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LEGISLATION, REGULATIONS & STANDARDS

U.S., States Aim to Regulate Cosmetics Ingredients and Research Methods

Federal and state legislatures aimed to bring more scrutiny to cosmetics in 2019 by considering measures that would regulate ingredients, limit research methods and grant additional authority to regulatory agencies.

At the federal level, lawmakers have considered the Safe Cosmetics and Personal Care Products Act of 2019 and the Cosmetic Safety Enhancement Act of 2019, which would give the U.S. Food and Drug Administration (FDA) more authority to recall personal care products. The House Subcommittee on Health, part of the Committee on Energy and Commerce, held a hearing on December 4, 2019, that focused on the reasoning behind the proposed bills. "The proposed bipartisan bill currently under consideration in Congress would reform the U.S. approach to cosmetics regulation, potentially in significant ways," Shook Partner Laurie Henry told Corporate Disputes for the magazine's October-December 2019 issue.

Other federal efforts included the November introduction of the Natural Cosmetics Act, which aims to define the term "natural" as applied to cosmetics. Rep. Frank Pallone sent a letter in June urging FDA to provide updated information on inspections of imported cosmetics after he learned that the agency had not conducted "any foreign cosmetics inspections in Fiscal Year (FY) 2019 and does not intend to conduct any inspections in FY 2020." The Children's Product Warning Label Act of 2019 was introduced in March following headlines about the identification of asbestos

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.

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in talc-based children's cosmetics, although the bill has not progressed beyond introduction.

A bipartisan federal bill to ban animal testing for cosmetics, the Humane Cosmetics Act of 2019, was introduced, coinciding with state legislatures banning the sale of cosmetics produced with animal testing; Illinois and Nevada joined California in passing such bans, which take effect January 1, 2020.

In addition, California updated its laws to require safety data sheets for cosmetic products, while New York banned 1,4-Dioxane, which can be found in cosmetics and other personal care products.

FDA Increases Scrutiny of Dietary Supplements

The U.S. Food and Drug Administration promised an increased focus on dietary supplements in a February 2019 press announcement from then-Commissioner Scott Gottlieb. "[T]oday we are announcing a new plan for policy advancements with the goal of implementing one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years," the announcement stated. FDA promised additional efforts in "communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that our regulatory framework is flexible enough to adequately evaluate product safety while also promoting innovation, continuing to work closely with our industry partners, developing new enforcement strategies and continuing to engage in a public dialogue to get valuable feedback from dietary supplement stakeholders." The announcement accompanied the posting of 12 warning letters and 5 online advisory letters sent to companies that the agency asserted were "illegally selling more than 58 products, many that are sold as dietary supplements, which are unapproved new drugs and/or misbranded drugs that claim to prevent, treat or cure Alzheimer's disease and a number of other serious diseases and health conditions." In April, FDA unveiled its Dietary Supplement Ingredient Advisory List, a tool intended to alert the public when the agency "identifies ingredients that do not appear to be lawfully marketed in dietary supplements."

As part of Shook's 60 Seconds of Legal Science video series, Houston Managing Partner Jennise Stubbs noted FDA's role in reviewing dietary supplements. "As dietary supplement popularity increases and the number of companies manufacturing these supplements grows, FDA is reviewing the regulatory framework for these products to ensure its processes and procedures of

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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.

oversight are flexible enough to evaluate product safety but also promote scientific innovation," she explains.

FDA continued issuing warning letters to companies with production facilities the agency deemed to be not up to Current Good Manufacturing Practices, including Hi-Tech Pharmaceuticals, SomaLabs Inc., Nutra Solutions USA and Goldstar Distribution, as well as companies that allegedly claimed benefits about their products that would amount to the products being unapproved new drugs. A large portion of 2019 warning letters in this category were sent to manufacturers of cannabidiol (CBD) products; in addition, FDA sent several letters to manufacturers of products containing dimethylhexamine (DMHA), including eight manufacturers that appeared in an April posting of warning letters.

FTC Continues Efforts to Reduce Deceptive Practices

The U.S. Federal Trade Commission (FTC) has frequently targeted dietary supplement and cosmetics companies for enforcement actions, arguing that companies engage in marketing tactics the agency found to be misleading or harmful. These actions continued apace in 2019, with challenges focused on unsubstantiated claims, "risk-free" trial offers and undisclosed marketing partnerships.

FTC settled a number of cases with supplement producers and distributors, including the makers of Synovia, which was allegedly marketed as a treatment for arthritis. The marketing included a testimonial in which the endorser purportedly "gave away his walker" after using Synovia. An aloe supplement maker was alleged to have misleadingly marketed its products as "effective treatments for a range of conditions affecting seniors, including chronic pain, ulcerative colitis, diabetes, and acid reflux." Under a settlement agreement, the makers will pay $537,000 of an $18.7 million judgment. Unsubstantiated claims about cognitive improvements also drew a complaint from FTC; 12 corporate defendants settled with the agency after they allegedly claimed the products had been shown in "over 2,000 clinical trials" to improve focus by "up to 121%."

The agency also filed an action against a company that marketed its bath and beauty products as organic and vegan despite containing non-organic ingredients that appear "only in lists that are buried among other text on product labels and websites." Some of the company's products also contained honey and lactose, which are not vegan ingredients. In addition, FTC mailed checks to consumers confused by negative-option marketing for

"risk-free" trials of skin care products and sued a supplement company that allegedly ran an illegal pyramid scheme.

FTC continued to focus on supplement and cosmetics companies partnering with influencers or other non-traditional brand representatives who fail to disclose their paid relationships. In November, FTC released "Disclosures 101 for Social Media Influencers," a guide aiming to clarify the measures that social media posters must pursue to ensure their audiences understand that a post is an advertisement. The agency also looked for misleading reviews and testimonials shown online by seemingly impartial users of personal care products. In February, FTC announced "its first case challenging a marketer's use of fake paid reviews on an independent retail website," which it brought against the distributor of a Garcinia cambogia supplement. FTC also settled with skin care company Sunday Riley following allegations that the company's executives directed employees to leave highly positive reviews on Sephora's website to ensure the company's products retained high star ratings.

Industry Self-Regulator Identifies Issues with Marketing Claims

The National Advertising Division (NAD), which reviews challenges to marketing claims brought by competitors or advocacy organizations, considered several dietary supplement and cosmetics advertising complaints in 2019, including a complaint brought by the Council for Responsible Nutrition. The group challenged the marketing for Plavinol, a dietary supplement purported to aid in treating metabolic syndrome, and NAD found that the research study cited by Nexus Formulas LLC lacked credibility "because it was unclear who authored it."

The ad board also faced resistance following some of its determinations, including from Guthy-Renker. NAD told the company that marketing for its Crepe Erase "antiaging body care system" featured misleading numbers on the percentage of users who saw improvements after using the product and that the testimonials from a doctor and Dorothy Hamill were misleading. The celebrity endorsement did not reflect the evidence in the record about the product's efficacy, NAD found, and the doctor's testimonial implying the product was better than its competitors was misleading because the doctor did not review competing products' efficacy. Guthy-Renker told NAD it intended to appeal on several grounds.

Wink Naturals received multiple complaints about its products, which include sleep supplements, anxiety-relief supplements and cough-syrup supplements. The challenges largely focused on

Wink's marketing towards children, including such statements as, "I get asked A LOT if we make an anxiety product for kids—WE DO" and "Helps to improve your child's school performance: A good night sleep can lead to more energy, focus, concentration, information retention, and creative problem solving." NAD determined the latter phrasing could be slightly modified into separate sentences to highlight the benefits of sleep and the relationship between the product and sleep, but the board recommended a number of changes to Wink's marketing throughout all three products' advertising campaigns.

HOT TOPICS

CBD Explodes in Popularity But Hits Regulatory Wall

Following the passage of the 2018 Farm Bill, which legalized the cultivation of hemp, cannabidiol (CBD) became the star ingredient of 2019, suspended by itself in oil or featured in supplements, beverages and food. The U.S. Food and Drug Administration (FDA) struggled to keep up with the hype; while CBD stayed in legal limbo, U.S. lawmakers and other public officials urged the agency to take action and create a legal framework for a burgeoning industry capitalizing on the popularity of CBD and its purported calming and healing effects. Several companies went too far in their marketing claims, however, according to the U.S. Food and Drug Administration's and Federal Trade Commission's warning letters focused on the claimed benefits of the product. One letter noted that the company sold CBD oil as a dietary supplement; "however, it cannot be a dietary supplement because it does not meet the definition of a dietary supplement," the letter advised. "FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition." In November, FDA issued a consumer update clarifying that the agency "is concerned that people may mistakenly believe that trying CBD 'can't hurt'" while studies have identified possible effects on the liver, male reproductive health and drug interactions.

Shook's Cannabis Law practice, led by Partners Katie Gates Calderon and Greg Wu, helped companies navigate the regulatory minefields of CBD and other cannabis-derived products. Shook also released a white paper, "Wild West or New Frontier? Global Cannabis Market Spurs Legal Spend Across All Sectors," drawing on feedback from in-house counsel in, among other sectors, health and wellness companies.

Sunscreen Questions Come to Light

Between beachfront jurisdictions banning chemicals that block ultraviolet light and scientific inquiries into the safety of sunscreen found in the bloodstream, questions about the use of sunscreen entered the mainstream in 2019. After Hawaii banned oxybenzone- and octinoxate-containing sunscreens based on their purported effects on coral reefs in 2018, additional jurisdictions followed suit, including Key West and the U.S. Virgin Islands. While *Outside* asked if sunscreen is "the new margarine," focusing on the importance of vitamin D and sunscreen's role in preventing the skin from making its own form, the U.S. Food and Drug Administration (FDA) set forth an updated proposal for sunscreen regulations, including a proposal to raise the maximum proposed labeled SPF to 60+ from 50+, and reported that the agency was unable to deem 12 sunscreen active ingredients as safe and effective due to a lack of research. A study published in May made headlines by imparting that sunscreen active ingredients can be absorbed into the bloodstream, but FDA emphasized to the public that absorption does not mean the ingredients are unsafe and encouraged the continued use of sunscreen. The Personal Care Products Council proposed a work plan to provide safety data for eight of FDA's questioned ingredients. Although the 2014 Sunscreen Innovation Act set a deadline of November 26, 2019, for a final rule on sunscreen, FDA's proposed monograph remains in draft form.

LITIGATION

Plaintiffs Target Ingredients in Putative Class Action Complaints

While some 2019 putative class actions focused on undeclared allergens or missing federal disclaimers, many plaintiffs targeted products that allegedly could not live up to the promises made in the marketing. Protein and muscle-building supplements were frequently challenged, including for the omission of an essential amino acid resulting in an "incomplete protein." BPI Sports and Iovate Health Sciences USA, for example, allegedly sold protein dietary supplements that negatively affected protein synthesis, according to putative class plaintiffs.

"Natural" personal care products were also hit with lawsuits alleging they contained synthetic ingredients, including Tarte Cosmetics, Shikai hair and body care products and Thayer's Natural Remedies deodorants, wipes and dry-mouth sprays. Another lawsuit echoed a warning from the U.S. Food and Drug

Administration about dimethylhexamine (DMHA), arguing that Hi-Tech Pharmaceuticals reformulated its supplements with DMHA after federal regulations forbade the use of a similar stimulant the company reportedly said would have the same effects as DMHA.

Plaintiffs also targeted skin care products for failing to deliver on promised anti-aging results, such as a putative class action arguing L'Oréal Revitalift is marketed as able to lift and firm skin or repair wrinkles without qualifying the benefits as helping "the appearance" of those targeted lines. Putative class actions also challenged whether biotin could benefit hair and skin, whether raspberry ketones could help consumers lose weight and whether a supplement can lower cholesterol.

A plaintiff asserted that a hair styling product could not feasibly be marketed as "no flake" if it contained an ingredient with a "natural tendency to produce flaking," while another plaintiff argued that Vitamin Shoppe sells a daily supplement containing enough arsenic to harm daily users. S-adenosylmethionine (SAM-e) supplements were also targeted, and one lawsuit alleged that Nature Medic Fucoidan products could cause cancer cells to "self-destruct" and prevent cancer from spreading in the body.