Defending Class Action Claims of False Cosmetics Labeling

hugheshubbard.com

eALERT

The cosmetics industry's labeling practices have recently garnered unwelcome attention from the U.S. Food and Drug Administration ("FDA") and the plaintiffs' bar, subjecting the industry to an increase of unwanted press and potentially costly class action lawsuits. Specifically, the FDA and plaintiffs' bar have focused on cosmetic industry labeling practices that allegedly blur the line between "cosmetics" and "drugs," prompting a new wave of FDA warning letters and class action lawsuits for claims based on deceptive or misleading advertising.

FDA's Recent Focus On Cosmetic Labeling

In the last year alone, the FDA has issued and published at least eight warning letters admonishing cosmetics manufacturers for promotional claims on their websites and product labels deemed by the FDA to blur the line between "cosmetics" and "drugs." In particular, the FDA takes issue with any promotional claims for cosmetics that indicate the product is intended to affect the structure or a function of the human body, including skin and hair.

Under the Federal Food, Drug and Cosmetic Act (the "Act"), the testing, marketing, and labeling of both cosmetics and drugs are subject to different regulations enforced by the FDA. A "drug" includes any product that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or is "intended to affect the structure or any function of the body." 28 U.S.C. §§ 321(g)(1)(B)-(C). Any product classified as a "drug" must either be generally recognized as safe and effective when used as labeled or have passed the FDA's new drug application and approval process. Conversely, any product classified as a "cosmetic" does not require FDA approval, although the FDA does offer a voluntary cosmetic registration program. Any product classified as both a "drug" and a "cosmetic" must comply with the regulations promulgated for both classifications.

The FDA has recently increased it scrutiny of any promotional claims or consumer testimonials for products classified only as "cosmetics" which have not gone through the FDA's new drug application and approval process that indicate an ability to cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body. In the realm of cosmetics, this includes any claims related to topical skin care or treatments, hair care preparations, and eyelash and eyebrow treatments, that address the condition, structure, or function of skin or hair follicles or cells. A few examples of claims singled out by the FDA include:

- "Helps promote cell regeneration."
- "[The product] induced a significant increase in the length."
- "It's easy to apply and you do get growth where you put it."
- "The at-home answer to wrinkle-filling injections. Start rebuilding collagen in just 48 hours."
- "Help tighten the connections between skin's layers."
- "Promotes collagen production . . . repairing existing wrinkles . . . ."
- "Provides BOTOX®-like results without needles . . . ."
- "It deposits . . . Vitamin C to build collagen, and Vitamin E to heal blemishes and scarring."
- "Repairs sun damaged tissues at the cellular level."
- "Triggers your body's own skin regeneration activators."
- "Dual Source Vitamin C Promotes Collagen Synthesis."
- "[C]an . . . protect the skin while helping to prevent blemishes . . . ."

- "[H]elps to strengthen hair growth . . . and combat . . . hair loss."

Given the increased focus in the cosmetics industry on products that improve skin and hair, and the FDA's increased scrutiny, promotional programs and labeling practices should be reviewed by cosmetics makers to ensure compliance with the Act.

Cosmetic Labeling Class Actions and Applicable Defenses

The recent volley of warning letters by the FDA has also triggered a wave of follow-on class action lawsuits against cosmetic manufacturers in general, including manufacturers not singled out via FDA warning letters. Typically, such class action lawsuits are broader in scope than the FDA warning letters, and include claims for false or misleading advertising, unjust enrichment, breach of warranty, and state-specific consumer protection law violations. If certified, the cost and potential class-wide damages associated with such class action lawsuits can threaten to overwhelm or even bankrupt the targeted cosmetic manufacturers.

Despite the upswing in these types of class action lawsuits, there is a glimmer of hope. Two recent U.S. Supreme Court decisions (*Comcast Corp. v. Behrend*, - S. Ct. - (March 27, 2013); *Wal-Mart v. Dukes*, 131 S. Ct. 2541 (2011)) are filtering through the U.S. District Courts and providing effective defenses to class certification. These defenses include (1) requiring a rigorous analysis of all prerequisites for class certification under both Rule 23(a) and Rule 23(b)(3) of the Federal Rules of Civil Procedure, (2) requiring an analysis of the merits of the underlying claims whenever they overlap with class certification issues, (3) requiring damages be measurable on a class-wide basis and not necessitate individual damage calculations for each purported class member, and (4) raising the possibility that any expert testimony proffered for class certification purposes be subjected to the heightened scrutiny of a *Daubert*-style analysis.

- A judge in the U.S. District Court for the Central District of California recently refused to certify a putative class action lawsuit against Neutrogena that alleged false and deceptive advertising with respect to certain Neutrogena brand anti-aging products. *Chow v. Neutrogena Corp.*, No. 2:12-CV-04624 (C.D. Cal. Jan. 22, 2013). In its decision, the court applied the rigorous analysis required under *Dukes*, and in denying class certification, held that individualized inquiries were required to determine (i) whether each purported class member was exposed to the same advertisements, (ii) whether each "class member relied upon the representations in the advertisements," and (iii) "whether the product worked as advertised for each individual class member." *Chow v. Neutrogena Corp.*, No. 2:12-CV-04624 (C.D. Cal. Jan. 22, 2013).

- A judge in the U.S. District Court for the Northern District of Illinois denied certification of a class action asserting claims of deceptive advertising against a manufacturer of a weight-loss supplement, because individualized inquiries were required to determine if each putative class member was exposed to, and deceived by, the alleged misleading advertising, and what damages, if any, each putative class member incurred. *Linton v. Chattem, Inc.*, No. 11-C-2952, (N.D. Ill. Feb. 8, 2013).

- A judge in the U.S. District Court for the Central District of California in 2012 denied class certification in a misleading advertising case against a dietary supplement manufacturer, because of a lack of commonality and the predominance of individualized inquires required to determine if each putative class member was exposed to, and relied upon, the same alleged advertising, and whether or not the product was efficacious, and if so, to what degree, for each putative class member. *Moheb v. Nutramax Laboratories Inc.*, No. CV-12-3633-JFW (JCx) (C.D. Cal. Sept. 4, 2012).

- Several jurisdictions have adopted the requirement, hinted at in *Dukes*, that any expert testimony proffered at the class certification stage is subject to *Daubert*-style scrutiny, offering defendants another avenue of challenging the evidence presented at the class certification stage. *See, e.g.*, *Dukes*, 131 S. Ct. 2541; *Messner v. Northshore University Health System*, 669 F.3d 802 (7th Cir. 2012); *In re Zurn Pex Plumbing Products Liability Litig.*, 644 F.3d 604 (8th Cir. 2011).

Best Practices

In light of the increased attention by both the FDA and the plaintiff's bar, cosmetic makers should be proactive in reviewing their current labeling and promotional practices to ensure compliance with the Act and FDA regulations by not blurring the line between "cosmetics" and "drugs." Such action may well preempt any negative FDA action and the unwanted press associated therewith, although it is no guarantee against a possible class action claim. Nevertheless, cosmetic makers should take heart from the recent decisions of the U.S. Supreme Court that bolster the available defenses against the often ruinous prospect of class certification.

Rita Haeusler
(213) 613-2896
haeusler@hugheshubbard.com

Alex Spjute
(213) 613-2853
spjute@hugheshubbard.com

Litigation and Class Actions Practice Areas
April 2013

Hughes Hubbard & Reed LLP
One Battery Park Plaza | New York, New York 10004-1482 | 212-837-6000