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ISSUE 70

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SHOOK SPOTLIGHTS

Shook Attorneys Discuss California 'Junk Fee' Amendment

On July 1, 2024, the "junk fee" amendment to the California Consumers Legal Remedies Act (CLRA) will take effect. Under this new provision, a company can violate the CLRA if it advertises, displays or offers goods or services at a price without disclosing all mandatory fees or charges. Businesses failing to abide by this requirement could face regulatory enforcement and consumer class actions seeking statutory damages, punitive damages and attorney's fees.

In a client alert, Shook Partner Rachel Straus, Naoki Kaneko and Associate Emily Pedersen discuss the law and how retailers can prepare.

LEGISLATION, REGULATIONS & STANDARDS

FDA Issues NDIN Draft Guidance

Shook 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. For additional information about Shook's capabilities, please contact

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The U.S. Food and Drug Administration (FDA) has issued draft guidance for industry titled "New Dietary Ingredient Notification Master Files for Dietary Supplements." FDA said the draft guidance comes in response to requests from the dietary supplement industry for specific guidance on recommendations about Master Files for new dietary ingredient notifications (NDINs).

"NDIN Master Files are not required by statute or regulation, but, as explained in today's draft guidance, can be used to facilitate the submission of NDI-related identity, manufacturing, and/or safety information to the FDA for use in evaluating a potential future NDIN," FDA stated in a Constituent Update. "The intent of the guidance, once finalized, will be to help industry comply more easily with the NDIN requirement by providing recommendations on the content, submission, and use of Master Files."

NAD Finds Fenty Skin Cleanser Claims Supported, Recommends Changes for Influencer Disclosures

BBB National Programs' National Advertising Division (NAD) has ruled that Fenty Skin LLC provided a reasonable basis for certain product claims made during product demonstrations on social media featuring influencers but recommended the company modify its paid partnership disclosures. In a news release, NAD said the determination was part of its routine monitoring program. NAD reviewed claims made by influencers Sarah Novio and Crème Fatale during product demonstrations on TikTok, reposted by Fenty Skin to its Instagram page, about Fenty Skin's Melt AWF Jelly Oil Makeup-Melting Cleanser, including:

- "From longwear or waterproof makeup, sunscreen, dirt, oil + impurities melt that… AWF in one go."
- "This unique jelly texture gently delivers clean, nourished + conditioned skin without the stripping or drying."

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ABOUT SHOOK

Shook, Hardy & Bacon attorneys counsel consumer product manufacturers on FDA, USDA and FTC regulatory compliance and risk management issues, ranging from recalls and antitrust matters to facility inspections, labeling, marketing, advertising, and consumer safety. We help these industries develop early legal risk assessments to evaluate potential liability and develop appropriate policies and responses to threats of litigation or product disparagement.

The firm's lawyers also counsel manufacturers on labeling audits and a full range of legal matters such as U.S. and foreign patent procurement; licensing and technology transfer; venture capital and private financing arrangements; joint venture agreements; patent portfolio management; research and development; risk assessment and management; records and information management issues and regulations; and employment matters, including confidentiality and non-compete agreements.

- “In a study of 52 people after 1 use ‘100% agreed it gently cleanses skin leaving it clean and fresh, 96% agreed that it cleansed skin without stripping, 92% agreed it removes makeup.’”

NAD concluded that product demonstrations were supported by the evidence and the videos were accurate and not enhanced. However, the board recommended Fenty Skin modify how the influencers disclosed their paid partnerships; during its proceeding, Crème Fatale's Instagram was updated to include both the “paid partnership” disclosure and hashtags #AD and #SPONSORED in the caption, and Fenty Skin's Instagram post was updated to include #AD in the caption.

“Although NAD found that Crème Fatale’s ‘paid partnership’ disclosure tells viewers there is a material connection between Fenty Skin and Crème Fatale, NAD recommended that Fenty Skin require Crème Fatale to modify the challenged video demonstration post to include a clear and conspicuous material connection disclosure in the video itself,” NAD said. “NAD further recommended that Fenty Skin’s re-post of this video to its own Instagram page should likewise have a modified disclosure.” Fenty Skin indicated it requested that Novio update the challenged TikTok and Instagram posts to include a clear disclosure she received the product for free, and Fenty Skin removed the post from its Instagram and will only repost with the updated disclosure.

Proposed California Bill Prohibits Sale of Anti-Aging Skincare, Cosmetics to Those Under 13

A California Assembly Bill seeking to prohibit sales of anti-aging skincare products to children and pre-teens will proceed after passing the Environmental Safety and Toxic Materials Committee, a key first committee. AB 2491, which would take effect January 1, 2025, if passed in its current form, prohibits the sale or delivery to a person under 13 of an over-the-counter skincare product or cosmetic product advertised to address skin

aging that contains vitamin A or its derivatives, or an alpha hydroxy acid. The bill would also require entities that conduct business in California to take any of a list of several specified actions to ensure purchasers are not underage, including placement of a prominent notice next to the physical product or in the product's online description or collection of the purchaser's date of birth. The law allows the state attorney general, district attorneys or city attorneys to bring civil actions against persons or entities that violate the law.

The bill was sponsored by Assemblymember Alex Lee (D-San Jose), who said in a statement that the beauty industry is failing to take meaningful action to address the problem of kids using strong products that aren't meant for them. “Kids don’t need anti-aging products, and AB 2491 will protect children and preteens from the potential harms of using products that may lead to short- or long-term skin challenges they wouldn’t otherwise have,” he said.

Vermont Enacts Law Requiring Schools to Allow Children to Have Sunscreen

Vermont Gov. Phil Scott has signed a bill requiring public schools and approved independent schools in the state to allow students to possess and self-administer sunscreens while on school property. SB 187 allows students with written parental or guardian authorization to have or use topical, non-aerosolized sunscreens on school property or at school-sponsored events without supplying a medical provider's note or prescription or storing the sunscreen in a specific location. According to the Consumer Healthcare Products Association, Vermont is the 27th state to approve such a law, which takes effect July 1.

Senator Signals Intent to Reintroduce Dietary Supplement Listing Act

Sen. Dick Durbin (D-Ill.) has announced he will reintroduce the Dietary Supplement Listing Act this year, amid rising concerns about the sale of products containing tianeptine. Durbin

discussed his intent to reintroduce the law, which he introduced in 2022, in letters to the heads of four dietary supplement industry groups urging them to take action against the inclusion of dangerous or illegal ingredients marketed as dietary supplements. He pointed to the U.S. Food and Drug Administration's (FDA's) warning indicating consumers should not purchase or use products marketed as dietary supplements that include tianeptine. The Dietary Supplement Listing Act would have given FDA "much-needed insight into the market and improved its abilities to initiate enforcement action against the companies that market dangerous or illegal ingredients, such as tianeptine, in their supplement products," he said.

LITIGATION

Makers of Benzoyl Peroxide Cleansers Face Benzene Claims

The makers of several skincare products containing benzoyl peroxide (BPO) face claims that the products contain high levels of benzene, a known carcinogen, including products sold under the brands of L'Oréal, La Roche-Posay, CeraVe, Proactiv and Clinique. *Snow v. L'Oreal USA Inc.*, No. 24-0110 (D. Haw., filed March 8, 2024); *Mraz v. L'Oreal USA Inc.*, No. 24-1974 (S.D.N.Y., filed March 15, 2024); *Grossenbacher v. L'Oreal USA Inc.*, No. 24-0663 (E.D. La., filed March 15, 2024); *Judt v. Alchemee LLC*, No. 24-2718 (S.D.N.Y., filed April 10, 2024); and *O'Dea v. Clinique Laboratories, LLC*, No. 24-2750 (N.D. Ill., filed April 5, 2024).

Consumers allege that BPO degrades over time to become benzene, a carcinogenic impurity linked to leukemia and other cancers, rendering them adulterated, misbranded and illegal for sale under federal and state law. The suits follow a citizen petition filed by independent laboratory Valisure asserting that, based on its own testing, a number of benzoyl peroxide products

contain high levels of benzene and that benzene concentrations are increased when the products are stored above normal room temperatures. Shook Partners Patrick Oot, Veronica Gromada, Kimberly Penner and Tom Sheehan discussed the filing in a Shook client alert.

Consumers Allege Babe Lash Products Contain Prescription Ingredient

Two New York consumers have filed a proposed class action alleging the maker of Babe Lash Essential Serum and Babe Brown Amplifying Serum misled consumers into believing the products are legal and safe when they are unapproved drugs. *Cohen v. Elixir Cosmetics OPCO, LLC*, No. 24-3327 (E.D.N.Y., filed May 5, 2024). They allege the products contain isopropyl cloprostenate (ICP), a chemical compound used in prescription drugs, as indicated in a U.S. Food and Drug Administration (FDA) warning that products containing ICP are drugs as defined by the Federal Food, Drug and Cosmetic Act.

"Because the Products are drugs, Elixir was required to seek regulatory approval for safety and efficacy before selling them to consumers," the plaintiffs allege. "Elixir failed to seek such approval, and instead deceptively marketed and sold the Products as cosmetics, even though they are unapproved drugs." The plaintiffs allege violations of Sections 349 and 350 of New York's General Business Law and breach of express warranty and seek class certification, restitution, damages, attorney's fees, and pre- and post-judgment interest.

Consumer Claims GNC's 'Super Magnesium' Contains Less Than Half Advertised Amount of Magnesium

An Illinois man has filed a proposed class action alleging GNC Holdings' "Super Magnesium" dietary supplement does not contained the advertised amount of magnesium. *Soto v. GNC Holdings, LLC*, No. 24-3613 (N.D. Ill., filed May 3, 2024). The

plaintiff argued that GNC sells “Super Magnesium” dietary supplements with a label claiming that one serving consists of two caplets containing 400mg of elemental magnesium, but independent testing allegedly showed that the supplements contain about 152 milligrams of elemental magnesium per serving.

“The difference between the Magnesium Supplements promised and the products sold is significant and material because the sold products contain less than half of the 400 mg of magnesium per serving advertised and warranted,” the plaintiff alleges. “The amount of actual magnesium provided, and the measure of magnesium per serving, has real impacts on the benefits provided to consumers by the Magnesium Supplements and the actual value of the Supplements.” The plaintiff alleges fraudulent concealment, unjust enrichment, breach of express warranty, violation of the Illinois Consumer Fraud and Deceptive Business Practices Act and breach of implied warranty of merchantability and seeks class certification, equitable and injunctive relief, damages and attorney's fees.

Court Allows Part of Dr. Squatch ‘Natural’ Labeling Suit to Proceed

An Illinois federal court has trimmed a lawsuit alleging Dr. Squatch LLC misleads consumers by using the term “natural” on its shampoo labeling despite allegedly containing synthetic ingredients. *Fleming v. Dr. Squatch, LLC*, No. 22-4842 (N.D. Ill., issued April 18, 2024). The plaintiff also alleges the labeling misleads by featuring the terms “Oat Protein, Jojoba Oil, [and] Honey” despite containing less of the named ingredients than expected.

The defendant moved to dismiss the claims, arguing the plaintiff failed to sufficiently allege the product label is misleading because she did not provide a plausible definition of the word “natural,” and noting that the defendant’s website identifies two ingredients as “man made.” The court found neither argument persuasive and declined to presume that because the plaintiff

purchased the product on the defendant's website that she also reviewed the ingredient list or was even aware of it.

"Indeed, if, as Plaintiff alleges, it is important to her that products she purchases are 'natural,' then it would make little sense for her to have reviewed the website showing two ingredients are 'Man Made' and still bought the Product," the court said. "Ultimately, these are questions of fact that will need to be explored during discovery, but at this juncture, the Court cannot say, as a matter of law, that Defendant has shown that Plaintiff has failed to state a claim for consumer fraud violations." The court allowed her consumer fraud unjust enrichment claims to proceed, but dismissed her warranty claims and claim for injunctive relief.

New York Court Tosses 'Clean at Sephora' Claims

A federal court in New York has thrown out claims that Sephora's "Clean at Sephora" cosmetics misled consumers into thinking they did not contain synthetic ingredients. *Finster v. Sephora USA Inc.*, No. 22-1187 (N.D.N.Y., issued March 15, 2024). The plaintiff filed a putative class action against Sephora in 2022 after buying cosmetics labeled "Clean at Sephora." She alleged she relied on the "Clean at Sephora" seal to believe the cosmetics did not contain ingredients that were synthetic or "connected to causing physical harm or irritation."

In its motion to dismiss the complaint, Sephora argued that it has not marketed, labeled or sold its "Clean at Sephora" cosmetics under the guise that they are all natural or free of any harmful ingredients. The court sided with the defendant, finding that the plaintiff's allegations fall short of the reasonable person standard. "Plaintiff's complaint leaves the Court guessing as to how a reasonable consumer could mistake the 'Clean at Sephora' labeling and/or marketing to reasonably believe that the cosmetics contain no synthetic or harmful ingredients whatsoever," the court said, dismissing all claims but allowing

leave to amend.

First Amendment Challenge to New York Diet Pill Law Survives Dismissal Bid

A federal court has narrowed a lawsuit challenging a New York law restricting over-the-counter sales of diet pills and dietary supplements for weight loss or muscle building to minors, allowing a First Amendment claim to proceed. *Council for Responsible Nutrition v. James*, No. 24-1881 (S.D.N.Y., filed May 13, 2024). The Council for Responsible Nutrition (CRN) filed suit seeking a ruling that AB A5610 is facially invalid and an injunction barring the state's attorney general from enforcing it. The court denied CRN's request for a preliminary injunction, allowing the law to take effect April 22, and the state moved to dismiss the suit.

The court found CRN met its minimum burden to suggest a First Amendment injury. "While the Court has expressed serious doubt about CRN's likelihood of success on the merits—namely that even if the Statute implicates the First Amendment, it likely survives intermediate scrutiny—we cannot conclude at this stage that Plaintiff has failed to plead factual allegations to sufficiently 'raise a right to relief above the speculative level,'" the court said. The court dismissed CRN's additional claims that the law is void for vagueness, an excessive use of police powers and preempted by federal law. CRN's suit is one of two lawsuits brought by industry groups; the Natural Products Association also filed a lawsuit in the U.S. District Court for the Eastern District of New York. *Natural Products Association v. James*, No. 23-8912 (E.D.N.Y., filed December 4, 2023).

SCIENTIFIC / TECHNICAL

Study of Dietary Supplements Marketed to Military Members Finds Prohibited Substances

A *JAMA Network Open* study of 30 dietary supplement products marketed to military members found that one-third contained substances prohibited by the U.S. Department of Defense for use by those in the military. The authors of the study, "Label Accuracy of Weight Loss Dietary Supplements Marketed Online With Military Discounts," analyzed products purchased from online companies advertising military discounts for products with claims about weight loss. Of the 30 products analyzed, 25 had inaccurate labels, 24 were misbranded, seven had hidden components detected, and 10 contained substances prohibited for military use. The study's authors said that predatory marketing to servicemembers poses a threat to military members and the public.

"Beyond the dangers to one's health and career, the cost of these products may create financial burdens on individuals, often without a positive return on investment, and may contribute to a financial readiness issue for military families," they said. "Overall, the findings from this study are problematic and require solutions. As of now, the only way to know the actual ingredients in a product is to ensure it has been tested by an independent third-party organization."

Study Purportedly Finds Use of Fish Oil Supplements Might Be Risk Factor for Atrial Fibrillation, Stroke

A study published in *BMJ Medicine* found that regular use of fish oil supplements might be a risk factor for atrial fibrillation and stroke among the general population but could be beneficial for the progression of cardiovascular disease from atrial fibrillation to major adverse cardiovascular events. The study's authors analyzed data on more than 415,000 people between the ages of 45 and 69 participating in the UK Biobank, a community-based cohort study of United Kingdom residents, to estimate the associations between fish oil supplements and specific clinical cardiovascular disease outcomes. The authors purportedly found that regular use of fish oil supplements was associated with an increased risk of atrial fibrillation and that for participants with a

diagnosis of atrial fibrillation, regular use of fish oil supplements had a protective effect or no effect on transitions to major cardiovascular events, atrial fibrillation to death, and major adverse cardiovascular events to death.

"When we divided major adverse cardiovascular events into three individual diseases (i.e., heart failure, stroke, and myocardial infarction), we found associations that could suggest a mildly harmful effect between regular use of fish oil supplements and transitions from a healthy cardiovascular state to stroke, whereas potential beneficial associations were found between regular use of fish oil supplements and transitions from atrial fibrillation to myocardial infarction, atrial fibrillation to death, and heart failure to death," the authors said.