Cosmetic or Drug? California Federal Court Refuses to Say.

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Despite the lack of a private right of action to enforce the U.S. Federal Food, Drug and Cosmetics Act ("FDCA"), the plaintiffs' bar continually tries to use the FDCA to support other causes of action, and more often than not class actions, challenging the marketing or labeling of cosmetics. A recent decision by the Southern District of California, where many of these cases are filed, will hopefully deter this practice. *See Franz v. Beiersdorf Inc. et al.*, Case No. 3:14-cv-02241, (S.D. Cal. Apr. 15, 2020).

The FDCA defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body… for cleansing, beautifying, promoting attractiveness, or altering the appearance." Drugs, by contrast, are articles "intended to affect the structure or any function of the body of man." While a seller must seek approval from the FDA before selling a drug, there is no pre-approval requirement for cosmetics, and Congress gave FDA the *sole* authority to police violations of the FDCA.

The original complaint in *Franz*, filed in 2014, alleged that Beiersdorf's Nivea Skin Firming Hydration Body Lotion (the "Lotion") claimed on its label that it provided skin firming hydration, improved skin's firmness in as little as two weeks, and was proven to firm and tighten skin's surfaces in as little as two weeks. According to the plaintiff, because the Lotion was marketed to affect the structure or function of the skin, it was a drug (not a cosmetic), and should have gone through FDA's pre-approval process.

After an amended complaint and two motions to dismiss, as well as an appeal to the Ninth Circuit, the Defendant filed a third motion to dismiss, arguing that the complaint failed to state a claim that the Lotion was, in fact, a drug. The Court denied the motion. Beiersdorf then filed a motion for summary judgment arguing that the plaintiff was preempted by the FDCA from privately enforcing the federal pre-market approval process for drugs and, in the alternative, asked the court to find that the Lotion was a cosmetic as a matter of law.

The Court granted Beiersdorf's motion, explaining that claims seeking to enforce the FDCA must thread a "narrow gap" to escape preemption – the plaintiff must be suing for conduct that *violates* the FDCA, but not *because* the conduct violates the FDCA. The plaintiff failed to meet this standard because she repeatedly referenced provisions of the FDCA and specifically alleged that "Defendant engaged in illegal conduct by unlawfully making skin firming representations about [the Lotion] that resulted in its being deemed a drug under FDA regulations, but did so without obtaining required FDA approval through the FDA NDA [New Drug Approval] process." Because there was "no reasonable way to construe this allegation except as an attempt to privately enforce the FDCA," the claim was preempted.

Interestingly, the Court noted that because the relevant facts were not in dispute and because the motion largely turned on a question of law, a motion to dismiss would have been the better procedural vehicle for resolving the issue. Cosmetics companies should always consider whether they have valid preemption arguments at the motion to dismiss stage. This decision (from one of the more plaintiff-friendly jurisdictions in the country no less) is hopefully another tool to resolve costly class actions litigation at an early stage.

The decision was appealed to the 9th circuit on May 18, 2020.