Ninth Circuit affirms summary judgment in favor of dietary supplement manufacturer in deceptive labeling class action

January 23, 2019

The US Court of Appeals for the Ninth Circuit recently affirmed a California district court's grant of summary judgment for defendants NBTY, Inc. and Nature's Bounty, Inc. Plaintiff Paul Dachauer alleged that defendants' vitamin E supplements violated California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 and Consumers Legal Remedies Act, Cal. Civ. Code § 1770 in that they claim to "support cardiovascular health" and "promote [] immune function," "immune health," and "circulatory health."

The FDA allows manufacturers of supplements to make general claims—such as "promotes heart health"—and to substantiate them with evidence that a supplement has some structural or functional effect on a given part of the human body. 65 Fed. Reg. at 1012. The Federal Food, Drug, and Cosmetic Act (FDCA) distinguishes between "disease claims" and "structure/function" claims that manufacturers make about their products. A structure/function claim describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." 21 U.S.C. § 343(R)(6). Conversely, a disease claim "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly. 21 C.F.R. § 101.93(G)(2)(II).

The Ninth Circuit held that § 343-1(a)(5) of the FDCA preempts plaintiff's state law claim that defendants' advertising claims are false or misleading because their supplements do not prevent cardiovascular disease. Defendants did not claim that their supplements treat or prevent cardiovascular disease. The court also noted that by definition, defendants' *structure/function* claims "*do not*" and " *may not* claim to diagnose, mitigate, treat, cure or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6). Nevertheless, plaintiff sought to require proof that the vitamin E supplements treat or prevent cardiovascular disease. The Court found, however, that such a requirement is not identical to the requirement of § 343(r) and is therefore preempted under § 343(1)(a)(5) of the FDCA.

The Court also held that the FDCA preempted plaintiff's state law claim that defendants' labels stating that their supplements promote immune health, were false and misleading because the supplements failed to *reduce* all-cause mortality. The Court found that plaintiff's claim was preempted because manufacturers are not required to substantiate structure/function claims about immune health with proof that their supplements reduce the risk of all-cause mortality. 21 U.S.C. § 343(r)(6).

Finally, the court also considered whether defendants' claim that their supplements promoted immune health was false and misleading because the supplements allegedly *increased* the risk of all-cause mortality. The Court noted that this part of plaintiff's claim was not preempted because the FDCA and California law both require disclosure of an increased risk of death. However, because plaintiff failed to offer evidence that vitamin E supplements were "actually harmful," as opposed to "simply useless," in promoting immune health, plaintiff failed to create a genuine issue of material fact as to whether the immune-health claim was misleading. As a result, the Ninth Circuit affirmed defendants' summary judgment.

We shall see if this decision deters the plaintiffs' bar from bringing deceptive labeling suits against dietary supplement

makers, at least where the labeling simply describes the role of the dietary ingredient (as opposed to claiming to mitigate a specific disease) or when the supplement is just “useless,” rather than “harmful.”

---

1 Dachauer v. NBTY, Inc., No. 17-16242, (9th Cir. Jan. 10, 2019)

2 *Structure/function claims* must meet three requirements: (1) the manufacturer has substantiation that the statement is truthful and not misleading; (2) the statement contains a prominent disclaimer that the Food and Drug Administration (FDA) has not evaluated the statement and that the product “is not intended to diagnose, treat, cure, or prevent any disease”; and (3) the statement itself does not “claim to diagnose, mitigate, treat, cure, or prevent” disease. 21 U.S.C. § 343(r)(6).

Your Key Contacts

Bety Javidzad
Partner, Los Angeles
D +1 213 623 9300
bety.javidzad@dentons.com

Michael J. Duvall
Partner, Los Angeles
D +1 213 892 2818
M +1 314 570 2382
michael.duvall@dentons.com

Avedis Bekhloyan
Associate, Los Angeles
D +1 213 243 6041
avedis.bekhloyan@dentons.com