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Timely commentary from WLF's blog May 18, 2023

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Which Is to Be Master? A Preemption Win in the Dietary Supplement Space

by Katie Bond & Samuel Butler

"The question is," said Alice, "whether you *can* make words mean so many different things." "The question is," said Humpty Dumpty, "which is to be master—that's all."

A recent Ninth Circuit decision holds that the FDA is to be master of the "common or usual name" of dietary ingredients in a supplement, precluding state law claims that a product's name is misleading when the product is named in accordance with FDA requirements. There was no dispute that FDA requirements applied to the identification of ingredients in the supplement facts panel; what the majority's decision does is to confirm that the Food, Drug, and Cosmetic Act permits a company to use those same standards in identifying active ingredients on the front of the label, as well—including in the product's name.

Hollins v. Walmart involves a supplement Walmart has sold as "glucosamine sulfate" or "glucosamine sulfate potassium chloride." The plaintiff alleged that the product was a mixture of glucosamine hydrochloride and sodium sulfate, as opposed to the (allegedly more valuable) compound glucosamine sulfate potassium chloride. The test validated by the FDA for glucosamine sulfate does not distinguish between the mixture and the compound, although other tests, at least allegedly, can do so—the district court held that the methods of the plaintiff's expert "raised *Daubert* concerns." There is no dispute that the FDA-validated test determines how the ingredient is to be identified on the supplement facts panel, but can claims elsewhere on the label be deceptive if they suggest that a product consists of the compound when it actually consists of the mixture?

The FDA's preemption of state labeling standards seems straightforward: a state can establish standards where the FDCA is silent, but where the FDCA has spoken, the state-law standard must be identical. Last month, a WLF blog post discussed a failed preemption argument in a citric acid "no preservatives" case where the court concluded that the plaintiff did not assert that different or additional labelling beyond that mandated by the FDCA was necessary to avoid deception. Rather, the plaintiff admitted that citric acid was appropriately identified as an ingredient but alleged that the "no preservatives" label claim was deceptive in light of the preservative effect of the citric acid.

Similarly with the Ninth Circuit's 2019 decision in *Dachauer v. NBTY*: there, the court held that the FDCA's regime of structure/function claims preempts a plaintiff's attempt to impose additional substantiation requirements on such claims. If a product's "immune health" structure/function

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claim is appropriately substantiated under the FDCA's standards, there is no path for a plaintiff to insist that a defendant must *also* provide proof that the product reduces the risk of all-cause mortality. Conversely, a plaintiff is not preempted from pursuing a claim premised on the idea that a defendant's failure to disclose an *increased* risk of all-cause mortality from use under normal conditions is deceptive. Indeed, the FDCA itself requires disclosure of such material facts.

The Ninth Circuit followed this same logic in its 2021 decision in *Greenberg v. Target*. The plaintiff bought a biotin supplement hoping that it would slow or reverse his hair loss, owing to a "helps support healthy hair and skin" structure/function claim made for the product. The Ninth Circuit had little difficulty finding that the FDCA preempted state-law deceptive advertising claims where the claim met the FDCA's requirements for structure/function claims. Because the FDCA provides the requirements for such claims, and because the company met those requirements, the company could not face state-law liability for the claim.

In each of these cases, the defendant followed the relevant FDA rules. Plaintiffs have been successful, however, when their allegations have targeted additional claims beyond those specifically authorized by the FDCA and its regulations. *Hollins* is interesting, however, because it apparently overrules, with a single footnote (note 11), a California district court decision from two years ago with extremely similar facts.

Ultimately, though, it is of a piece with the decisions discussed here; if anything it is on firmer footing in holding the plaintiff's state-law claims precluded. Like the cases discussed above, Walmart followed FDA rules in identifying the dietary ingredient in its supplement. Beyond those cases, however, there is in *Hollins* a specific FDCA provision—21 U.S.C. § 343(s)(2)(B)—that permits the company to use as its product's name the "common and usual" name of its active ingredient. That "common and usual" name, in turn, is given by the relevant validated test, which—as above—does not distinguish between glucosamine sulfate potassium chloride and a mixture of glucosamine hydrochloride and sodium sulfate.

Had the court held the plaintiff's claims not precluded, a company could find itself compelled to identify its active ingredient in one manner in the supplement facts panel yet unable to use the same term on the remainder of the packaging—including where specifically permitted by the FDCA. If the FDCA is going to say what a word means, it must retain the power to do so uniformly. The *Hollins* decision correctly reaches that result.

