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LEGISLATION, REGULATIONS & STANDARDS

Former FDA Commissioners, Industry Groups Show Support for Modernized FDA Regulatory Framework

In recent months, two former U.S. Food and Drug Administration (FDA) commissioners and the heads of four major cosmetics industry groups have called on Congress to pass legislation that would modernize FDA's regulatory framework for dietary supplements and cosmetics.

In October, Former FDA Commissioners Scott Gottlieb and Mark B. McClellan called on Congress to act in an article in *JAMA Forum*. They called Congress' failure to advance provisions regarding dietary supplements and cosmetics as part of legislation that will reauthorize user fee programs that help fund FDA work "a profound missed opportunity."

The provision relating to dietary supplements would require all dietary supplement manufacturers to notify FDA when a product is introduced or modified, as well as disclose the composition of ingredients and factors, such as the product's intended dosage and serving size, they wrote.

In discussing the provision regarding oversight of cosmetics, the two said that while most cosmetics are safe, consumers "currently have no reliable way to know what is in their products, to be alerted if a product has safety issues, or to be protected if a manufacturer fails to act to address clear safety problems."

They said the proposed legislation would give FDA authority to recall cosmetics found to contain ingredients that are likely to

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cause serious harm. The proposed legislation would also require cosmetics companies to report serious adverse health effects to FDA.

Their article follows a September 15 letter to lawmakers from the presidents and CEOs of the Personal Care Products Council, Fragrance Creators Association, Independent Beauty Association and Consumer Healthcare Products Association.

The groups thanked the lawmakers for their work on the Modernization of Cosmetics Regulations Act of 2022 and said they stand ready to work with Congress and other stakeholders on "a bipartisan, comprehensive and uniform national framework for cosmetics regulation that advances science, safety, innovation, and consumer confidence."

"[FDA] and the personal care products industry continuously strive to ensure cosmetics safety – beauty and personal care products have an excellent safety record," they said in the letter. "However, because the key statutory provisions authorizing FDA regulation of these products have not been updated since enactment of the Federal Food, Drug, and Cosmetic Act of 1938, we support modernizing cosmetics regulation to ensure that FDA has the appropriate authority and resources it needs to oversee our sector for decades to come."

FDA Issues Warning Letters to Cardiovascular Dietary Supplement Makers

The U.S. Food and Drug Administration (FDA) has issued warning letters to seven companies it says illegally sold dietary supplements claiming to cure, treat, mitigate or prevent cardiovascular disease or related conditions, the agency announced November 17.

FDA issued warning letters to Essential Elements (Scale Media Inc.); Calroy Health Sciences LLC; Iwi; BergaMet North America LLC; Healthy Trends Worldwide LLC (Golden After 50); Chambers' Apothecary; and Anabolic Laboratories, LLC for violating the Federal Food, Drug, and Cosmetic Act.

Under the law, products intended to diagnose, cure, treat, mitigate or prevent disease are considered drugs and are subject to the requirements that apply to drugs, even if they are labeled as dietary supplements. Unlike drugs that are approved by the agency, FDA has not evaluated whether the dietary supplements that are the subject of the warning letters are effective for their

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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.

intended use, what the proper dosage might be, how they could interact with FDA-approved drugs or other substances, or whether they have dangerous side effects or other safety concerns.

“Given that cardiovascular disease is the leading cause of death in the U.S., it’s important that the FDA protect the public from products and companies that make unlawful claims to treat it,” Cara Welch, director of the Office of Dietary Supplement Programs in FDA’s Center for Food Safety and Applied Nutrition, said. “Dietary supplements that claim to cure, treat, mitigate or prevent cardiovascular disease and related conditions could potentially harm consumers who use these products instead of seeking safe and effective FDA-approved treatments from qualified health care providers.”

FDA has requested the companies respond within 15 working days by stating how they will address the issues raised in the letters or provide reasoning and supporting information as to how they think their products are not in violation of the law. If they fail to correct the violations, legal action may result, including potential product seizure and/or injunction.

Governor Vetoes Bill Banning Sale of Weight Loss Supplements to Minors

California Gov. Gavin Newsom has vetoed AB 1341, a bill prohibiting retailers in the state from selling certain weight-loss dietary supplements without a prescription or ID to minors.

The bill sought to prohibit retailers from selling, transferring or providing dietary supplements for weight loss or over-the-counter diet pills to anyone under 18 years old without a prescription or valid ID prior to purchasing. It also required the California Department of Public Health (CDPH) to establish a list of dietary supplements that would be subject to the bill.

In a September 29 veto message, Newsom commended the work of the bill’s author, saying it “raises an important public health issue related to the safety of diet or weight loss pills that can result in injury.

“However, dietary supplements for weight loss are not considered drugs and, therefore, this measure would require CDPH to evaluate every individual weight loss and dietary supplement product for safety, which is beyond the scope of the department's capabilities,” he said.

Newsom directed CDPH to form a work group to study the issue. He also said CDPH is prepared to work with the legislature in its

next session “to address sales age limits and other potential legislative actions to address the responsible sale of dietary supplements for weight loss and over-the-counter diet pills that do not require the state to undertake lengthy and costly pharmacological studies on the many supplements on the market today.”

LITIGATION

Following NIH Study on Hair-Straightening Chemicals, Lawsuit Alleges Product Caused Cancer

A consumer has alleged that L’Oréal USA Inc.’s hair-straightening products—Motions, Organic Root Stimulator Olive Oil Relaxer and Dark & Lovely—contain endocrine-disrupting chemicals (EDCs) that, through repeated exposure, purportedly caused the plaintiff’s uterine cancer. *Mitchell v. L’Oréal USA Inc.*, No. 22-5815 (N.D. Ill., filed October 21, 2022).

The plaintiff's complaint argues that phthalates—“known EDCs which interfere with natural hormone production and degradation and are detrimental to human health”—are used in the products despite alleged links to various health risks. She also alleges that her development of uterine cancer “was the direct and proximate result of the unreasonably dangerous and defective condition of the Products at the time of sale and consumption, including their lack of warnings.” She alleges failure to warn, strict liability for a design or manufacturing defect, fraud, failure to recall and negligence and seeks damages, costs and attorney’s fees.

The complaint cites a number of studies, including a study published by the National Institutes of Health on October 17, 2022, reportedly finding that “women who reported frequent use of hair straightening products, defined as more than four times in the previous year, were more than twice as likely to go on to develop uterine cancer compared to those who did not use the products.”

The methodology and findings of the study have been questioned by some in the industry. “A fundamental principle of epidemiology is that association is not the same as causation; one does not necessarily lead to the other,” a director at the Personal Care Products Council said in a statement. “The association observed in the study is with people who straighten their hair, not the ingredients in hair products or any specific chemicals, as this data was not collected.”

Ingredients in ColourPop Eye Makeup Unsafe for Use Around Eye, Plaintiff Alleges

A consumer has filed a putative class action alleging that the eye makeup manufactured and sold by ColourPop Cosmetics LLC contains "color additives and ingredients that are dangerous when used on the immediate eye area." *Wilson v. ColourPop Cosmetics LLC*, No. 22-5198 (N.D. Cal., filed September 12, 2022). The products at issue include eyeshadow palettes and eyeliner products.

The plaintiff argues that more than 10 of the color additives used by ColourPop are designated by the U.S. Food and Drug Administration as "unsuitable and unapproved for cosmetic use in the eye area." She further asserts that the disclaimer language on ColourPop's website does not mitigate the harm. The website language notes, "[W]hile not intended for use in the immediate eye area, these shades can be used anywhere else on your face or body! [W]e recommend using these shades to enhance your overall look - for example, using the pigments on your temples or underneath your brow."

According to the complaint, "This is neither a safety warning nor an adequate disclaimer because: (1) it does not assist the consumer in understanding the danger; (2) it is designed and displayed in such a manner that a reasonable consumer would not see, receive, or understand it; (3) it does not actually instruct consumers to not use the product in the eye area, and (4) it specifically instructs consumers to use the Products in the immediate eye area, which *includes* 'underneath your brow.'"

The plaintiff seeks damages, class certification, injunctive relief and attorney's fees for alleged violations of California consumer-protection statutes, fraud and breach of warranties.

Adulterated, Misbranded Dietary Supplements Prompt FDA Consent Decree

An Arizona dietary supplement maker accused of allowing its products to become adulterated and selling misbranded products has entered into a consent decree with the U.S. Food and Drug Administration (FDA). *U.S. v. Global Vitality, Inc.*, No. 22-1744 (D. Ariz., filed October 12, 2022).

FDA filed the consent decree and complaint against Global Vitality, which does business as Enzyme Process International.

According to the complaint, during an inspection of the company's Arizona plant in 2021, FDA investigators documented significant deviations from current good manufacturing processes for dietary supplements, including a failure to maintain and clean equipment, utensils and all food-contact surfaces.

FDA also found problems with product labeling, calling the labeling on the company's Enzyme Process-branded shark cartilage product "false and misleading" because it states that the product contains shark cartilage that is freeze-dried, concentrated and bottled without added ingredients, but the product also contains magnesium stearate in addition to shark cartilage.

According to the complaint, FDA has repeatedly warned the company about its ongoing violations, and in January 2020 the agency issued the company a warning letter for introducing into interstate commerce unapproved new drugs, misbranded drugs and adulterated and misbranded dietary supplements.

Under the consent decree, Global Vitality is required to retain independent experts to perform a comprehensive inspection of the facility, review the company's dietary supplement labeling, conduct audit inspections of the facility and certify that the company has brought its operations into compliance. The company and its leaders consented to the entry of the decree, FDA stated in the filing.

'Natural' Shampoo Subject of Consumer Complaint for Synthetic Ingredients

An Illinois woman has filed a proposed class action against cosmetics manufacturer Dr. Squatch, alleging the company's labeling on its Men's Natural Shampoo misleads consumers into believing it is natural when it contains synthetic ingredients. *Fleming v. Dr. Squatch, LLC*, No. 22-4842 (N.D. Ill., filed September 8, 2022).

The plaintiff alleges that the shampoo is misleading because while it is labeled as "natural," it contains several synthetic ingredients, including glycerin, citric acid, fragrance and decyl glucoside.

For alleged violations of the Illinois Consumer Fraud and Deceptive Business Practices Act, as well as other state consumer-fraud acts, the plaintiff is seeking class certification, injunctive relief, damages and reasonable attorney's fees.

Consumer Challenges 'Natural' Ingredients in Drip Drop

A plaintiff has alleged that Drip Drop Hydration Inc. misleads consumers about the nature of the ingredients that flavor its rehydration drink mixes. *Helems v. Drip Drop Hydration Inc.*, No. 22-1419 (S.D. Cal., filed September 20, 2022). The complaint includes pictures on the front of the product packaging that show fruit in a glass of water and asserts that the depictions "emphasize the purported natural flavors of the Products."

"By using depictions of fruits on the packages, Drip Drop signals to consumers, and consumers reasonably understand Drip Drop to be claiming, that the Products are flavored only by the depicted fruits. These claims made on the labels and associated marketing materials of the Products are false. The Products are artificially flavored," the complaint argues. The plaintiff alleges that the flavoring comes from malic acid. "DL malic acid is not a 'natural flavor' as this term is defined by federal and state regulations and is not derived from a fruit or vegetable or any other natural source," the plaintiff asserts.

The plaintiff alleges violations of California's consumer-protection statutes and seeks class certification, damages, injunctive relief, attorney's fees and costs.

Court Allows Consumers' Collagen Claims Against L'Oréal to Proceed

A federal court in New York has denied L'Oréal USA Inc.'s bid to throw out a proposed class action claiming it misleads consumers about the anti-aging properties of its topical products containing collagen. *Lopez v. L'Oréal USA, Inc.*, No. 21-7300 (S.D.N.Y., entered September 27, 2022).

The court denied L'Oréal's motion to dismiss a lawsuit brought by consumers in New York and California. The plaintiffs allege that the company marketed certain topical products as anti-aging because they contained collagen, despite knowing that the collagen in the products could not sufficiently penetrate the skin to produce the purported anti-aging effects.

In the opinion, the court found that the narrow question was whether a reasonable consumer would believe that the term "collagen" on the label referred to collagen molecules that provide cosmetic benefits. He held that the plaintiff has plausibly alleged that the term "collagen" is associated with the skin-related benefits of the collagen molecule.

"The Products contain no qualifying language regarding the inability for the collagen or collagen-related ingredients to penetrate the skin," the court noted. "Instead, the language on the

Products serve to further link the products with the benefits of collagen. The Products promise to deliver benefits by 'smoothing wrinkles' and 'restore skin's cushion.' These benefits purport to reverse signs of aging, namely the dehydration and thinning of the skin, that are commonly associated with the decrease in production of natural collagen."

8th Cir. Affirms Ruling for Memory Drug Maker

A consumer may not proceed on her claims that Natrol, LLC violated Missouri law by failing to disclose the retraction of clinical studies the company used to tout the benefits of its memory supplement, a federal appeals court has ruled. *Vitello v. Natrol, LLC*, No. 21-3150 (8th Cir., entered October 6, 2022).

The plaintiff purchased Natrol's Cognium supplement after seeing it advertised as improving memory and concentration. She was diagnosed with attention-deficit disorder and prescribed Adderall, but quit "cold turkey" after taking the drug for 13 years to try Cognium, according to the opinion.

At the time of her purchase, the product's box contained language claiming that in nine clinical studies in adults, seniors and children, participants showed statistically significant improvements in memory and cognition.

After taking the product and seeing no noticeable improvements, she filed a putative class action against Natrol, alleging that prior to her purchases, two of the clinical studies indicated on the packaging had been retracted for data manipulation and fraud/fabrication and Natrol failed to update its packaging or inform consumers of the retractions. She claimed she would not have purchased the product and sustained the loss had Natrol disclosed the information.

Natrol moved for summary judgment, which the district court granted after ruling that the plaintiff failed to establish an ascertainable loss. On appeal, the 8th Circuit panel agreed.

"Here, [the plaintiff] purchased a product that expressly stated on the label it was 'not intended to' do what she stated she purchased it for, serve as a substitute treatment for her prescription medication," the court said. "Thus, for [the plaintiff], the actual value of the Cognium she purchased, and the value of Cognium without Natrol's alleged marketing misrepresentations, was the same—as [the plaintiff] said in her interrogatory answers, 'zero.'"

Consumer Claims REBBL Beverages' Protein Claims are Misleading

A California woman has filed a proposed class action against REBBL, alleging the company's Plant Based Elixir beverage packaging misleads consumers as to the amount of usable protein in its products. *Roffman v. REBBL, Inc.*, No. 22-5290 (N.D. Cal., filed September 16, 2022).

The plaintiff said in the complaint that REBBL prominently displays on the front of its beverages that they contain 16 grams of protein. She asserts that the U.S. Food and Drug Administration (FDA) requires food manufacturers to calculate the corrected amount of protein per serving based on the quality of the product's protein and to use that calculation to provide a statement of the corrected amount of protein per serving in the nutrition facts panel expressed as a percent daily value, which she alleges REBBL failed to do.

"Consumers reasonably expect that Defendant's products will actually provide nutritionally the full amount of protein per serving claimed on the front of the package and stated in the protein quantity section of the NFP," the plaintiff said in the complaint. "But Defendant's products do not do so on account of their low protein quality. Had Defendant included a statement of the corrected amount of protein per serving in the NFP, as it was required to do under the law, it would have revealed that the product provides nutritionally as little as half of their total protein quantity."

The plaintiff is alleging violations of California's Consumers Legal Remedies Act and False Advertising Law, among other claims, and is seeking class certification, injunctive relief, damages, restitution, pre- and post-judgment interest and reasonable attorney's fees.