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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

FDA Warns Zarbee's Against Unsolicited Testimonial "Likes" on Facebook

In a letter to dietary-supplement maker Zarbee's Inc., the U.S. Food and Drug Administration (FDA) has warned that "liking" or commenting on testimonials posted to the company's Facebook page could amount to endorsing the testimonial, resulting in sanctions for medicinal claims not approved by FDA.

On the Zarbee's company Facebook page, customers posted praise about the therapeutic value of various products, including Zarbee's Naturals Children's Cough Syrup. Zarbee's then "Liked" those posts or added appreciative comments despite the fact that the claims in the posts would subject the products to FDA oversight as drugs. "Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, these products are 'new drugs'" under the Federal Food, Drug, and Cosmetic Act, the agency told Zarbee's.

According to FDA draft guidance documents on drug companies' social media usage, companies are generally not responsible for content posted by third parties about their products if the company has not endorsed the content.

LITIGATION AND REGULATORY ENFORCEMENT

Second Circuit Affirms Dismissal of Clinique Repairwear Putative Class Action

Affirming the district court's ruling, the Second Circuit has dismissed a purported class action accusing Clinique Laboratories and Estee Lauder Companies of falsely advertising Clinique's Repairwear line on the grounds of failure to plead a fraud claim with particularity, failure to show plausibility and lack of standing. *DiMuro v. Clinique Laboratories,* No. 13-4551 (2d Cir., order entered July 10, 2014). The court also affirmed the district court's denial of leave to amend the complaint.

SHB offers expert, efficient and innovative representation to clients targeted by plaintiffs' lawyers and regulators. We know that the successful resolution of health, wellness and personal care product-related matters requires a comprehensive strategy developed in partnership with our clients.

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In the initial complaint, plaintiffs argued that Clinique's Repairwear line of seven products, as a whole, were falsely advertised to achieve impossible anti-aging results after application to the skin. The district court found that the plaintiffs had no standing to challenge four of the seven products because none of the named plaintiffs had purchased or used those four products. Before the Second Circuit, the plaintiffs argued that the court's own decision in *NECA-IBEW Health & Welfare Fund v. Goldman Sachs & Co.*, 693 F.3d 145 (2d Cir. 2012), applied to the plaintiffs' claims as well. In *NECA*, the circuit court allowed plaintiffs to assert claims on behalf of purchasers of related—but not identical—securities because the defendants' representation was misleading across all of the offering documents. The four Clinique products that they had not purchased or used, plaintiffs argued, were similar enough to the products they did purchase that they should be allowed to represent class members who purchased those four products as well. The court rejected this argument because each of the seven products had different ingredients and Clinique made different advertised claims about each. Thus, each would require its own set of evidence to prove the claims of fraud and false advertising.

Turning to the three products that plaintiffs did purchase, the circuit court dismissed the plaintiffs' consumer fraud claims because they failed to plead with the particularity required of accusations of fraud. The court found that the complaint "fails to allege facts explaining how each product did not work as advertised and why any specific advertising claim for each product is false." Plaintiffs provided no explanation for why the products would not work, the court held, and in addition, they failed to allege "that any of the named Plaintiffs even *used* the product, let alone used the product as directed." Failing to find any particularity or plausibility in the complaint's allegations, the circuit court also affirmed the dismissal of the plaintiff's unjust enrichment and breach of warranty claims.

Court Approves Settlement in Hair Loss Class Action Against Unilever

An Illinois federal court has reportedly approved a $10.25-million settlement agreement between Unilever PLC and a class of consumers who alleged that one of Unilever's Suave hair products caused hair loss. *Reid v. Unilever U.S.*, No. 12-6058 (U.S. Dist. Ct., N.D. Ill., order entered July 9, 2014). The lawsuit alleged that Suave Professionals Keratin Infusion 30-Day Smoothing Kit, which sold in the United States for about five months in 2012, contained a dangerous chemical that caused scalp damage and hair loss, apparently leading to consumer injuries. The settlement—including a $10-million fund to cover injury claims and $250,000 to reimburse purchasers—was approved by the court despite objections that some of the injuries were potentially more severe than the $25,000 cap on injury awards.

Plaintiff Accuses Guthy-Renker of Racketeering for Proactiv Business Practices

Alleging that the company illegally bills customers for products they did not order and ignores cancellation requests, a plaintiff has filed a putative class action against Guthy-Renker, maker of the Proactiv line of anti-acne products. *Gomez v. Guthy-Renker*, No. 14-1425 (U.S. Dist. Ct., C.D. Cal., filed July 11, 2014). In the complaint, the plaintiff argues that Guthy-Renker "engages in a systematic fraudulent scheme to charge consumers for its products when Defendant is not authorized to do so."

She alleges that she bought Proactiv products and was enrolled in a continuity program that Guthy-Renker advertised would charge her monthly, but instead she was charged every 28 days, resulting in 13 charges in one year. The complaint further alleges that Guthy-Renker charged the plaintiff for $347.68 worth of products from Meaningful Beauty, a different line sold by the company, that she had never ordered nor received, and when she requested a refund, she received only $139.91 back. The plaintiff requests class certification, declaratory judgments that Guthy-Renker engaged in racketeering, an injunction, damages, and attorneys' fees.

Sensa Accused of Unjust Enrichment and Deceptive Trade Practices in Purported Class Action

Weight-loss product manufacturer Sensa Products has been accused of deceiving consumers with advertisements for its Sensa powder, which the company says will cause users to lose weight by sprinkling on food before consuming it. *Stokes v. Sensa Products*, No. 14-5411 (U.S. Dist. Ct., C.D. Cal., filed July 11, 2014). The plaintiff seeks class certification, an injunction, restitution, and attorneys' fees.

Sensa and the Federal Trade Commission (FTC) settled charges in January 2014 that Sensa misleads consumers into believing its products lead to easy weight loss, with Sensa agreeing to pay $26.5 million to reimburse purchasers of the product. The putative class action argues similar allegations and cites the FTC settlement to support its argument that Sensa's "weight loss promises are false and deceptive." The complaint also cites video testimonials as misleading consumers, including one from celebrity endorser Patti Stanger of Bravo's "Millionaire Matchmaker." Sensa also faces a breach of contract suit from celebrity endorser Octavia Spencer, who accused the company of failing to pay her the $1.2 million it promised for the limited use of her image in promotion as well as sponsored tweets. *Spencer v. Sensa Products*, No. BC519632 (Super. Ct. Cal., Los Angeles Cnty., arguments heard July 16, 2014).

TriVita to Pay $3.5 Million for Deceptive Claims About Cactus Juice Product

The Federal Trade Commission (FTC) has settled with dietary supplement marketer TriVita over accusations that the company advertised its cactus-based drink, Nopalea, as providing health benefits such as relieving inflammation without evidence to support the claims. *FTC v. TriVita*, No. 14-1557 (U.S. Dist. Ct., Ariz., stipulation approval order entered July 11, 2014). The suit, resolved the day after its filing, accused TriVita of manufacturing Nopalea and marketing it as an "anti-inflammatory wellness drink" that scientific studies have shown "reduces or eliminates the effects of inflammation on the body, relieves pain, relieves swelling, improves respiration, and provides skin health benefits," even though no scientific studies had been conducted to support the claims. Under the settlement order, TriVita can no longer make health claims about Nopalea without clinical tests by qualified researchers supporting them. *See FTC Press Release*, July 15, 2014.

EMERGING TRENDS

Consumer Reports Investigation "Uncovers Hidden Makeup Health Risks" in U.S. Products

An August-September 2014 investigative article in *Consumer Reports* "Shop-Smart" guide asserts that while many personal care products may contain aloe or shea butter, "there might also be lots of stuff you don't want to rub on your body every day."

According to the article, while some American manufacturers have chosen to eliminate such chemicals as triclosan, phthalates and formaldehyde from their products, "the biggest problem is our cosmetics laws. The reason makeup is loaded with risky ingredients is because when compared with Europe, the U.S. is a regulatory free-for-all." The author champions passage of federal legislation (H.R. 1385) that would, among other things, require the Food and Drug Administration to prohibit the use of purportedly toxic chemicals in cosmetics and personal care products and mandate adverse events reporting by manufacturers. Consumers are also advised to avoid products stating "natural," "dermatologist tested" and "hypoallergenic" on the label or those containing formaldehyde, 1,4-dioxane, phthalates, triclosan, triclocarbon, coal tar, and nanomaterials.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

SCCS Rules on Three Hair Dye Substances

The European Commission's Scientific Committee for Consumer Safety (SCCS) recently published three opinions finding that 3-amino-2,6-dimethylphenol, hydroxyethoxy aminopyrazolopyridine HCl and Basic Brown 17 are safe for use in hair dyes at a maximum concentration of 2 percent. The committee provides opinions on the health and safety risks of non-food consumer products and services on the basis of dossiers submitted by industry applicants or member state authorities to satisfy EU regulatory requirements.

As part of its toxicological evaluation for each of these substances, SCCS assessed acute oral, dermal and inhalation toxicity; skin irritation and mucous membrane irritation; skin sensitization; percutaneous absorption; repeated dose toxicity; mutagenicity/genotoxicity; carcinogenicity; reproductive toxicity; toxicokinetics; and photo-induced toxicity. Concluding from these data that hydroxyethoxy aminopyrazolopyridine HCl is "a strong sensitizer," SCCS also noted "a sensitization potential" for 3-amino-2,6-dimethylphenol and Brown Basic 17. The committee also added that, "Basic Brown 17 may contain up to 4.5 % (w/w) Basic Red 118, corresponding to maximum 0.09% in a hair dye formulation. Basic Red 118 according to the Cosmetic Regulation (Regulation 1223/2009) is not permitted for use in cosmetics except as an impurity in Basic Brown 17."

Research Backs Use of Pharmacological Intervention to Curb Obesity

Researchers with Barts and the School of Medicine and Dentistry, Queen Mary University of London, have published a study suggesting that specially-designed nutrient capsules could activate cell receptors in the intestines to help regulate feelings of satiety, thus reducing overall food intake. Erin L Symonds, et al., "Mechanisms of activation of mouse and human enteroendocrine cells by nutrients," *Gut*, July 2014.

Noting that gastric bypass surgery curbs appetite by shunting nutrients to the distal gut where dietary sugars, amino acids and fatty acids stimulate enteroendocrine cells (EEC) to release gut hormones, the study's authors assessed the mRNA expression of 17 nutrient receptors and EEC mediators in mouse and human gut epithelium to determine "which nutrient receptors are expressed in which gut regions and in which cells in mouse and human, how they are associated with different types of EEC, how they are activated leading to hormone and 5-HT [5-Hydroxytryptamine] release."

The results evidently showed that "the distal gut of humans and mice is extensively equipped with sensors for products of fat and protein digestion, and that these associate with specific signaling pathways," which in turn "are associated with the release of specific mediators." Based on these findings, the researchers hypothesized that "refining nutrient preloads and formulating them to target the distal gut" could constitute a successful anti-diabetic strategy to complement or even replace gastric bypass surgery.

"We believe it's possible to trick the digestive into behaving as if a bypass has taken place," Professor of Enteric Neuroscience Ashley Blackshaw explained in a media statement. "This can be done by administering specific food supplements which release strong stimuli in the same area of the lower bowel. It's a bit like sending a specific food parcel straight to the body's emergency exit, and when it gets there, all the alarms go off." *See The Telegraph*, July 15, 2014.

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