Not a Food, but Not Yet a Drug

Dietary Supplement Litigation and the Role of FDA

By Sarah A. Westby and Sarah E. Carlow

Dietary supplement use has exploded over the past decade, with products such as probiotics, collagen protein, and CBD oil flooding the market. According to the 2018 Council for Responsible Nutrition (CRN) Consumer Survey on Dietary Supplements, 75 percent of Americans report using dietary supplements. Yet the U.S. Food and Drug Administration (FDA) has limited oversight over the supplement industry. These factors have created a space ripe for consumer and product liability litigation.

The FDA currently classifies dietary supplements as foods, rather than drugs. Drugs are defined by their use; that is, they are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," whereas foods and dietary supplements are defined by their ingredients. *See Human Drugs,* Regulated Products, U.S. Food & Drug Admin., https://www.fda.gov. The regulations that are applicable to dietary supplements, however, contain elements of both. Clinical trials are not required for supplements, but manufacturers must satisfy specific labeling requirements and obtain pre-approval for certain labeling claims. *See* Dietary Supplement Health and Education Act of 1994, Pub. L. 103-417 (DSHEA); 62 Fed. Reg. 49,826 (Sept. 23, 1997); 63 Fed. Reg. 30,615 (June 5. 1998). While the current regulatory scheme benefits supplement manufactures from a cost perspective, supplement manufacturers cannot get or rely on a pre-sale determination that their product is safe and effective for use, or that the label meets FDA requirements.

Regulations pertaining to dietary supplements fall into three principal categories: labeling, claims, and Current Good Manufacturing Practices (CGMP). A supplement manufacturer must identify the product's contents, the quantity of certain ingredients, and the name and place of business of the manufacturer, packer, or distributor on the label. *See* Dietary Supplement Labeling Guide, U.S. Food & Drug Admin. (Apr. 2005, content current as of Sept. 20, 2018), https://www.fda.gov. The FDA requires premarket notification only if the dietary supplement contains a "new dietary ingredient," defined as an ingredient that was not marketed in the United States before October 15, 1994. *Id*. at ch. VII.

The FDA also regulates the types of claims that supplement manufacturers can make on the label. Claims generally fall into three categories: nutrient content claims, structure/function claims, and health claims. Nutrient content claims characterize the level or value of a nutrient in a supplement, such as "good source of" and "high in." *Id*. at ch. VI. Manufacturers may only use the specific nutrient content claims set forth in 21 C.F.R. §101, subpart D. Structure/function claims describe the role of a substance in maintaining the structure or function of the body. 21 U.S.C. 343(r)(6). Notably, a structure/function claim does not require preapproval by the FDA. A structure/function claim cannot be misleading and must include a disclaimer that the statement has not been evaluated by the FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. 21 C.F.R. §101.93. A health claim describes the effect that a supplement has on reducing the risk of or preventing a disease, *e.g.*, "calcium may reduce the risk of osteoporosis." This type of claim requires prior authorization from the FDA and "significant scientific agreement" that the claim is supported by evidence. 21 C.F.R. §101.14(a)(1) & (c).

Finally, supplement manufacturers must comply with CGMP to reduce the likelihood of mislabeling, misrepresentations, and contamination. *See* Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 21 C.F.R. §111, (May 8, 2007) (Dietary Supplement CGMP). The Dietary Supplement CGMP contain a number of testing and reporting requirements, but do not require FDA review or approval of test results or procedures before sale. Rather, the FDA reserves the right to issue a warning letter or to remove a product from the market if issues arise post-sale.

The current regulatory framework presents several pitfalls for supplement manufacturers. First, such a busi-

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ness must consider the threat of product liability litigation due to contamination. The FDA does not conduct regular inspections of manufacturing and packaging facilities, and it does not review batch-manufacturing records or test results pre-sale. *See* Dietary Supplement CGMP, 21 C.F.R. §111. As with drugs, liability due to adverse events from a dietary supplement can be catastrophic. *See, e.g., Navitas LLC v. Health Matters America, Inc.*, No. 16-CV-699V, 2018 WL 1317348, at *1 (W.D.N.Y. Mar. 14, 2018) (involving a salmonella outbreak from contaminated chia seed powder). Unlike drugs, however, there is no mechanism to root out adulteration before sale.

Ambiguity in FDA regulations regarding health claims, coupled with a patchwork of state laws and inconsistent case law, leaves dietary supplement manufacturers vulnerable to consumer suits, as well. In *Mullins v. Premier Nutrition Corporation*, for example, the court denied a supplement manufacturer's motion for summary judgment, finding sufficient evidence that claims that the product "helps keep cartilage lubricated and flexible" and "hydrate[s] and lubricate[s] your joints" were misleading because they created an implied message that the product helped alleviate joint pain. 178 F. Supp. 3d 867, 891 (N.D. Cal. Apr. 15, 2016). In contrast, the court in *In re Bayer Phillips Colon Health Probiotics Sales Practices Litigation* granted a manufacturer's motion for summary judgment, finding insufficient evidence to prove that the probiotic product's claims were false or misleading. The claims included statements that the product "promote[s] overall digestive health" and "helps defend against occasional constipation, diarrhea, gas and bloating." No. 11-CV-03017, 2017 WL 1395483, at *12 (D.N.J. Apr. 18, 2017). As these cases demonstrate, courts have discretion in determining the level of scientific support sufficient to substantiate a claim, and they may even find liability for *implied* claims.

The prevalence of dietary supplement use has increased pressure on the FDA to take a more active role in regulating the supplement industry. *See* Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on Efforts to Strengthen Dietary Supplement Regulation (Feb. 11, 2019). While additional regulations will likely increase costs to manufacturers, there are potential benefits in terms of risk mitigation and preemption of legal claims.