Shook, Hardy & Bacon L.L.P.

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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

House Subcommittee Approves Sunscreen Bill

A U.S. House Energy & Commerce Health subcommittee has approved an amended version of a bill (H.R. 4250) that would require the Food and Drug Administration (FDA) to establish a framework with the goal of ensuring more rapid approval of sunscreen ingredients that have already been approved in Europe, Canada and other countries. According to bill-sponsor Rep. Ed Whitfield (R-Ky.), "The framework we have in front of us today will ensure all sunscreen ingredients receive a transparent review within a predictable time frame." With melanoma rates increasing in young women by 800 percent and in young men by 400 percent during the past 40 years, the proposal's sponsors reportedly expressed their concern that FDA has not approved a new sunscreen ingredient in nearly 20 years. Companion legislation has been introduced in the Senate. *See Bloomberg BNA Product Safety & Liability Reporter™*, June 20, 2014.

U.S. Congress to Consider Banning Microbead Use

U.S. Rep. Frank Pallone (D-N.J.) has introduced a bill (H.R. 4895) that would prohibit the sale or distribution of cosmetics and personal care products containing synthetic plastic microbeads. Under the proposal, manufacturers would have until January 1, 2018, to change their products. Pallone noted that substitutes, such as ground walnut husks, pecan shells, cocoa beans, and other biodegradable products are already available on the market. He said, "These tiny plastic particles that are polluting our environment are found in products specifically designed to be washed down shower drains. And many people buying these products are unaware of their damaging effects" in the nation's waterways. *See Rep. Frank Pallone News Release*, June 18, 2014.

Meanwhile, Illinois Gov. Pat Quinn (D) has signed a bill (S.B. 2727) that reportedly makes the state the first in the nation to prohibit the manufacture and sale of microbeads by the end of 2019. He said, "Banning microbeads will help ensure clean waters across Illinois and set an example for our nation to follow.

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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Lake Michigan and the many rivers and lakes across our state are among our most important natural resources. We must do everything necessary to safeguard them." *See Gov. Pat Quinn News Release*, June 8, 2014.

Senate Subcommittee Considers Deceptive Weight-Loss Supplement Claims

Among those who recently testified before the Senate Subcommittee on Consumer Protection, Product Safety and Insurance were Federal Trade Commission (FTC) and industry representatives, as well as Mehmet Oz, who was apparently grilled about the weight-loss product promotions on his afternoon TV program, "The Dr. Oz Show." Subcommittee Chair Sen. Claire McCaskill (D-Mo.) led the panel investigating false advertising for weight-loss products and asked Oz, "I don't get why you need to say this stuff when you know it's not true. When you have this amazing megaphone, why would you cheapen your show? . . . With power comes a great deal of responsibility."

Among the products discussed were green coffee beans, which FTC targeted in May 2014 when it sued their manufacturer for deceptive practices. Oz promoted the product during his show, and product sales reportedly increased with some companies using video from the program to promote them. Details about the litigation appear in Issue 25 of this *Report*.

During the hearing, FTC Associate Director for Advertising Practices Mary Koelbel Engle reported on efforts the agency has undertaken to rein in the $2.4-billion weight-loss industry, noting that little evidence supports claims that pills or supplements alone will cause sustained weight loss without other changes to diet and lifestyle. During the past decade, FTC has apparently brought 82 weight loss-related enforcement actions, and since 2010 has collected some $107 million in restitution for consumers. It has also launched an interactive consumer video and game, in English and Spanish, to help consumers think critically about manufacturer claims for weight-loss products. Still, for all of its efforts, American consumers continue to spend billions every year on these products without any noticeable impact on obesity rates. *See The National Law Journal*, June 17, 2014; *CNN*, June 18, 2014.

FDA Issues Guidance on Nanotech Use in Cosmetic Products

The U.S. Food and Drug Administration (FDA) has issued a document titled "Final Guidance for Industry: Safety of Nanomaterials in Cosmetics." The guidance "describes the FDA's current thinking on the safety assessment of nanomaterials when used in cosmetic products and encourages manufacturers to consult with the FDA on test methods and data needed to support the substantiation of a product's safety."

Among other matters, the guidance recommends that safety assessments should address (i) "the physicochemical characteristics," (ii) "agglomeration

and size distribution of nanomaterials under the conditions of toxicity testing and as expected in the final product," (iii) "impurities," (iv) "potential routes of exposure to the nanomaterials," (v) "potential for aggregation and agglomeration of nanoparticles in the final product," (vi) "dosimetry for *in vitro* and *in vivo* toxicology studies," and (vii) "*in vitro* and *in vivo* toxicological data on nanomaterial ingredients and their impurities, dermal penetration, potential inhalation, irritation (skin and eye) and sensitization studies, mutagenicity/genotoxicity studies." *See FDA News Release*, June 24, 2014.

FDA Warns of Tainted Bee Pollen Weight-Loss Supplements

The U.S. Food and Drug Administration (FDA) has issued a warning about potentially dangerous undeclared ingredients found in some bee pollen weight-loss supplements. The agency has apparently received more than 50 reports of problems allegedly caused by products tainted with sibutramine and/or phenolphthalein, including one possible death, serious heart issues, chest pain, heart palpitations, increased heart rate, elevated blood pressure, seizures, suicidal thoughts, anxiety, insomnia, and diarrhea. According to FDA National Health Fraud Coordinator Gary Coody, "When people buy these tainted bee pollen products, they are unknowingly taking one or more hidden drugs that have been banned from the market." *See FDA Consumer Update*, June 19, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Class Certified in Cobra Sexual Energy Supplement Action

A California federal court has granted statewide class certification in a case against Nutraceutical Corp. alleging that the company's sale of its Cobra Sexual Energy dietary supplement violated state unfair competition and false advertising laws. *Ortega v. Natural Balance Inc.*, No. 13-5942 (U.S. Dist. Ct., C.D. Cal., order entered June 19, 2014). Assessing the plaintiffs' motion under Rule 23's class-certification requirements, the court concluded that "the class action procedure is superior to other available methods for fairly and efficiently adjudicating the controversy."

The plaintiffs allege that Cobra's ingredients had not been proven individually or in combination to enhance virility as Nutraceutical's packaging claimed and seek full refunds for the $16 to $17 purchase price. They claim that some ingredients—including yohimbe bark extract and Brazilian "potency wood"—are potentially harmful for customers with particular medical or psychological conditions and fail to increase sexual desire or ability. A similar case against Nutraceuticals was denied class certification in 2011 because the plaintiff had purchased the supplement for her husband's use rather than her own, so the court deemed her atypical of the potential class.

In its analysis, the court dismissed the previous class-certification denial as irrelevant because the plaintiffs here were typical class members who had purchased the product for themselves. The court limited the class, however, from the plaintiffs' proposed group encompassing Californians who purchased the product after January 1, 2006, to only those purchasers whose claims were not barred by a statute of limitations. The plaintiffs argued that claims as old as 2006 should be allowed because of the delayed discovery rule despite the four-year statute of limitations, but the court dismissed that argument because the plaintiffs had "no personal interest" in asserting the rule. The court also found the class to be ascertainable, the plaintiffs to be adequate representative parties, and the class-action procedure to be the most efficient method of resolving the claims.

Class Certification Denied in Challenge to Efficacy of Natrol Supplements

A California federal court has denied class certification and dismissed a complaint against Natrol Inc. on subject matter jurisdiction grounds in a putative class action challenging company claims that its L-Arginine supplements cause vasodilation to support muscularity and the immune system, among other health-related claims. *Kachi v. Natrol Inc.*, No. 13-0412 (U.S. Dist. Ct., S.D. Cal., order entered June 19, 2014).

The plaintiff alleged that three nutritional supplements produced with L-arginine purported to increase vasodilation to increase metabolism of nitric oxide, but with the support of an expert's report, he argued that several scientific studies show that oral arginine supplementation does not increase nitric oxide levels. The court distinguished the cited studies from those Natrol presented by pointing to the subjects of the plaintiff's studies as "healthy populations," while Natrol argued that its supplement could help other populations like the elderly, overweight or diabetes-afflicted. The court concluded that the plaintiff failed to satisfy the commonality and typicality requirements of Rule 23(a), which establishes class-action prerequisites.

The court also assessed whether it had subject matter jurisdiction under the Class Action Fairness Act. With 200,000 bottles of supplements sold at about $10 each, the court calculated that the amount in controversy failed to exceed the $5-million jurisdictional threshold; in addition, the court found that the parties were not diverse because all plaintiffs and defendants were California citizens. Accordingly, the court dismissed the complaint, but did so without prejudice.

European-Wide Remedy Imposed in Online "Lush" Infringement Action

With the parties unable to agree on a remedy in litigation against Amazon for intellectual property infringement involving beauty brand Lush, a court has imposed broad injunctive relief that will be effective throughout Europe,

rather than limited just to the United Kingdom as Amazon.co.uk Ltd. had requested. Additional details about the litigation appear in Issue 20 of this *Report*. To remedy claims that Amazon infringed the Lush trademark by diverting customers who searched for the personal-care product company's products to equivalent goods made by others, the court will reportedly require the online retailer to change its software as to any use of the Lush brand and to display a notice about the court ruling on its Website. *See Cosmeticsdesign-europe.com*, June 10, 2014.

Misleading Labeling of Sunscreen Products Alleged

A Florida resident has filed a putative class action against Neutrogena Corp. alleging that the company misleads consumers in the labeling and marketing of certain of its sunscreen products. *Dapeer v. Neutrogena Corp.*, No.14-22113 (U.S. Dist. Ct., S.D. Fla., filed June 6, 2014). The plaintiff specifically challenges claims that the products are "water resistant" or provide "water + sun barrier" protection and further contends that the company's SPF 55, 60, 70, 85, 100, or 110 products cannot, as advertised, labeled and marketed, provide sun protection superior to lower SPF sunscreen products.

Seeking to certify nationwide and statewide classes, the plaintiff alleges violation of the Florida Deceptive and Unfair Trade Practices Act, unjust enrichment and negligent misrepresentation. He requests injunctive relief, restitution, disgorgement, attorney's fees, costs, and interest.

Putative Class Action Filed Against Manufacturer of Go Away Gray Supplement

A consumer has filed a putative class action claiming that Rise-N-Shine LLC falsely advertises its Go Away Gray product line of natural supplements, shampoo and conditioner by claiming that it can restore natural hair color. *Wiggins v. Rise-N-Shine LLC*, No. 14-2733 (U.S. Dist. Ct., N.D. Cal., filed June 12, 2014).

The complaint alleges that defendants Rise-N-Shine and its self-proclaimed holistic-healer president Cathy Beggan advertise Go Away Gray as a scientifically proven method of restoring a person's original hair color by taking supplements and using the line's shampoo and conditioner, while the "scientific studies" they cite amount to a single study. The supplement purports to supply to the hair the natural enzyme "catalase," which Beggan and Rise-N-Shine allegedly advertise will result in the prevention of new gray hair growth within about six to eight weeks.

According to the complaint, Rise-N-Shine and Beggan regularly cite a 2009 study linking low levels of catalase to the occurrence of gray hair, but it does not support their argument that oral or topical catalase application will stop the production of gray hair and rather is "biologically impossible" because of "[b]asic laws of biochemistry." In addition to class certification, plaintiff seeks damages and an injunction preventing Beggan and Rise-N-Shine from marketing the product as a gray-hair-reversal product.

INTERNATIONAL DEVELOPMENTS

Danish Nano Product Registry Takes Effect

Companies that manufacture or import mixtures or articles incorporating nanomaterials and intended for sale to the Danish general public are now obligated to disclose this information annually under an order that took effect June 18, 2014. The first reports for the period June 20, 2014, to June 20, 2015, must be made by August 30, 2015. A number of products, including drugs and cosmetic products, are exempt from the disclosure requirements, but these exempted items are not further defined and do not appear to include dietary supplements or personal care products. The register will not be publicly available, and trade secrets will be protected.

ASA Upholds Teeth-Whitening Ad Complaint

Britain's Advertising Standards Authority (ASA) has upheld a complaint targeting TV and YouTube promotions for a teeth-whitening product and stated that the "ad must not appear again in its current form." Fdd International Ltd. ran the ad showing a "woman smiling and a graphic of eight different shades of tooth colour" with a voiceover stating "White teeth whitening kit. Instant results in up to eight shades whiter, and clinically proven safe and effective." The large text at the top of the screen stated "INSTANT results*" with smaller text at the bottom stating "*Instant results, up to 8 shades whiter after 1 application of 20 minutes."

The company provided a copy of a study purportedly supporting its claims, as well as the underlying raw data, but ASA, noting that it was not peer-reviewed, pointed to several shortcomings, including that (i) "it did not contain details or any calibration exercise undertaken by the investigator to demonstrate a consistent approach to assessing tooth colour," (ii) it was not blinded, (iii) no control group was used, (iv) the investigator and participants "appeared to be aware of the objectives of the study," and (v) the sample size of 25 participants was small and not likely sufficient "to deliver statistically significant results." ASA also observed that the tooth-whitening scale used in the ad contained just eight shades of color, but was based on a shade guide containing16 incremental shades thus "exaggerating the possible degree of change that could be achieved from use of the product."

Skin Lightening Products Stir Controversy Worldwide

From allegations about mercury-laden skin lightening creams in the Philippines to new draft guidelines in India about advertising such products in a non-discriminatory manner, recent weeks have brought continuing headline stories in the media concerning these popular products.

According to one news source, the Japanese cosmetics company Kanebo has apparently begun providing interim payments to 4,000 people who complained that the "Rhododenol" in its whitening creams caused their skin blotches and discoloration. The company had been criticized for delaying compensation, but a spokeswoman reportedly said that Kanebo was already paying medical expenses for those affected and will provide initial compensation for damages and any leave taken for treatment. She said, "In the past we said we will pay compensation and leave expenses when patients fully recuperate, but we have now decided to make interim payments if these customers wish." Some 15,000 complaints have been made by users in Japan of 54 products containing the chemical. *See AgenceFrancePresse*, June 20, 2014.

The Advertising Standards Council of India (ASCI), meanwhile, has **issued** draft guidelines for advertising skin lightening products. According to the preamble, "[T]here is a strong concern in certain sections of society that advertising of fairness products tends to communicate and perpetuate the notion that dark skin is inferior and undesirable." Thus ASCI proposes that advertising for these products should not (i) "communicate any discrimination as a result of skin colour"; (ii) "use post production visual effects on the model/s to show exaggerated product efficacy"; (iii) "associate darker or lighter colour skin with any particular socio-economic strata, caste, community, religion, profession or ethnicity"; or (iv) "perpetuate gender based discrimination because of skin colour." ASCI has requested comments on the draft guidance from stakeholders.

The Malaysia Health Ministry has **warned** consumers to avoid buying and using two cosmetic products from Ireland because they apparently contain hydroquinone and tretinoin. The ministry states that while cosmetic products "adulterated with hydroquinone" are typically marketed to lighten skin and to treat blemishes and uneven skin tone, this chemical "can cause skin redness, discomfort, skin discoloration, hypersensitivity and a gradual blue-black darkening of the skin." Cosmetics "adulterated with tretinoin are commonly promoted for use in acne and to reduce wrinkles," but, the ministry said, preparations with this chemical should be used under the supervision of a health-care professional because unsupervised usage "can cause redness to the skin, discomfort, stinging, peeling and sensitivity to lights." *See Malaysia Ministry of Health Press Release*, June 13, 2014.

A public interest coalition in the Philippines has reportedly questioned whether Cebu City has become "the toxic whitening cosmetics capital of the Philippines." According to the EcoWaste Coalition, unapproved skin lightening creams containing mercury have been found openly displayed and sold in city markets. The group has urged city government to take immediate action to stop the sale of these and other cosmetics and personal care products that have not been approved. Of 13 products tested, the coalition reportedly found that 11 contained elevated levels of mercury, ranging from 3,218 parts per million (ppm) to 13,900 ppm, far exceeding the ASEAN threshold limit of 1 ppm for mercury in cosmetics. *See EcoWaste Coalition Blog*, June 18, 2014.

EMERGING TRENDS

Brazil Adopts Animal-Testing Ban

Under compromise legislation (Bill 6602/13) recently passed by Brazil's Chamber of Deputies, manufacturers will not be allowed to use animals in tests for cosmetics where alternatives have been established and approved internationally. The prohibition, which takes effect in September 2014, will not apply to novel ingredients—those with "unknown effects"— developed for use in cosmetics nor will it prohibit the sale of newly animal-tested products. Be Cruelty-Free Brazil campaigned for the legislation, but claims that it should be immediately amended to avoid certain "unfortunate loopholes" that will, for example, allow companies to test their products on animals in other countries and sell them back to Brazil. According to supporters, the bill was fast-tracked due to the World Cup and had the support of politicians, celebrities and nearly 100,000 individuals who signed a petition urging an animal-testing ban. *See Humane Society International Press Release*, June 5, 2014; *Cosmeticsbusiness.com*, June 18, 2014.

Harvard Researchers Develop Potential Animal-Testing Alternative

Scientists with Harvard University's Wyss Institute for Biologically Inspired Engineering have reportedly developed microchips lined with human cells—so-called "organs-on-chips"—that could mimic functions of living organs, such as the lung, heart and intestine, and allow the rapid toxicity, safety and efficacy assessment of cosmetics, chemicals or new drug candidates. They suggest that the technology, involving a clear flexible polymer about the size of a computer memory stick containing hollow microfluidic channels lined by living human cells, could reduce science's reliance on animal testing. The institute team is focusing on building 15 different human organs-on-chips that will be linked to allow whole-body physiology testing. *See ABC News*, June 3, 2014.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Researchers Find Banned Amines in Hairdressers' Blood

Swedish researchers have found that, while aromatic amines classified as carcinogens have been prohibited from use in cosmetics in the European Union, several have been measured in the blood of hairdressers and the concentrations increase significantly with the frequency of light-color permanent hair dye and hair waving treatments. Gabriella Johansson, et al., "Exposure of hairdressers to ortho- and meta-toluidine in hair dyes," *Occupational & Environmental Medicine*, June 9, 2014.

The researchers measured eight potentially carcinogenic aromatic amines in the blood of 295 hairdressers, 32 users of hair dyes and 60 controls. All were non-smoking women. According to the study, "A comparison of the adduct concentrations found in hairdressers, consumers and controls showed no statistically significant differences," but for hairdressers, o- and m-toluidine concentrations increased with the number of dye and waving treatments performed each week. The researchers recommend that future studies focus on "finding exposure sources of o- and m-toluidine in products used by hairdressers" who are at an excess risk for urinary bladder cancer, which has purportedly been associated with these chemical exposures.

Nanoparticles in Dietary Supplement Drinks Likely Reaching Environment

Researchers studying the metallic nanomaterials in eight commercially available dietary supplement drinks have found that the drinks changed the normal organization and significantly decreased the number of human intestinal microvilli—cell projections that help digest food—and that daily use, assuming release to sewer systems, where large percentages of nanomaterials are not efficiently removed, likely result in these substances making their way into surface water with the potential to adversely affect aquatic life. Robert Reed, et al., "Characterization of Nanomaterials in Metal Colloid-Containing Dietary Supplement Drinks and Assessment of Their Potential Interactions after Ingestion," *ACS Sustainable Chemistry & Engineering*, June 2, 2014.

According to the study, the drinks, which claim to improve "human health and function for a variety of organs," contained metal nanomaterials in the 1-100 mg/L concentration range. The researchers "investigated the interaction of NMs [nanomaterials] in the drinks with an in vitro cell system that faithfully mimics human intestinal cells [and] found that the number of microvilli

decreased relative to untreated controls for all drinks." They also studied nanomaterial removal by biosolids in wastewater treatment plants using the nanomaterials in the supplement drinks and found "variable removal" rates ranging from 99 to 30 percent.

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LEGAL TRENDS REPORT

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. The firm helps 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.

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