Cosmeceuticals: The next wave of class-action litigation

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By Elizabeth M. Chiarello, Laura Sexton July 15, 2015

Dr. Albert Kligman, the dermatologist who invented the widely used acne medicine Retin-A, is credited with coining the term “cosmeceutical,” a term that consumers and the media use to refer to cosmetic products that claim to have medicinal or drug-like benefits. Cosmeceuticals are reported to be the fastest growing segment of the personal care industry. Not surprisingly, this trend has caught the attention of the plaintiffs’ bar, which has recently seized on a new theory in class action litigation: that cosmeceuticals are, in fact, drugs that cannot be sold without an approved New Drug Application (NDA).

As background, products are classified as drugs and/or cosmetics depending on their “intended uses,” not their actual effects. The Federal Food Drug and Cosmetics Act (FDCA) defines “drugs” as, among other things, “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles intended to affect the structure or any function of the body of man . . .” 21 U.S.C. § 321(g)(1) (emphasis added). “Cosmetics,” in contrast, include “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part for cleansing, beautifying, promoting attractiveness, or altering the appearance.” 21 U.S.C. § 321(i)(1) (emphasis added).

While the Food and Drug Administration (FDA) has not defined or even recognized the term “cosmeceutical,” it has taken regulatory action against cosmetics it believes are making drug claims. The FDA recently sent several warning letters to cosmetics manufacturers, asserting that their cosmetics were unapproved new drugs based on their labeling or advertising. L’Oreal received such a warning letter for its Rosalic AR Intense and Mela-D Pigment Control products, as did StriVectin for its Potent Wrinkle Reducing Treatment and TL Advanced Tightening Neck Cream, and Skin Authority for its Wrinkle Reversing Serum. The FDA took issue with the following claims, among others:

- “localized redness intensive serum;”
- “recommended for: redness-prone skin, experiencing overall redness, flushing and sensations of discomfort;”
- “I have rosacea on my neck when I get warm or under stress. This product really works to keep it under control!!!!!”;
- “clinically proven to change the anatomy of a wrinkle;” and
- product includes “TGF-b(1-3) (Transforming Growth Factor Beta) to help stimulate collagen, to help inhibit cellular breakdown.”

These FDA warning letters (and others) appear to have given rise to a new theory of class-action litigation. The theory follows this syllogism: The plaintiff (and the proposed class members) purchased product X. Product X was marketed as a cosmetic but in fact was a drug sold without an approved NDA. Plaintiff and the class members would not have purchased the product had they known that it was an unapproved new drug, and were therefore harmed in the amount they spent on the product. Plaintiffs also often seek injunctive relief, arguing that the company must stop selling the product until it obtains an approved NDA.
This approach has been taken in several recent cases. For instance, in *Reid v. GMC Skin Care USA Inc.*, the plaintiffs brought a consumer fraud class action, challenging what they referred to as the “Phyto Stem Cell+” line of anti-aging products. No. 8:15-cv-00277 (N.D.N.Y filed Mar. 11, 2015). The plaintiffs argued that the products are not only ineffective, but are in fact unapproved new drugs. See id. Compl., at ¶¶ 3, 54-55, 70-75 (asserting claims under California law). Similarly, in *Marshall v. PH Beauty Labs, Inc.*, the plaintiff claimed that the defendant falsely advertised Eclos skin care products as providing “anti-aging” results through an apple stem cell extract derived from a rare Swiss apple, and that the products are “unlawfully marketed new drugs.” No. 2:15-cv-02101 (C.D. Cal. filed Feb. 9, 2015), Compl., ¶ 5. In *Margolis v. The Dial Corp.*, the plaintiff claimed that a rinse-off body wash was an unapproved new drug because it allegedly made aphrodisiac drug claims. No. 12-cv-00288 (S.D. Cal. filed Feb. 3, 2012), First Am. Compl., ¶¶ 38-39, 44 (voluntarily dismissed).

One might wonder how a private plaintiff can bring claims for violation of the FDCA after *Buckman Co. v. Plaintiff’s Legal Comm.*, 531 U.S. 341 (2001), which has been interpreted as holding that there is no private cause of action for violation of the FDCA. These plaintiffs do not sue for violation of the FDCA, however. Instead, they claim that companies violated California consumer protection law through a predicate violation of the Sherman Law, which is California’s state-law version of the FDCA. The California Supreme Court has held that, in certain circumstances, claims premised on violations of state laws identical to the FDCA may not be preempted by the FDCA. See *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1184 (Cal. 2008).

Lawsuits alleging that cosmetics were sold as unapproved new drugs have not advanced far enough to report on how the theory is faring. But plaintiffs should have an uphill battle because the theory defies common sense. Consumers do not purchase products with their regulatory classification in mind; they purchase products for what they have learned from friends, advertising, or other sources. This is a lawyer-driven theory, being advanced perhaps because it offers a potentially strong remedy to be leveraged during settlement negotiations (i.e., companies may be at risk if they continue to sell the product if the court determines that it is an unapproved new drug), or perhaps because some see it as easier to prove than a theory of ineffectiveness, which often requires expensive expert work. In the coming months, if litigation in these cases advances past the pleadings stage, we will begin to see how this theory is faring and which defenses are most successful in defeating it.