

Dietary Supplement Makers Achieve Preemption Win in 9th Circuit

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The Ninth Circuit recently found that federal law preempted a consumer's state law causes of action regarding the labeling of a hair health dietary supplement. *Greenberg v. Target Corp.*, 2021 WL 116537 (9th Cir. Jan. 13, 2021). The plaintiff, experiencing hair loss, consumed the supplement biotin to stimulate hair growth. He argued that biotin's labeling claim ("it 'helps support healthy hair and skin'") was misleading because "most people obtain enough biotin from their regular diets and thus this product provides no health benefit for them." *Id.* at *1. He brought a putative class action with causes of action "under California's Unfair Competition Law ... and California's Consumers Legal Remedies Act" against certain manufacturers of biotin on this basis. *Id.* at *2.

The Ninth Circuit agreed with the district court that these state law causes of action were preempted by the Federal Food, Drug, and Cosmetic Act. The FDCA expressly permits manufacturers to make certain labeling claims about dietary supplements. In particular, "[t]he FDA [] allows the product labels to feature so-called 'structure/function' claims that describe the role of a nutrient or ingredient on the structure or function of the human body." *Id.* at *1. For example, "a vitamin product can tout that 'calcium supports strong bones' because scientific evidence backs that claim, even if not everyone needs or benefits from more calcium." *Id.*

Structure/function claims must meet three requirements: (1) the claim has substantiation and is accurate, (2) the claim must include appropriate disclosures that the FDA did not evaluate the statement, and (3) the statement cannot include a claim to treat diseases. *Id.* at *3. The court found that the biotin labeling met all three requirements. *Id.* at *3, *5.

With regard to the first requirement—substantiation and accuracy—the Plaintiff argued that "a mega-dosage of biotin benefits only a tiny percentage of the public with biotin deficiency," and therefore, the labeling on the particular product issue "is misleading for most people." *Id.* at *4.

The Ninth Circuit found that "the plain language of the statute makes clear that a structure/function claim addresses only the nutrient's role in the human body, not the product's health impact on the general population." *Id.* at *1. Here, it was undisputed "that scientific evidence exists showing that biotin ... supports health hair and skin." *Id.* at *4. Thus, the plaintiff's "state law claims challenging the biotin product's efficacy [were] preempted because the [FDCA] only requires substantiation for *the ingredient's* function on the human body"—i.e., biotin supports hair and skin—"not the health impact of the product as a whole" on conditions in the general population. *Id.*

The plaintiff’s claim that the statement violated “the FDCA’s general prohibition against false or misleading statements” also failed. *Id.* at *5. The plaintiff argued that the statement was misleading “because very few people have biotin deficiency and thus would not benefit from the product.” *Id.* But the court found that such a reasoning would conflict with the purpose of allowing for structure/function claims, and “virtually any structure/function claim for dietary supplements would potentially be misleading to the great majority of people.” *Id.* (providing the example that “calcium helps maintain bones’ would be misleading to most consumers because an extra dosage of calcium would be superfluous for them”).

The label also easily satisfied the other two requirements for a structure/function claim by disclosing that the FDA had not evaluated the statements, and stating that the product was not meant to diagnose, treat, cure, or prevent any disease. *Id.*

Overall, this decision supports the conclusion that “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 benefit to each consumer.” *Id.* For any questions, please contact Matthew Saxon, or your Winston relationship attorney.

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