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From the Editors

By Heather Howard and Jennifer A. Eppensteiner


Fall brings change. Our cold-brew coffees are now of the hot, pumpkin spice variety. We may soon trade flip-flops for scarves. More importantly, though, we are in a presidential election year with a vacancy on the Supreme Court. With that, we have one message for our readers: vote. Vote early, vote by mail, vote in-person, but regardless of how you do it, please vote.

After the election, we look forward to "seeing" you all at this year's virtual Drug and Medical Device Seminar, on November 5–6, 2020. We hope to reunite in-person in the new year.

Should you find yourself with extra time on your hands, or have an interesting topic idea for a future issue of *Rx for the Defense*, please contact Heather Howard at hhoward@kslaw.com or Jenn Eppensteiner at jeppensteiner@reedsmith.com to find out more information about the publication guidelines and the selection process.

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Legal Developments

Buckman Implied Preemption Wipes Out Misbranding Claims that a Product Is Not a Cosmetic *but a Drug*

By Kelly Jones Howell and Marina Plotkin

"Mirror, mirror on the wall, is this product I am using a cosmetic or is it a drug after all?"


Courts presiding over lawsuits where a plaintiff asserts misbranding or mislabeling claims that a defendant's product is not a cosmetic but a drug have provided a firm answer: the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §301 *et seq.*, (the "FDCA") impliedly preempts these claims. Since the FDA has exclusive enforcement power over the FDCA, a plaintiff cannot privately enforce alleged violations of the FDCA. 21 U.S.C. §337(a).

Intended use carves out the distinction between a cosmetic and drug under the FDCA. The terms cosmetic and drug are statutorily mutually exclusive—that is, a cosmetic is not a drug and a drug is not a cosmetic. Cosmetics are "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." FCDA §201(i), (21 U.S.C. §321(i)). Drugs are defined as "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 […]." 21 U.S.C. §321(g)(1). Over-the-counter (OTC) drugs are drugs that can be purchased without a doctor's prescription or consultation from a pharmacist. When a product meets the criteria as a cosmetic and an OTC drug, its labeling must

comply with the regulations for both cosmetic ingredient and OTC drug labeling. 21 CFR §701.3(d).

Most drugs—but not cosmetics—require pre-market approval. As such, the legal and regulatory framework of drugs significantly differ from cosmetics. A cosmetic is misbranded under the FDCA when marketed with drug claims without undergoing the pre-market approval process. Determining the distinction between a cosmetic and drug is a question reserved exclusively by the FDA, which has exclusive enforcement of FDCA violations. 21 U.S.C. §337(a).

Increasingly plaintiffs have filed class suits which creatively allege false advertisement claims for cosmetics labeled or marketed as a *drug*. Latching on to state-law analogs that either explicitly adopt the FDCA or incorporate its terms, these claims are predicated on the theory that by violating the FDCA, defendants in turn violate state law. The suits may also allege that the sale of the misbranded cosmetic constitutes a sale of an unapproved drug in violation of the FDCA and/or state law.

However, recent cases provide a framework for defending against these artful claims on implied preemption grounds. Courts seem to be sending the message to plaintiffs that the "narrow gap " revealed in *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001) and its progeny is tightening.

A 2015 decision by the Eastern District of New York in *Elkind v. Revlon*, No. 14-CV-2482, 2015 WL 2344134 (E.D.N.Y. May 14, 2015), preempting mislabeling claims where plaintiffs alleged that the alleged mislabeling rendered defendant's Powder and Concealer products drugs not cosmetics, emphasized that plaintiffs' mislabeling claims do not exist independent of the FDCA. In this putative class action, plaintiffs claimed, among numerous other state law claims, that defendant's use of the phrases *"Age Defying [with] DNA Advantage*" and *"[H]elps protect skin's DNA to fight the signs of aging*" on its products manifested an intent that the products be used to manipulate the cells, rendering these products drugs as defined by FDCA. Plaintiffs argued that these products were mislabeled under the FDCA for not listing all of a drug's ingredients, and therefore violated New York and California laws prohibiting the unlawful sale of products. The court firmly rejected plaintiffs' mislabeling claims, as violations of the FDCA "lies squarely within the province of the FDA, and therefore "do not squeak through the narrow gap to escape express or implied preemption." *Id.* at *9.

Applying the reasoning in *Elkind,* in January 2016, the Northern District of New York in *Reid v. GMC Skin Care USA, Inc*., No. 8:15-CV-277, 2016 WL 403497, at *14 (N.D.N.Y. Jan. 15, 2016), dismissed plaintiffs' misbranding and mislabeling claims that defendant's stem cell skin care products violated the FDCA on preemption grounds. The court rejected plaintiffs' assertion that their claims were actionable under California and Washington law, not the FDCA. Plaintiffs' Complaint also alleged that defendant's stem cell products were misbranded because their labels violated FDCA regulations for over-the-counter drugs; that the products constituted unapproved drugs; and that "placing an unapproved drug into the stream of commerce is an independent wrongful act under the FDCA." *Id.* * 10. The court held that plaintiffs' claims disputing whether defendant's products were cosmetics or drugs were preempted under the FDCA. *Id.*

The April 2020 decision by a California District Court in *Somers v. Beiersdorf, Inc.,* 14cv2241-LAB (AGS), 2020 WL 1890575 (S.D. Cal. Apr. 15, 2020), granting defendant's motion for summary judgment on preemption grounds, reinforced that plaintiffs cannot privately enforce the FDCA. *Appeal docketed*, No. 20-55541 (9th Cir. May 19, 2020). In this proposed class action, plaintiffs alleged that defendant's sale of Nivea lotion was a "drug" and thus "unlawful" under California's Unfair Competition Law because it was sold without undergoing prior approval of the FDA. *Id.* at *1. Specifically, plaintiff alleged that the Nivea lotion label stating "*provides skin firming hydration," "improves skin's firmness [...],"* and *"proven to firm and tighten skin's surface [...]"* rendered it a drug under FDCA because it suggests the lotion is intended to "affect the structure of the body." *Id.* Having found plaintiffs' claims preempted under the FDCA, the court did not—and in fact *could not*—reach the question of whether the lotion at issue was a drug or a cosmetic. *Id.*

Echoing the *Buckman* proposition that a plaintiff's claims must "thread a narrow gap" to escape preemption, the court found—"[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else [the] claim is expressly preempted by §360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* at *3. Plaintiff's claim that the sale of the Nivea lotion without new drug approval under the federal act clearly indicates that Plaintiff was attempting to privately enforce the FDCA. Plaintiff's claim therefore could not avoid the broad sweep of the *Buckman* broom.

In a similar recent case, *Borchenko v. L'Oreal, Inc.,* 389 F. Supp. 3d 769 (C.D. Cal. 2019), a California federal court granted defendant's motion to dismiss for failure to state a claim on implied preemption grounds. Plaintiff commenced suit under the California Unfair Competition Law ("UCL") alleging that several of defendants' skin care products contained "skin structural representations" that rendered the products *drugs* under California's Sherman Food, Drug, and Cosmetic Law and the FDCA. *Id.* Plaintiff sought injunctive relief to prevent sale of the skin altering care products until defendant underwent the FDA New Drug Approval process ("NDA"). *Id*. at 773.

The court held that, first, plaintiff's UCL claim was a private enforcement of the FDCA and therefore interfered with the FDA's exclusive enforcement and regulatory authority. *Id.* Next, plaintiff's claims under the Sherman Law, which relies on and mirrors the parallel provisions of the FDCA, fail because "[the] Court cannot grant any relief to plaintiff without referring to and applying the provisions of the FDCA." Since plaintiff was suing *because* defendant's conduct violates the FDCA, plaintiff's claim was impliedly preempted.

The tidal force of the preemption waves revisited the East Coast. In its May 2020 decision, *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31 (2d Cir. 2020), the Second Circuit affirmed dismissal of state consumer protection claims and common law claims for unjust enrichment and breach of implied warranty of merchantability as preempted by the FDCA. Unable to squeeze liquid eye products down to the last drop, plaintiffs, former consumers, alleged that defendant deceived them into buying more cosmetics than they could use in violation of 21 U.S.C. §362(a). Plaintiffs argued that the state laws mirror the FDCA requirements that labels not be "false and misleading." *Id.* at 37.

Plaintiffs alleged that the liquid eye cream was misbranded because the label failed to accurately state the total amount of product, and that defendant failed to disclose that consumers will not be able to access the amount identified on the label. *Id.* at 36.

The court noted that federal law does not impose an obligation to disclose the usable net weight of a cosmetic. The court concluded, "Plaintiffs cannot avoid the sweeping preemptive force of the FDCA. Their state law claims—all of which seek to impose labeling requirements that are additional to, or different from, those that federal law has established—are barred." *Id.*

This line of cases illustrates that while plaintiffs' claims were well-greased, they could not slip through the narrow preemption gap. Defendants may use these cases as analogies to prevail on a motion to dismiss or summary judgment on implied preemption grounds.

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