutory mandate and expertise to codify the term’s meaning, identify conditions of its use, and specify labeling requirements for “natural” claims.

2. The FDA should address the misleading nature of health and nutrition claims and revise its regulations accordingly. Although the research conducted by the FDA and other groups proves that consumers are confused about these claims, the FDA has not increased its enforcement efforts.

In 2011, the Government Accountability Office (GAO) investigated the FDA’s oversight of qualified health claims and structure/function claims. The report concluded that consumers find it difficult to understand the differences between qualified health claims and health claims with significant scientific agreement. Accordingly, the FTC has stated that qualified claims based on evidence that is inconsistent with the majority of scientific evidence could potentially mislead consumers and, therefore, are likely to violate the FTC Act.¹⁴⁶ The American Medical Association has also vigorously objected to the use of qualified health claims on foods because research demonstrates that qualifying language does not remedy the possible deceptiveness of qualified health claims. The FDA should reexamine its position regarding the use of qualified health claims in light of considerable evidence of consumer confusion.

Consumers have similar difficulties understanding the differences among health, structure/function, and other health- and nutrient-related claims.¹⁴⁷ For example, a study conducted by the AARP revealed that more than a third of the respondents could not distinguish between health claims and structure/function claims. When asked to compare “calcium reduces the risk of osteoporosis” (which is a health claim) and “calcium builds strong bones” (a structure/function claim), thirty-eight percent (38%) of respondents thought the claims had the same

meaning.¹⁴⁸ As discussed above, the FDA pre-approves health claims, but does not authorize or pre-approve structure/function claims. Furthermore, the FDA has not indicated the level of scientific support needed to prevent false or misleading information for this type of claim. Because consumers cannot distinguish between structure/function claims and health claims for foods, the FDA should develop clear rules for the use of structure/function claims and should also apply the significant scientific agreement standard to these claims. Requiring pre-approval of structure/function claims could also help protect consumers from deceptive use of these claims.

3. The FDA should increase its monitoring and enforcement of labeling practices.

Policing labeling violations is the responsibility of the FDA, not plaintiffs' attorneys. To properly fulfill its statutory mission, the FDA will require an increased budget and the political will to monitor the marketplace. As the above discussion of labeling litigation has demonstrated, the FDA's Warning Letters have had little to no success in deterring companies from violating the FDCA and its regulations. The FDA should increase its enforcement efforts to monitor misleading claims.

Unlike the FTC, which may compel food companies to substantiate claims by providing the scientific support for statements made in advertisements,¹⁴⁹ the FDA bears the burden of proving that a structure/function claim, which does not require FDA's pre-approval, is false or misleading without having the authority to compel companies to produce the evidence asserted by companies as support for their labeling claims.¹⁵⁰ Unless the FDA obtains authorization from Congress to require substantiation for claims, it will be costly and time consuming for the FDA to establish whether structure/function claims are supported by scientific evidence. However, because the line between labeling and advertising is often blurred and the misleading claims may be made on the label, on a company's website, in print, and on television, the FDA could work more closely with the FTC to monitor these claims. As discussed above, developing clear rules for the scientific support required for structure/function claims would also help food companies understand the requirements for asserting these claims.

Although the FDA has been given an inspection mandate for the first time under the Food Safety Modernization Act, the legislation requires inspections to be based on food safety risk. While "high risk" facilities will be inspected once every three years, all other domestic food facilities must be inspected at least once every five years. Inspections conducted this infrequently will be unlikely to keep the FDA current on labeling practices. The FDA should develop a system for monitoring labeling violations of products on supermarket shelves in addition to routine company inspections, when food safety issues are primarily at issue. The FDA should also conduct consumer research on common claims, such as "wholesome," "pure," and "simple" to understand consumer expectations and whether the products bearing these claims meet these expectations. This research can be used to determine which claims are misleading.

As the GAO recommended in its 2011 report, FDA inspectors must be better trained to review food labels.¹⁵¹ Although the *Compliance Program Guidance Manual*, which provides instructions for inspectors, contains the requirements for the nutrition facts panel, identifies allergens that must be declared, and identifies the statute and regulations for health and nutrient content claims, it does not provide instructions to help inspectors identify potentially false or misleading structure/function claims on food. FDA can provide inspectors with more specific instructions on how to identify potentially false or misleading claims.

CONCLUSION

Certainly, food manufacturers are responsible for the claims they make on their products. However, in the absence of clear FDA guidance on certain issues such as what level of scientific support is required for structure/function claims, what constitutes a “natural” product, and whether GMOs should be labeled, both consumers and food producers are confused. Clarity from the FDA is required for food producers to understand the rules, and enforcement by the FDA is necessary to ensure a level playing field in the marketplace.

Ultimately, litigation should be unnecessary if the FDA is funded and properly staffed to fulfill its regulatory mission—to protect consumers from misleading claims on food labels. In the absence of effective regulatory enforcement action against food and beverage manufacturers making misleading claims, consumer protection groups and plaintiffs’ attorneys have stepped in to fill a void. However, regulation by litigation is a costly and slow process that is unlikely to affect widespread change. Furthermore, ceding authority over food labeling to judges is contrary to the Nutrition Labeling and Education Act’s purpose of establishing uniform food labeling laws. Failure to enforce regulations and monitor the marketplace for deceptive and misleading labeling undermines Congress’ intention to provide consumers with truthful food labeling information that enables them to make healthy food choices.

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