Shook, Hardy & Bacon L.L.P.

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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

Bipartisan Proposal Introduced to Overhaul Chemical Regulation

U.S. Senators Frank Lautenberg (D-N.J.) and David Vitter (R-La.) have introduced a bipartisan bill (S. 1009) to amend the Toxic Substances Control Act (TSCA), the primary federal statute regulating chemical substances. According to Lautenberg, the proposed legislation would "significantly update and improve TSCA," which has "proven ineffective" and has been highly criticized by both public health officials and industry representatives. The new bill aims to ensure that "all chemicals are screened for safety to protect public health and the environment, while also creating an environment where manufacturers can continue to innovate, grow, and create jobs."

"This bipartisan agreement is an historic step toward meaningful reform that protects American families and consumers," Lautenberg said. "Every parent wants to know that the chemicals used in everyday products have been proven safe, but our current chemical laws fail to give parents that peace of mind. Our bipartisan bill would fix the flaws with current law and ensure that chemicals are screened for safety."

To that end, the new bill would (i) require safety evaluations for all active chemicals in commerce; (ii) protect public health from unsafe chemicals and give the U.S. Environmental Protection Agency (EPA) authority to take action, such as banning a chemical; (iii) prioritize chemicals for review; (iv) screen new chemicals for safety, including giving EPA authority to prohibit unsafe chemicals from entering the market; (v) secure necessary health and safety information from chemical manufacturers; (vi) promote innovation and safer chemistry; (vii) protect children and pregnant women by adding a new provision requiring risk evaluation for vulnerable populations; and (viii) give states and municipalities an opportunity to provide input.

The legislation would also bar states and local governments from banning or restricting the use of any chemical (i) identified as a high-priority substance by the EPA administrator (as of the date on which EPA publishes a schedule), or (ii) determined to be a low-priority substance. States and local governments would also be unable to require chemical reporting or information collections already required under federal law. They would be allowed to seek waivers

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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from these requirements under certain circumstances and on certification of a "compelling local interest to protect human health or the environment." Lautenberg continues to add sponsors to the bill and announced that *The New York Times* and *Washington Post* have endorsed it. *See Senator Frank Lautenberg News Releases*, May 22 and 30, 2013.

Minnesota Governor Signs Bill Banning Formaldehyde in Children's Products

Minnesota Governor Mark Dayton (D) has signed legislation (H.F. 458) that will prohibit manufacturers and wholesalers from selling personal care products, such as shampoo or lotion designed for use by children younger than age 8, that contain formaldehyde or ingredients that release formaldehyde. Sponsored by Rep. John Persell (D-05A), the bill specifically targets products designed to be "physically applied to or introduced into a child's body, including any article used as a component of such a product and excluding a food, beverage, dietary supplement, or medical device as defined in the federal Food, Drug, and Cosmetic Act." The ban will take effect on August 1, 2014, for manufacturers and wholesalers and on August 1, 2015, for retailers. Additional details about the bill appear in Issue 2 of this *Report*.

DSC Holds Dietary Supplement Briefing

The Congressional Dietary Supplement Caucus (DSC) recently held its 17th educational briefing, "Sports Health and Fitness: The Role of Dietary Supplements," for Capitol Hill staff. The event, held in cooperation with five trade associations representing the dietary supplement industry—the American Herbal Products Association, Consumer Healthcare Products Association, Council for Responsible Nutrition, Natural Products Association , and United Natural Products Alliance—featured NFL wide receiver Larry Fitzgerald Jr. of the Arizona Cardinals and Ed Wyszumiala, general manager of NSF International's Dietary Supplement Certification Programs.

The briefing was one of several that DSC and the supplement industry trade associations hold throughout the year "to provide educational opportunities to ensure that newly elected members of Congress have accurate information about dietary supplements and their role in good health."

According to the trade groups, key messages included "the significant role dietary supplements play in supporting the nutritional needs of active individuals and athletes, and the importance of good manufacturing practices, product certification and testing programs to help ensure safe dietary supplements for athletes and consumers." *See American Herbal Products Association News Release,* May 13, 2013.

FDA Warns Companies About Links to Web Sites with Health Benefit Claims

The U.S Food and Drug Administration (FDA) recently issued a warning letter to dietary supplement manufacturer EuroPharma, Inc., stating that because the company's Web site contains links to articles with health benefit claims, FDA considers the products to be drugs. EuroPharma reportedly disputed the alleged claims, stating that the articles were separated by a disclaimer, but according to FDA, "The therapeutic claims on your web site establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease . . . and the marketing of these products with these claims violates the [Federal Food, Drug, and Cosmetic] Act."

EWG Claims New FDA Sunscreen Rules Are Ineffective

Sunscreen testing and labeling rules that the U.S. Food and Drug Administration (FDA) finalized in December 2012 are now in effect for the first summer season. Among other things, the new rules require that (i) sunscreen labeled "broad spectrum" provide equal protection against both UVA and UVB rays; (ii) any product with a sun protection factor (SPF) lower than 15 carry a label warning indicating that the product does not protect against skin cancer; and (iii) products claim only to be water resistant, not waterproof or sweatproof, indicating the duration of water-resistant protection.

Industry watchdogs such as the Environmental Working Group (EWG) assert that the new FDA rules "have not led to dramatically better sunscreens than those offered in previous years." EWG reported that its review of sunscreen products found only "minimal improvements" in those on the market for the 2013 season, noting that "many sunscreens available on the U.S. market do not filter skin-damaging rays safely and effectively." EWG researchers also purportedly found that out of more than 1,400 sunscreens, lotions, lip products, and make up products that the advocacy group reviewed, only 25 percent offer adequate sun protection and contain no "harmful ingredients."

Speaking about more stringent regulations recently proposed by the Canadian government, EWG Senior Analyst Sonya Lunder said, "Sunscreen companies won't make better products until they are forced to. EWG welcomes Canada's efforts to improve sunscreen protection, particularly because the U.S. Food and Drug Administration appears unable or unwilling to wrap up its sunscreen rules more than thirty years in the making."

Meanwhile, representatives of the Personal Care Products Council (PCPC) have criticized EWG's claims. "Despite the extensive and growing body of credible science demonstrating the safety, efficacy, and health benefits of sunscreens, the Environmental Working Group continues to promote false and misleading assertions about sunscreen products and their ingredients. Once again, the

EWG report lacks the rigor and reliability of formal, expert scientific evaluation and is not peer-reviewed," said Farah Ahmed, chair of PCPC's sunscreen committee. "Our concern is that confusing, unsubstantiated claims could actually serve to discourage consumers from using sunscreen on themselves and their children." *See FDA Consumer Health Information*, May 2013; *Personal Care Products Council News Release,* May 20, 2013; *EWG News Release,* May 20 and May 23, 2013.

LITIGATION & REGULATORY ENFORCEMENT

Court Narrows Claims in Consumer Fraud Suit Against Skin Product Manufacturer

A federal court in California has dismissed putative class claims seeking injunctive relief against a company that manufactures and sells a product advertised as an effective skin tag remover made with an exclusive and "100% natural" formula. *Mason v. Nature's Innovation, Inc.*, No. 12-3019 (U.S. Dist. Ct., S.D. Cal., order entered May 13, 2013). Among other things, the plaintiff alleges that Naturasil skin tag remover is ineffective, not "100% natural," has not been "FDA registered," and does not contain "exclusive" ingredients.

Acknowledging a split among the district courts in the Ninth Circuit, the court was persuaded by those ruling that a plaintiff lacks standing to enjoin a seller or manufacturer from making false or misleading misrepresentations about an item the plaintiff previously purchased but no longer intends to purchase in the future. According to the court, "Plaintiff has not established the likelihood of future injury from Defendant's alleged misrepresentations regarding the product and lacks Article III standing to seek injunctive relief," because he alleged that the "the product has no efficacy with respect to the removal of skin tags, the reason why Plaintiff bought it in the first place." The court thus dismissed claims for injunctive relief that the plaintiff brought under California's Consumers Legal Remedies Act, Unfair Competition Law and False Advertising Law.

The court declined to dismiss the breach of implied warranty and Magnuson-Moss Warranty Act (MMWA) violation claims on the ground of insufficient notice. The notice provisions do not apply "in actions by injured consumers against manufacturers with whom they have not dealt." Here, because the plaintiff purportedly purchased the product from a retailer, not directly from the defendant, the court found that he was not required to give the defendant notice of his implied warranty and MMWA claims.

Court Dismisses Fraud Claims Following Settlement with Anti-Fungal Product Maker

A federal court in California has dismissed claims filed against Kramer Labo-

ratories, Inc. alleging that the company's Fungi-Nail® products are falsely advertised as a cure for nail fungus; the order reportedly follows a confidential settlement between the parties and an earlier ruling denying a request for class certification. *Minkler v. Kramer Labs., Inc.*, No. 12-9421 (U.S. Dist. Ct., C.D. Cal., order entered May 22, 2013). According to a news source, the plaintiff claimed that the product labels included photos of fungus-infected nails and healthy nails, implying that they were before-and-after pictures, while displaying a disclaimer—i.e., the product "is not effective on the scalp or nails"—in fine print on the back of each box. The court apparently denied class certification due to the plaintiff's failure to prove the existence of an identifiable and ascertainable class, which would have included members who had derived a benefit from the products or received refunds due to the company's money-back guarantee. *See Law360*, May 23, 2013.

California Judge Indicates Approval of Settlement in Brazilian Blowout® Suit

According to a news source, a California state court judge has indicated from the bench that he would approve a $4.3-million settlement reached in consolidated consumer class actions charging GIB LLC, the company that makes Brazilion Blowout® hair-straightening products, with deception for failing to disclose that they emit formaldehyde. *In re GIB LLC Cases*, No. JCCP 4657 (Cal. Super. Ct., Los Angeles Cnty.). Under terms of an earlier deal, the company's insurer would have funded the settlement; now, GIB will contribute $300,000 to the fund. Other adjustments will also reportedly be made to the proposed agreement, which the court will consider during a June 5, 2013, hearing. *See Law360*, May 23, 2013.

Information about a Food and Drug Administration warning letter to GIB taking issue with "Formaldehyde Free" product labeling appears in the September 15, 2011, **issue** of Shook, Hardy & Bacon's *Product Liability Litigation Report*. The settlement of claims filed by California's attorney general over the company's allegedly deceptive "formaldehyde-free" advertising is addressed in the September 2, 2012, **issue**.

NASB Recommends Changes to Dietary Supplement Advertising

The National Advertising Review Board (NASB), an appellate unit of the advertising industry's self-regulatory system, has determined that Healthy Directions, LLC lacked sufficient competent and reliable scientific evidence to support advertising claims that its glucosamine-based dietary supplement product could reduce joint pain "in as little as seven days." According to NASB, "the vast body of studies on glucosamine demonstrates its effectiveness in improving joint health after approximately six weeks." The company's reliance on one 1980 study on hospitalized patients was "not sufficient to substantiate glucosamine's effectiveness at seven days."

In addition to recommending that the company no longer make such efficacy claims, NASB also recommended that the advertiser discontinue (i) "the claim that Joint Advantage Gold is 'formulated to work throughout your entire body, in EVERY joint from your neck and shoulders to your toes'"; (ii) "its claim that wild rosella and aniseed myrtle are herbs traditionally used in Australia to reduce inflammation or joint pain'; and (iii) "consumer testimonials" asserting that the product is effective "in eliminating joint pain," "in eliminating or reducing pain during strenuous exercise," "after 4 days use," and "for a particular age group."

The company has apparently agreed to modify future advertising to conform to the NASB recommendations. *See ASRC Press Release*, May 13, 2013.

EMERGING TRENDS

Biodiversity Is Reshaping Beauty Industry

The Union for Ethical BioTrade (UEBT), a non-profit group that encourages cosmetic and personal care product companies to adopt ethical sourcing practices and conserve biodiversity, has published a **report** detailing the proceedings of the 2013 Beauty of Sourcing with Respect Conference that was held in Paris on April 19, 2013. Featured speakers included European Commission officials as well as representatives of the ABS (Access and Benefit Sharing) Initiative and French industry association Fédération des Entreprises de la Beauté.

According to UEBT, consumer awareness about biodiversity increased from 56 percent to 65 percent in Germany, France, the United Kingdom, and the United States between 2009 and 2013. Reporting on biodiversity by cosmetic and personal care product companies also increased—from 13 percent in 2009 to 32 percent in 2013.

"There is a clear evolution with growing awareness among consumers, in company approaches and in government perspectives," said UEBT Board President Ricardo Faucon. UEBT reports that the private sector is increasingly aware of the importance of ethical sourcing of biodiversity, especially in emerging economies. Rémy Oudghiri, of global research firm IPSOS, commented, "There are clear opportunities for brands to position themselves around the issue of biodiversity, and anticipate increasing consumer interest on this issue." The Brazilian Beauty of Sourcing Conference is scheduled for June 25 in Sao Paulo.

INTERNATIONAL DEVELOPMENTS

UAE to Require Labeling of Nanomaterials in Cosmetics

The United Arab Emirates (UAE) has filed with the World Trade Organization a notice of its draft proposal to regulate cosmetics and personal care products, including a requirement for companies to label cosmetic products that contain nanomaterials. According to a news source, the regulations are similar to European Union cosmetic regulations scheduled to take effect in July 2013. Medical products and devices and biocidal products will evidently be excluded from the UAE's regulation. *See Nanotechnology Industries Association News Release,* May 22, 2013.

China Changes Cosmetics Registration Process

China's State Commission Office for Public Sector Reform has reportedly reorganized its food and drug administration authority. Formerly known as the State Food Drug Administration, the agency will now be called the China Food & Drug Administration (CFDA) and it will apparently have "strengthened responsibilities" of food, drugs, medical devices, and cosmetics.

According to the China-based Chemical Inspection and Regulation Service (CIRS), which provides certification, testing, registration, and compliance services to various industries, one of the most significant changes for cosmetic companies going forward will be that imported, ordinary-use cosmetics must be registered with CFDA authorities at provincial levels, rather than with the state authority in Beijing as the current system dictates.

According to CIRS, the reform is good news for (i) foreign companies that want to place ordinary-use cosmetics on the Chinese market because the cosmetics registration process may be shortened, and (ii) new Chinese cosmetic manufacturers because they will have to deal with one less government entity.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

New Study Contends That Fish Oil Does Not Prevent Heart Attacks

A recent study has reportedly concluded that taking omega-3—or n–3—*fatty* acid supplements does not improve heart health in patients with a high risk of cardiac problems who are already taking medicines to prevent them. Maria Carla Roncaglioni, et al., "n–3 Fatty Acids in Patients with Multiple Cardiovascular Risk Factors," *New England Journal of Medicine*, May 9, 2013. Led by the Mario Negri Institute for Pharmacological Research in Milan, the study analyzed data from 12,513 Italian men and women randomly chosen to ingest either 1 g of n–*fatty* acids daily or an olive oil placebo. None of the

study participants had experienced heart attacks but were deemed high risk because of diabetes, high blood pressure, high cholesterol, or obesity and many of them were taking statins or aspirin. After an average follow-up of five years, those taking the omega-3 supplements evidently did not reduce their risk of death or hospitalization from heart disease, compared with those who took the placebo.

CONFERENCES & SEMINARS

The Cosmetics Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of November 2009 conference is slated for July 2, 2013, in London. The event will focus on implementing new EU Cosmetics regulations that take effect July 11 and require all cosmetic products on the EU market to be fully compliant with EC No. 1223/2009. Topics of discussion will include (i) an overview of the new regulations; (ii) ensuring that cosmetics currently for sale comply; (iii) understanding what makes a product a cosmetic; (iv) labeling requirements; (v) responsibilities of cosmetic importers and distributors; (vi) the documentation necessary for marketing cosmetics in the United Kingdom and the EU; and (vii) differences between cosmetic legislation in the EU compared to other countries. *See Reuters,* May 13, 2013.

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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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