Up & Up & Out. Structure/Function Claims Preempted by the FDCA

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Last week, in a substantial win for the dietary supplement industry, the Ninth Circuit Court of Appeals upheld the Northern District of California's grant of summary judgment to Target, ruling that state law false advertising challenges to permissible structure/function claims are preempted by the Federal Food, Drug and Cosmetic Act ("FDCA").

Plaintiff Todd Greenberg alleged that he bought a bottle of Up & Up Biotin, a private label vitamin sold by Target, as part of his battle with hair loss. Up & Up Biotin's label states that biotin "helps support healthy hair and skin." The label also states that "[t]his statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Greenberg conceded that biotin is a nutrient that supports healthy hair and skin, but nevertheless claimed the label was misleading because most people obtain all the biotin they need from their diet, rendering the vitamin superfluous to all but a tiny percentage of people who have a biotin deficiency.

Under the FDCA, dietary supplement labels are required to be truthful and not misleading. The statute also authorizes certain categories of statements, including structure/function claims, provided they are adequately substantiated. As a general matter, structure/function claims "describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function[.]" 21 C.F.R. § 101.93(f). Statements suggesting an ingredient's ability to "strengthen," "improve," or "protect" a structure or function in the human body are structure/function claims so long as they do not suggest disease prevention or treatment. The FDCA was intended to establish a national and uniform labeling standard for dietary supplements, expressly preempting any state law labeling requirement "that is not identical to" the labeling requirements in the FDCA.

The Ninth Circuit affirmed the District Court's ruling that Up & Up Biotin's label satisfied all of the statutory requirements for a structure/function claim under the FDCA, namely that: (1) there was substantiation for the claim, (2) the label included the proper disclosures, and (3) the label did not suggest the product could treat diseases. More specifically, and in contrast to a disease claim, the FDCA "only requires substantiation for *the ingredient's* function on the human body, not the health impact of the product as a whole." In other words, "manufacturers may make structure/function claims about a nutrient's general role on the human body without disclosing whether the product will provide a health benefits to each consumer."

Accordingly, the Court found that the plaintiff's state law false advertising claims "essentially

s[ought] to impose an additional requirement that dietary supplement labels can make structure/function claims only if consumers are likely to benefit from the product." Because this requirement "is not identical to" the labeling requirements in the FDCA, the claims were preempted.

Dietary supplement companies are often targeted by class action plaintiffs asserting various theories about how carefully-drafted label claims are nevertheless deceptive to the proverbial "reasonable consumer." This decision brings a new level of comfort to the industry that if a structure/function claims complies with the FDCA, it is less likely to be challenged (at least in the Ninth Circuit).