Historically, dietary supplement companies faced legal enforcement actions only from federal agencies. Now, the threat of consumer-based, attorney-driven class-action lawsuits has emerged. This article explains why and tells you how to avoid such litigation.

In October 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA). Since then, the supplement industry has faced its share of scrutiny. The FDA—which enforces DSHEA and the rest of the Federal Food, Drug and Cosmetic Act (FFDCA)—wields authority over issues ranging from foreign-sourced products adulterated with tainted ingredients to compliance with current Good Manufacturing Practices (cGMP) required of all companies as of June 2010.

Congressional critics of the dietary supplement industry continue to introduce legislation to dilute DSHEA and impose stricter regulations. Meanwhile, dietary supplement companies are facing a new threat: class-action litigation over labeling and advertising claims.

Class-action litigation has exploded in scope and frequency in the past decade, with businesses of all sorts scrambling to avoid becoming the next target. Dietary supplement companies are no exception. Historically, the FDA and the Federal Trade Commission (FTC) handled legal action against supplement companies. But now the industry is being hit with civil litigation. Owing chiefly to some plaintiffs’ receipt of quick settlements from companies wishing to avoid protracted litigation, class-action lawyers have taken the reins and have, in effect, begun to “regulate” labeling claims in the courtroom.

California: Class-action epicenter

As actions have been filed across the country during this boom in civil litigation, no place has been hit harder than California, the veritable epicenter of class-action lawsuits over advertising and labeling claims. Why? Primarily because of three state statutes (details below), designed to address unfair, deceptive, and fraudulent acts. Class-action suits are often filed under at least one—and more often two—if not all three of these laws, which are extremely broad and provide a range of remedies for consumer plaintiffs and their attorneys.

California Consumers Legal Remedies Act. CLRA sets forth specific unlawful methods of competition and unfair or deceptive acts or practices undertaken in connection with the sale or lease of goods or services to consumers [1]. Such forbidden practices include representing goods as having characteristics, ingredients, uses, benefits, or qualities which they do not [2] or using deceptive representations or designations of geographic origin [3]. The CLRA is especially attractive because it allows consumers to obtain actual monetary damages, restitution of property, punitive damages, court costs and attorney’s fees, and any other relief deemed appropriate.

Unfair Competition Law. UCL is broadly written and includes five definitions of unfair competition, including: 1) an unlawful business act or practice; 2) an unfair business act or practice; 3) a fraudulent business act or practice; 4) unfair, deceptive, untrue, or misleading advertising; or 5) any act prohibited by Sections 17500-17577.5 of the California Business and Professions Code [4].
bring a claim, a plaintiff must show that the defendant(s) engaged in such activity and that the plaintiff(s) suffered “injury-in-fact,” losing money or property. Remedies allow both monetary damages and injunctive relief.

**False Advertising Law.** FAL is similarly broad and makes it unlawful for any person, firm, corporation, association, or employee of those entities to make any statement concerning goods or services that is untrue or misleading [5].

### Targeted claims

While the “state of litigation,” figuratively and literally, centers on California, class-action lawsuits are a threat to dietary supplement companies across the country. Below are examples of a few of the frequently targeted claims that illustrate the importance of knowing if your claims are legitimate and evaluating whether the anticipated reward of making such claims outweighs the risk of litigation.

**“Natural” litigation.** “All natural,” “100 percent natural,” and similar label claims have been the prevailing subjects of class-action suits in the past several years. A consumer-advocacy group, Center for Science in the Public Interest, ignited the controversy over these claims in 2002 when it asked the FDA to take action against a prominent American ice cream manufacturer for labeling some of its products “all natural.” The focus then switched to marketers of various beverage products containing high-fructose corn syrup, also labeled “all natural.” Today, the swath cut by “all natural” litigation is substantially wider.

While food and beverage products are most often the targets of such lawsuits, dietary supplements are in the crosshairs, too. Liquid supplement products in particular—i.e., those containing synthetic preservatives, processed ingredients, extracted ingredients, and, more recently, genetically modified organisms (GMOs)—are at substantial risk.

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The lack of a clear, formal definition has paved the way for a steady stream of plaintiffs to file class-action lawsuits over the use of “natural” and “all natural” claims and, without such a definition, these cases can take years to resolve. Plaintiff lawyers are well aware of this and count on defendants settling quickly to avoid the costs and hassle.

**False claims/lack of substantiation.** Lawsuits alleging that claims are unsubstantiated and therefore false have been filed with increasing frequency over the last year or two. Both the FDA and FTC require that any material health claims be substantiated by “competent and reliable scientific evidence.” But again, there is no clear definition of what constitutes the standard of “competent and reliable scientific evidence.” It has been defined in various FTC cases as “tests, analyses, research, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons that are generally accepted in the profession to yield accurate and reliable results” [7]. The “gold standard” of scientific evidence is generally recognized as a double-blinded, placebo-controlled, (human) clinical trial. But the FTC states that this “gold standard” is not its official standard and that evaluation must be handled case by case. Lately, however, many consent decrees between the FTC and industry have included the requirement of two double-blinded, placebo-controlled, clinical trials to support health claims.

While there is no specific private right of action for lack of substantiation, many actions that are essentially lack-of-substantiation lawsuits are brought about under the guise of false or misleading claims. Lawsuits against dietary supplement companies over product efficacy and alleged lack of substantiation have included a wide range of claims. At the top of the list are weight-loss claims, targeted by federal agencies and private litigants alike. Body-building products that purportedly increase muscle mass and performance have also been the subject of numerous class-action lawsuits. More recently, companies marketing supplements containing glucosamine and chondroitin to rebuild cartilage have been targeted. These cases demonstrate that companies not only have the FDA and the FTC to worry about, but civil litigants as well.

**Failure to warn of alleged dangerous or unsafe ingredients.** On April 27, 2012, the FDA announced that it had issued warning letters to 10 manufacturers and distributors of dietary supplements containing dimethylamylamine (DMAA). The agency asserted that DMAA is a new dietary ingredient that required notification to be filed before it could be used. Yet no such notification had been filed by any of the companies receiving the warning letters. The FDA indicated that it had serious concerns about the safety of DMAA, prompted in part by numerous adverse reports from military personnel consuming supplement products with DMAA. By the following
Tuesday, all 10 recipients of the warning letters were hit with putative class-action complaints filed in California, alleging that the defendant companies failed in their advertising to mention the risks associated with their products or warn of potential adverse effects. This is just one example of plaintiff lawyers taking their cue from the FDA and using warning letters or regulatory action as a green light for a class-action lawsuit.

A case was brought to federal court in California in 2009 against the marketer of an energy supplement product for allegedly failing to properly warn consumers of potential adverse events. In that case, the plaintiff alleged that the company failed to disclose risks associated with key ingredients, such as yohimbine, vinpocetine, tyrosine, and 5-hydroxytryptophan. Among the complaints were claims for breach of implied warranty and fraudulent concealment. In February 2012, the California federal judge refused to certify the class action, finding that the named plaintiff and his lawyers were inadequate to represent the class, in large part because the plaintiff admitted that he failed to read the warning on the product’s label. Before the year was out, a plaintiff filed a new putative class-action lawsuit against the same company in federal court in Florida, alleging that he was hospitalized as a result of the company’s failure to warn consumers of the alleged dangers associated with using its products. The Florida action includes claims for violation of Florida’s Deceptive and Unfair Trade Practices Act and the Magnuson-Moss Warranty Act, as well as common law claims for unjust enrichment and breach of warranty. (A motion to certify the class is currently pending.)

**Nutrient-content claims.** Nutrient-content claims—the most frequently cited in FDA warning letters over alleged labeling issues—have likewise been the cue for class-action lawsuits. Plaintiffs in California and other states have filed complaints disputing claims ranging from “no added sugar” and “zero calories” to “good source of calcium” and “rich in antioxidants.”

Nutrient-content claims are those that expressly or implicitly characterize the amount of a nutrient in a conventional food, beverage, or dietary supplement [8]. Nutrient content claims may only be made as authorized in 21 CFR 101.13 and the other claim regulations found at 21 CFR 101.54-21 CFR 101.65. Claims that indicate that a product is “rich in,” “high in,” or an “excellent source of” a particular nutrient (e.g., “rich in protein” or an “excellent source of vitamin C”) may be legally made only if the product contains 20 percent or more of the Daily Reference Value (DRV) for protein. Other authorized nutrient content claims include those that say a product is a “good source of” a nutrient [10], “low calorie” [11], or contains “no added sugar” [12].

In many cases, you can avoid actions involving alleged improper nutrient-content claims by reviewing the labeling in advance to ensure that such claims comply with the applicable regulations.

**Evaluating the risks**

In this age of class-action litigation, there is unfortunately no surefire way to protect yourself from a lawsuit. With little risk to plaintiff attorneys for bringing actions—even those that are ultimately dismissed—and with the potential for big settlements, the incentives to file suit have never been greater. It is thus imperative that you review all labeling and advertising and fully understand what claims you are making and the risks associated with them. Don’t rely on copying another company’s claims. With no premarket approval required for labeling, seeing someone else’s products on the shelves is no guarantee that their claims are necessarily compliant and immune from litigation. Each company must perform its own internal audits of claims or hire a consultant knowledgeable in labeling and advertising to review all claims. That way, you can make informed decisions about whether the benefits of a particular claim are worth the risk of litigation.

**References**

1. California Civil Code §§ 1750 et seq.
6. 58 Federal Register 2302, 2407 (January 6, 1993).
9. 21 CFR 101.54(b).
10. 21 CFR 101.54(c).
11. 21 CFR 101.60(b)(2).
12. 21 CFR 101.60(c)(2).

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