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June 6, 2019

Hand-Wringing over Hand Cream: "Unlawful" Moisturizer Class Action and the Slippery Slope

by Glenn G. Lammi

As anyone who's read a *WLF Legal Pulse* commentary on the "Food Court" knows, private enforcement of the federal Food, Drug and Cosmetic Act (FDCA) via crafty state-law consumer class actions really sticks in our craw. These suits end-run the FDCA's lack of a private right of action. Congress understood the risks of privatizing the regulation of products that account for about 20 cents of every dollar spent by U.S. consumers. And yet for nearly the last decade, federal judges have allowed suits targeting the labeling or advertising of FDA-regulated products to proceed when the applicable state law incorporates the FDCA wholesale. Here we focus on a recent decision in a class action involving Nivea skin lotion that endorses an untenable expansion of private FDCA enforcement and further greases an already slippery slope.

The Food Court Three-Step

Plaintiffs' lawyers believed they had found an untapped source of revenue in challenging statements consumer-product manufacturers made on product labels, in ads, and on their websites. But the FDCA not only denies the lawyers a private right to sue, it also preempts any state-law claims demanding actions different from or in addition to those required by federal law. So initial class actions failed.

A workaround plan was hatched. Because California is the lawyers' favorite venue for product-labeling class actions, we'll use that state as an example, but the approach can also work in some other states. First, find a labeling practice that appears to violate the FDCA. Second, invoke the California Sherman Food, Drug and Cosmetic Law (Sherman Law), which incorporates the FDCA's labeling rules. Third (because the Sherman Law provides no private right of action), allege the Sherman Law violation as a predicate act in support of claims under another California law, such as the Unfair Competition Act (UCA). This three-step maneuver has consistently helped plaintiffs' lawyers defeat business defendants' federal preemption arguments.

Franz v. Beiersdorf, Inc.

Ms. Franz filed a putative class action in the U.S. District Court for the Southern District of California, alleging that the Nivea Skin Firming Hydration Body Lotion she purchased was misbranded and was sold unlawfully as an unapproved drug. Certain statements on the product label such as "improves skin firmness within 2 weeks," Franz argued, intimated that the lotion "affected the

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structure or function of the body," terminology the FDCA views as indicia of a drug. Under this theory, Beiersdorf thus ran afoul of the state Sherman Law, a violation that rendered the product misbranded and unlawful under the UCA.

The district court decided in 2015 that Franz failed to state a cognizable claim for mislabeling, and that FDA had primary jurisdiction over whether the lotion was a drug or a cosmetic. Soon after, Franz filed a Citizen Petition with FDA asking it to warn Beiersdorf that it was marketing an unapproved drug. FDA denied the petition.

Undeterred by FDA's denial, Franz amended her complaint, paring it down to the single UCA claim that the Nivea product was an unlawfully sold, unapproved drug. The district court again dismissed Franz's suit for lack of standing under the UCA. Franz appealed, and the Ninth Circuit reversed and remanded in an unpublished opinion.

Beiersdorf moved yet again to dismiss the complaint this past January, arguing that Franz did not and could not plausibly allege that the lotion's intended use was as a drug.

On May 20, the district court denied Beiersdorf's motion. Beiersdorf's brief cited to past FDA warning letters, FDA's denial of Franz's Citizen Petition, and to an FDA guidance stating that products with moisturization or hydration claims are cosmetics, not drugs. The court held that the FDA documents the defendant relied upon were non-binding and thus did not warrant judicial deference. Franz had made a plausible case that the lotion was a drug, the court concluded. It did stress, however, that the holding was "limited" and it was not deciding, at this early stage, that "the lotion is a drug." It then suggested the court would welcome motions for summary judgment before considering class certification.

Analysis

While it's understandable that the court would not defer to FDA's non-binding warning letters and guidance documents, it could have dismissed Franz's complaint on other grounds argued in Beiersdorf's brief. First, in order to show that the Nivea lotion was being marketed as a drug, Franz had to allege that Beiersdorf *intended* that the product affect the structure or function of the body. Franz made no such allegation. Second, the product's name and the statements on the label, when taken as a whole, fit far more squarely within the FDCA's definition of "cosmetic" than "drug." A cosmetic includes articles that are "rubbed or poured" on and "applied to the human body for . . . beautifying . . . or altering the appearance." Federal-court caselaw establishes that a drug is a manufacturer's intended use if label statements "constitute a representation that the product will affect the structure of the body in some medical- or drug-type fashion."

Perhaps the arguments Beiersdorf made will be better fleshed out and successful at summary judgment. The court indicated its skepticism of Franz's unapproved-drug claim in a footnote, referencing both FDA's seven-year failure to take action against Nivea Skin Firming Hydration Body Lotion and the agency's rejection of the plaintiff's Citizen Petition as "instructive."

That Franz's claim made it this far, however, reflects just how pliable this indirect private right to enforce the FDCA can be. Franz's claim, in our estimation, stretches the theory well beyond its breaking point. Franz alleges the defendant violated under the Sherman Law when Beiersdor failed to obtain approval from FDA of a New Drug Application (NDA). But the state-law duty to get FDA

approval could not exist but for the FDCA requirement. And only FDA has the authority to review an NDA. The *only* law that Franz can ultimately enforce here through her state-law action is the FDCA.

No presumption against federal preemption applies to Franz's claim. The defendant's alleged marketing of an unapproved drug occurred solely because of the FDCA's requirement. Drug approval is not an area that implicates "'federalism concerns and the historic primacy of state regulation of matters of health and safety." *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). Beiersdorf could not go to California regulators to cure its supposed violation of state law.

Buckman explained how state tort-law "fraud on the FDA" claims would "skew" the "delicate balance of statutory objectives" Congress sought to achieve with the Medical Devices Act. The same certainly goes for enforcement of the FDCA's requirement that if a product is intended to be used as a drug, FDA must approve it. A proliferation of claims like that brought by Ashley Franz will undoubtedly skew the uniform, predictable legal framework Congress created in passing the Food, Drug and Cosmetic Act.

