Shook, Hardy & Bacon L.L.P.

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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

Cal/EPA Lists Trichloroacetic Acid as Reproductive Toxicant Under Prop. 65

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has added, effective September 13, 2013, trichloroacetic acid to its Proposition 65 (Prop. 65) list of chemicals known to the state to cause reproductive health effects.

Commonly used for cosmetic treatments, such as chemical skin peels, tattoo removal and the treatment of warts, skin tags and moles, trichloroacetic acid works by removing the top few layers of skin, allowing new skin cells to appear. Substances added to the Prop. 65 list are those identified as known to the state to cause cancer or reproductive risk. Companies using the chemicals in products sold in California must provide warnings to consumers.

NTP Seeks Information on Substances Nominated for Future RoC

The National Toxicology Program (NTP) has issued a request for information on 20 substances—six of which are commonly used in the cosmetics and dietary supplement industry—that have been nominated for possible review for future editions of the agency's Report on Carcinogens (RoC). Specifically, NTP seeks the following: (i) data on current production, use patterns and human exposure; (ii) information about published, ongoing or planned studies related to evaluating carcinogenicity; (iii) scientific issues important for assessing carcinogenicity of the substance; and (iv) names of scientists with expertise or knowledge about the substance.

Among the substances listed are (i) aloe vera whole leaf extract, an herbal remedy also used in health care products and cosmetics; (ii) coconut diethanolamide, used in cosmetics, shampoo and soap; (iii) the dietary supplements ginkgo biloba extract, goldenseal root powder and kava extract; and (iv) pulegone, a flavoring used as a fragrance and herbal medicine. Information submissions will be accepted until October 18, 2013. *See Federal Register,* September 20, 2013.

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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If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

NTP Seeks Information on Vinpocetine

The National Toxicology Program (NTP) has issued a request for information "to facilitate the design of toxicological studies for vinpocetine," a semi-synthetic derivative of the dietary supplement vincamine. The agency specifically seeks information regarding (i) exposure, pharmacokinetics, toxicity, safety, or efficacy in humans; (ii) production, use and consumption patterns in the United States; (iii) genotoxicity, repeated dose toxicity, prenatal developmental toxicity, reproductive toxicity, chronic toxicity, and carcinogenicity studies in experimental animals; and (iv) any other information relative to the safety or toxicity of vinpocetine. Comments will be accepted until November 4, 2013. *See Federal Register,* September 24, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

Federal Court Dismisses Claims About Dietary Supplement's Ineffectiveness

A federal court in Florida has dismissed without prejudice a putative class action against GNC Holdings, Inc. seeking damages under the state's Deceptive and Unfair Trade Practices Act for alleged false advertising of the defendant companies' TriFlex® line of products, containing glucosamine and chondroitin. *Toback v. GNC Holdings, Inc.*, No. 13-80526 (U.S. Dist. Ct., S.D. Fla., decided September 13, 2013). According to the complaint, scientific research shows that these ingredients do not, as advertised, promote joint health and function and that the product the plaintiff purchased did not provide him with the advertised benefit.

Finding Federal Rule of Civil Procedure 9(b) inapplicable, the court ruled that the plaintiff had pleaded fraud with sufficient particularity under the Florida statute despite failing to allege separately which deceptive acts the plaintiff attributed to each defendant and failing to plead which health-benefit representations he was exposed to and when or where that exposure occurred. The court further determined that while Florida state courts had not defined a clear causation standard under the statute, "the Eleventh Circuit has held that the element of causation is met when the alleged misrepresentations would have deceived an objectively reasonable person." According to the court, the plaintiff "pleaded facts suggesting that the representations at issue would have deceived reasonable consumers."

The court also rejected the defendants' argument that a plaintiff alleging a violation of Florida's statute must plead that the product representations were affirmatively false and misleading and not merely unsubstantiated. In this regard, the court noted that (i) it is unclear whether a lack of substantiation claim is unavailable under the statute, and (ii) the plaintiff affirmatively alleged that the studies showed that glucosamine and chondroitin, two ingredients in the TriFlex® products, were ineffective in promoting joint health, thus alleging

the existence of scientific evidence contradicting the representations and demonstrating their falsity.

Agreeing with the defendants as to the plaintiff's lack of standing to pursue claims with respect to products he did not purchase, the court noted the district court split over the issue. Some refuse to address the matter on a motion to dismiss, finding it properly addressed at the class-certification stage. Under Eleventh Circuit precedent, however, "at least one named plaintiff must establish Article III standing for each class subclaim . . . and deferring the standing determination to the class-certification stage would yield no different result." The court ruled that the plaintiff has standing to bring only those claims relating to the TriFlex® Vitapak.

The court also determined that because the complaint has a "laser-like focus on the shortcomings of glucosamine and chondroitin" and fails to address the efficacy of other ingredients, such as cutch tree extract, Chinese skullcap root extract, methylsulfonyl-methane, white willow bark extract, fish oil, and other substances, that are apparently part of "a comprehensive Vitapak program that supports improved joint health," the plaintiff's inefficacy allegations do not rise "above the speculative level." In a similar vein, the court found that the plaintiff's "conclusory allegation that the Vitapak 'did not help repair or preserve' his cartilage" was devoid of any further detail or support and was accordingly merely a "legal conclusion couched as a factual allegation" that the court "is not bound to accept as true." The plaintiff was given the opportunity to file an amended complaint by September 27, 2013.

Putative Class Claims Work-Out Supplements Lack Advertised Ingredients

A California resident has filed a putative nationwide consumer-fraud class action against a company that makes "Dark Rage," "Anadrox" and "Trac-Extreme" work-out supplements, alleging that laboratory tests show they lack the key ingredients purportedly responsible for their claimed muscle, energy, vascular, fat loss, and strength effects. *Janovick v. Maximum Human Performance, Inc.*, No. 13-2129 (U.S. Dist. Ct., S.D. Cal., filed September 11, 2013).

According to the plaintiff, "Dark Rage" does not contain L-Arginine AKG and the other two products do not contain l-citrulline or citrulline malate. While the company apparently promotes the efficacy of the "next generation ingredients" in its products, the plaintiff contends that lacking the specific ingredients for which the products were tested renders the efficacy claims "completely false." He alleges that he relied on the advertisements and would neither have purchased the products nor paid as much as he did for them had he known they lacked these ingredients.

Alleging violations of California's false advertising law and unlawful, fraudulent and unfair business practices, the plaintiff seeks damages, restitution, injunctive relief, interest, attorney's fees, and costs.

L'Oréal to Appeal Certain NAD Mascara Ad Recommendations

The National Advertising Division (NAD) of the Advertising Self-Regulatory Council (ASRC) has reportedly recommended that L'Oréal cease using "eyelash inserts in mascara advertisements that also make quantified performance claims or explicitly tell consumers—in the main message of the advertisement—that an image depicts the use of both mascara and lash inserts." L'Oréal has indicated that it will appeal the decision to the National Advertising Review Board. The company apparently contends that "artificially enhanced stylized glamour shots are not misleading because consumers understand that such visuals are not intended to represent typical consumer results from usage." The advertising at issue involved the company's Maybelline "Rocket" mascara and L'Oréal Paris "Telescopic Shocking Extensions" mascara. NAD is part of an industry self-regulatory system administered by the Council of Better Business Bureaus. *See ASRC Press Release*, September 17, 2013.

Online Ad Regulator Finds Support for Dietary Supplement Claims

The Electronic Retailing Self-Regulation Program (ERSP), an investigative unit of the advertising industry's system of self-regulation, has reportedly determined that clinical testing provides a reasonable basis for Farr Laboratories, LLC to make general performance claims in online ads for Prosta-Q, a dietary supplement. According to ERSP, the company can continue to claim that its product provides relief from the symptoms associated with chronic prostatitis and general pelvic pain, although it recommended that Farr Labs modify the claim that the product's ingredients "have been clinically proven to aid digestion." A banner ad asserting that the product is the "#1 doctor supported and recommended prostate supplement" was apparently disseminated by a third-party affiliate advertiser, and the company informed ERSP that it had requested that the advertiser stop running the banner. *See Advertising Self-Regulatory Council Press Release*, September 23, 2013.

EMERGING TRENDS

Report Suggests That Supplements Could Save Billions in Health Care Costs

A new **report**, *Smart Prevention—Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements,* issued by the economic firm Frost & Sullivan and commissioned by the Council for Responsible Nutrition (CRN) Foundation, suggests that dietary supplement use not only provides health benefits, but also offers significant savings, potentially "hundreds of millions of dollars—and in some cases billions" in health care costs.

To compile the report, researchers reviewed hundreds of scientific studies on eight dietary supplement regimens—omega-3, B vitamins, phytosterols, psyl-

lium dietary fiber, chromium picolinate, lutein and zeaxanthin, calcium and vitamin D, and magnesium—across four diseases to determine the reduction in disease risk from these preventative practices. The firm then projected the rates of medical events across high-risk populations and applied cost-benefit analyses to determine the cost savings if people at high risk took supplements at preventative intake levels.

The report cites data from the Centers for Disease Control and Prevention (CDC), which notes that 75 percent of U.S. health care dollars go to the treatment of chronic disease with only 3 percent spent on prevention. According to CDC, the expected cost for inpatient procedures and emergency room visits related to coronary heart disease are expected to cost $77.92 billion per year. Frost & Sullivan researchers contend that if men and women (ages 55 and older) with elevated cholesterol levels took psyllium dietary fiber at preventative intake levels on a daily basis, the cost savings for coronary heart disease-related treatment could be almost $2.5 billion a year. If all women older than 55 with osteoporosis took calcium and vitamin D at preventative intake levels on a daily basis, the cost savings could equal $1.5 billion a year, the report states.

Calling the report's findings "game changing," Frost & Sullivan Global Program Manager Chris Shanahan said, "I anticipate this report will fuel the critical conversation around the importance of preventive health care practices to control health care spending, and the critical role dietary supplements can play in reducing the risk of medical events associated with these diseases." *See Council for Responsible Nutrition Foundation News Release,* September 23, 2013.

Cosmetics Chemicals Markets Expected to Reach $21.91 Billion by 2016

International Research firm TechNavio has issued a report which forecasts that the global market for cosmetics chemicals will expand from $18.42 billion to $21.91 billion by 2016. North and South America and the Asia-Pacific region are expected to be the strongest areas of growth, driven by demand for bio-ingredients and skin care cosmeceuticals. Facial care products, apparently the largest driver of expansion, will be the strongest segment from 2011-2015, with sun care products, baby care products and skin care products for men expected to show high increases. Key industry trends will include the growing popularity of natural and organic products, increasing awareness about health and wellness, increasing acceptance of skin-whitening products, and an increased focus on marketing. Industry challenges will reportedly include regulatory barriers, particularly in the biotechnology and nanotechnology fields, and high research and development costs. *See Cosmeticsdesign-europe.com,* September 17, 2013.

INTERNATIONAL DEVELOPMENTS

CFDA Seeks Comments on Revisions to Cosmetics Regulations

The China Food and Drug Administration (CFDA) has issued a notice inviting comments on its "Regulations concerning the Hygiene Supervision over cosmetics," which the agency intends to amend for the first time in 23 years. According to a news source, the rapid development of China's cosmetics industry, combined with profound changes in the industry, social environment and regulatory and supervisory arenas, have rendered the existing legislation "grossly inadequate" to meet the demands of China's current market.

Following the comment period, CFDA reportedly intends to release a draft of the amended regulation by the end of 2013 for a second round of public consultation. Industry insiders have reportedly predicted that China plans to tighten control over cosmetics that make efficacy claims, such as skin-whitening and anti-wrinkle properties. Comments will be accepted until October 10, 2013. *See chemlinked.com,* September 18, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

OECD Report Identifies Priority Needs in Nano Risk Assessment

The Organization for Economic Cooperation and Development (OECD) has issued a report titled "Cooperation on Risk Assessment: Prioritization of Important Issues on Risk Assessment of Manufactured Nanomaterials—Final Report." Citing "major gaps" in knowledge as to "how traditional physico-chemical approaches can be used to assess the behaviour of nanomaterials, i.e., if and what physico-chemical properties are predictors of (eco)toxicity and environmental behavior," OECD identifies research priorities that include physical chemistry, nanomaterial identification, environmental fate and effects, exposure models, and adverse effects.

Antibacterial Products Linked to Resistant Bacteria in Waterways

A new study by scientists from the Cary Institute of Ecosystem Studies in Millbrook, New York, Loyola University Chicago and Illinois Sustainable Technology Center, has reportedly revealed that triclosan—a synthetic antibacterial widely used in personal care products—is fueling the development of resistant bacteria in streams and rivers. Bradley Drury, et al., "Triclosan Exposure Increases Triclosan Resistance and Influences Taxonomic Composition of Benthic Bacterial Communities," *Environmental Science and Technology,* August 6, 2013.

Invented for surgeons in the 1960s, triclosan is an antibacterial agent designed to slow or stop the growth of bacteria, fungi and mildew. It is used in many liquid soaps and toothpastes, deodorants and cosmetics. Previous research has shown that the substance enters streams and rivers through domestic wastewater, leaky sewer infrastructure and sewer overflows, with residues apparently common in waterways throughout the United States.

In what is considered to be the first study to document triclosan resistance in a natural environment, researchers explored how bacteria living in stream and river sediments responded to triclosan in both natural and controlled settings by conducting field studies at three sites in the Chicago metropolitan region—urban North Shore Channel, suburban West Branch Dupage River and rural Nippersink Creek—and artificial stream experiments at Loyola University.

Noting that urbanization correlated with a rise in both triclosan concentrations in sediments and the proportion of bottom-dwelling bacteria resistant to triclosan, the scientists reported a "strong link between the presence of triclosan in the environment and the development of triclosan-resistant bacteria."

"The bacterial resistance caused by triclosan has real environmental consequences," said Emma Rosi-Marshall, a study author and aquatic ecologist at the Cary Institute of Ecosystem Studies. "Not only does it disrupt aquatic life by changing native bacterial communities, but it's linked to the rise of resistant bacteria that could diminish the usefulness of important antibiotics."

The artificial stream experiments confirmed field findings that triclosan exposure triggers an increase in triclosan-resistant bacteria. In addition to the creation of these resistant bacteria, researchers also found a decrease in the diversity of benthic bacteria and a shift in the composition of bacterial communities. Most notable were a six-fold increase in cyanobacteria and a dramatic die-off of algae. *See Cary Institute of Ecosystem Studies News Release,* September 19, 2013.

Omega-3s Linked to Fewer Symptoms of Depression in Women

A recent **study** conducted by scientists at the National Institutes of Health, University of Delaware and Eastern Virginia Medical School, has reportedly revealed that American women with higher blood levels of omega-3 fatty acids have up to a 49-percent reduction in risk of elevated depressive symptoms." May Beydoun, et al., "Omega-3 Fatty Acid Intakes Are Inversely Related to Elevated Depressive Symptoms among United States Women," *Journal of Nutrition,* September 4, 2013.

The study evaluated the association between omega-3 intakes and symptoms of depression using the 20-item Center for Epidemiologic Studies-Depression

Scale in 1,746 adults ages 30 to 65. According to the researchers, the study findings "support the hypothesis of a protective effect of n-3 fatty acids, both [n-3 highly unsaturated fatty acids (HUFAs; at least 20 carbons), n-3 polyunsaturated fatty acids (PUFAs; at least 18 carbons)], against depressive symptoms, particularly among women."

The data also revealed that elevated depressive symptoms were prevalent in 25.6 percent of women and 18.1 percent of men. Adequate intakes of linoleic acid and alpha-linoleic acid were observed in 43 to 59 percent of men and women. Significantly fewer men and women, however, achieved adequate intakes of eicosapentaenoic acid plus docosahexaenoic acid, with levels ranging from 5.2 percent to 17.2 percent. The study also indicated that the highest intakes of omega-3 PUFAs were associated with a "significant" 49 percent reduction in the risk of elevated depressive symptoms in women. *See naturallysavvy.com,* September 24, 2013.

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LEGAL TRENDS REPORT

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