Shook, Hardy & Bacon L.L.P.

ISSUE 25 | MAY 22, 2014

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

Minnesota Becomes First State to Ban Triclosan

Minnesota Gov. Mark Dayton (D) has reportedly signed a bill (SF 2192) that will make Minnesota the first state to ban the use of the controversial chemical triclosan in most consumer retail products. Widely used as a germ-killing ingredient in soaps, toothpaste and deodorants, triclosan has purportedly been shown to disrupt reproductive and developmental hormones and contribute to the development of drug-resistant bacteria. The measure, effective January 1, 2017, would prohibit the sale of most hand sanitizers and personal care and cleaning products containing triclosan, with some exceptions for products approved by the U.S. Food and Drug Administration (FDA).

Noting that the chemical is used in approximately 75 percent of anti-bacterial liquid soaps and body washes sold across the United States, FDA announced last year that it would revisit the safety of triclosan and other germ-killing ingredients used in personal cleaning products and planned to ban sales of antibacterial hand soaps containing the chemical unless manufacturers could prove that it is safe for daily use and more effective than traditional soap and water. *See Law360*, May 20, 2014.

Study Shows Farm Sludge Contaminates Soil with Soap and Cosmetic Chemicals

Using biosolids—or sewage sludge—as fertilizer on farms could contaminate groundwater with a variety of chemicals, including prescription drugs and purportedly hormone-disrupting compounds from antibacterial soaps and other cosmetic products says a recent study by the U.S. Geological Survey (USGS). According to USGS Research Hydrologist Dana Kolpin, these types of compounds are not just sitting on the top soil layer, but moving down through the soil, where they can potentially enter groundwater.

After testing for several years on an eastern Colorado wheat field that uses treated sludge from a Denver wastewater treatment plant, the researchers noted that 57 "emerging" contaminants appeared with increasing regularity. They found 10 of the contaminants anywhere from seven to 50 inches

down in the soil 18 months after the sludge was applied at points where the contaminants did not previously exist. Other studies have found hormones, detergents, fragrances, drugs, disinfectants, and plasticizers in treated sludge, but this is evidently the first study to show how they can persist and move in soil. See Environmental Health News, May 12, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Court Awards $40 Million in Contempt Sanctions in Diet Supplement Case

A federal court in Georgia has imposed more than $40 million in sanctions against a weight-loss supplement company, its owner, a sales executive, and a medical professional for their failure to comply with orders obtained by the U.S. Federal Trade Commission (FTC) requiring that they cease making unsubstantiated claims about their products and include a health-risk warning on products containing yohimbe. *FTC v. Nat'l Urological Group, Inc.*, No. 04-3294 (U.S. Dist. Ct., N.D. Ga., Atlanta Div., order entered May 14, 2014). The court ordered that the funds be paid into a court registry for FTC to access with court permission to disburse to affected consumers. The court has also ordered a product recall.

Finding that the defendants (i) continued to make unsubstantiated claims about the products and did not remove violative advertising from the company Website until months after the court found them in contempt of 2008 injunction orders, (ii) provided inaccurate and incomplete information in compliance reports submitted to FTC, (iii) purchased other dietary supplement companies without informing FTC as required, (iv) paid a mere fraction of the judgment entered against them, (v) shopped around for legal opinions to support their conduct, and (vi) did not recall products with packaging and labels that included violative claims, the court ruled that their conduct was contumacious and justified a sanction order equal to gross receipts from the sale of violative products.

The medical professional was required to pay a compensatory sanction of $120,000, the amount he was paid to endorse one of the products.

Federal Court Denies Class Cert. Request in "Long-Lasting" Cosmetics Suit

A federal court in California has denied the motion to certify a class in litigation claiming that Maybelline, LLC misleads consumers by claiming that a line of its lip and skin products is effective for 24 hours. *Algarin v. Maybelline, LLC*, No. 12-3000 (U.S. Dist. Ct., S.D. Cal., order entered May 12, 2014).

Among other matters, the court determined that, on the basis of unrefuted expert evidence "of who the reasonable consumer in the target audience is and what drives her in making purchasing decisions," the two named plaintiffs would not be

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able to show that all putative class members had the same reason for purchasing the products or were dissatisfied with them. Maybelline's marketing expert Eli Seggev examined data on repeat and one-time purchasers and concluded, as to the lipcolor, that 45 percent were satisfied with the purchases, duration was not the only motivating factor in making the purchases, more than half of the purchasers could not recall what their expectations were about duration or were satisfied with the product's duration, and only 9 percent were one-time purchasers who expected the product to last 24 hours and were thus injured as alleged. The data for makeup purchasers were similar.

While the court agreed with Maybelline that many in the putative class would be unable to show injury or had already obtained refunds through the company's refund program, and therefore the class definition was overbroad, it did not find the class unascertainable on this ground. The court ruled instead that the court and parties would have to rely on class members to self-identify because they were unlikely to retain proof of purchase for products costing between $10 and $13, and Maybelline does not maintain a purchaser list. The court also noted, "given that the class period extends three years for the lipcolor and five years for the makeup, it is doubtful that class members will precisely recall the items purchased, the quantity purchased, and the amount paid."

The court further determined that the plaintiffs failed to meet the commonality requirement of Federal Rule of Civil Procedure 23(a)(2), stating "[i]n light of objective evidence showing that there was a substantial number of class members who were not misled by the 24 hour claim, whether Maybelline's conduct was false or misleading or likely to deceive is not subject to common proof on a classwide basis, [and] Plaintiffs have also failed to demonstrate that the elements of materiality and reliance are subject to common proof." Because the court also found that the plaintiffs were unable to establish typicality—"the named Plaintiffs' reliance on the alleged misrepresentations was not typical of other class members," it concluded that the plaintiffs failed to meet Rule 23(a)'s requirements.

Analyzing the Rule 23(b)(2) factors, the court found that the damages were incidental to the injunctive relief requested. In this regard, the court noted that it was "not dealing with products such as dietary supplements where the purported benefits are hard to ascertain or take time to actualize. These consumers will not benefit from the injunctive relief as they cannot demonstrate a probability of future injury; if they know the "truth" they cannot be further deceived."

Discussing the predominance requirement of Rule 23(b)(3), the court ruled that the plaintiffs, by relying on the difference in price between the subject products and Maybelline's other products—approximately $1 to $3, failed to provide an adequate method of determining class-wide damages. According

to the court, any number of reasons could explain the price of the class products, including that they contain higher quality ingredients, are offered in a different selection of colors or reflect the costs spent on research and development. The court also agreed with Maybelline that the plaintiffs could not rely on retail pricing to support their price-premium damages theory, because the company had no control over retail pricing.

Prop. 65 Litigation Ends in Agreements to Remove Cocamide DEA from Products

According to the Center for Environmental Health (CEH), which has sued some 150 personal-care product companies for failing to warn consumers about the presence in their products of a chemical known to California to cause cancer, 26 have agreed to remove the chemical, cocamide diethanolamine (cocamide DEA). Among those pledging to stop using it are Saks Inc., Colgate-Palmolive Co., Lush Handmade Cosmetics Ltd., and Todd Christopher International, Inc. Fourteen of the settlements have apparently been approved in Alameda Superior Court, and 12 others are expected to be finalized in June 2014.

The state added cocamide DEA, a foaming agent and thickener made by a chemical reaction between coconut oils and diethanolamine, to its Proposition 65 (Prop. 65) list in 2012, which meant that companies making products exposing consumers to the chemical were required to issue warnings that their shampoos, soaps, bubble baths, and shower gels contain a carcinogen. When CEH purchased these types of products at the end of the Prop. 65 grace period, it purportedly found products with the chemical but lacking the warnings required by law.

In a May 2014 report titled "Safer Suds: Eliminating a Cancer-Causing Chemical in Shampoos and Soaps," CEH calls on Congress to pass the Safe Cosmetics and Personal Care Products Act of 2013 and adequately fund the U.S. Food and Drug Administration to "more effectively regulate the cosmetics industry." CEH also calls on the industry to ensure that the 10,000 chemicals used in cosmetics and personal-care products are safe.

FTC Seeks to Halt Sales of Weight-Loss Supplement

The U.S. Federal Trade Commission (FTC) has filed a complaint in a Florida federal court against companies and individuals responsible for the sale and marketing of a weight-loss supplement—Pure Green Coffee—allegedly in violation of the FTC Act. *FTC v. NPB Advertising, Inc.*, No.14-1155 (U.S. Dist. Ct., M.D. Fla., Tampa Div., filed May 15, 2014).

According to the complaint, the product appeared in the marketplace shortly after Mehmet Oz claimed in April 2012 on his TV talk show—"The Dr. Oz Show"—that a study of green coffee extract had shown it to be a "magic weight loss cure." Explaining that the study of 16 subjects in India underlying the claims was neither valid nor reliable, FTC challenges the defendants' reliance

on the study in Website ads, but does not otherwise highlight that it was the only clinical study on which they relied, a matter at issue in proceedings against beverage maker POM Wonderful. FTC also bases its claims on defendants' Website ads that (i) include the TV show segment; (ii) purport to be news sites but are fake; (iii) contain testimonials by purported product purchasers, who were actually paid by the defendants to discuss their experience with the product through video; and (iv) fail to disclose that the video testimonials were paid for.

Alleging false or unsubstantiated efficacy claims, false proof claims, failure to disclose material connection (testimonials), and misrepresentations (fake news reports), FTC seeks permanent injunctive relief; redress of consumer injury by rescission or reformation of contracts, restitution, refunds, and disgorgement; as well as costs.

RICO Claims Filed over Testosterone-Boosting Supplements

California and Delaware residents have filed a consumer-fraud lawsuit including allegations under the Racketeer Influenced and Corrupt Organizations Act (RICO) on behalf of a putative nationwide class of those who purchased dietary supplements containing Testofen, an herbal extract derived from fenugreek and advertised as a clinically proven "testosterone booster." *O'Toole v. Gencor Nutrients, Inc.*, No. 14-3754 (U.S. Dist. Ct., C.D. Cal., W. Div., filed May 15, 2014).

Citing research debunking claims that Testofen increases free testosterone levels and describing how the clinical tests conducted by the defendants failed to achieve statistical significance, the plaintiffs contend that they purchased more than 20 products sold in General Nutrition Corp. (GNC) stores relying on false representations made through a variety of media. Among the defendants are the founders and executive officers of the companies that make the products as well as GNC, which purportedly provides the "exclusive launch platform" for the supplements. The plaintiffs refer to the enterprise as "Testofenterprise" and allege that the defendants participated in it to defraud in violation of RICO thus causing economic injury to the class.

Seeking to certify a nationwide class, various product-related subclasses and a New York subclass, the plaintiffs also allege violations of California's Consumers Legal Remedies Act, Unfair Competition Law and False Advertising Law; breach of express warranty and implied warranties of merchantability and fitness for a particular purpose; fraud; negligent misrepresentation; restitution; and violation of New York's General Business Law. They request injunctive relief; compensatory, actual, punitive, and treble damages; attorney's fees; and costs.

Herbal Supplement Group Vows Lawsuit in UK Courts

Claiming that new rules requiring the registration of supplement-like products are discriminatory, misinformed and non-transparent, the UK Association of Traditional Chinese Medicine and Acupuncture (ATCM) has reportedly indicated that it will challenge the European Union Traditional Herbal Medicinal Products Directive in U.K. courts. Unregistered products may not be sold in retail facilities under the directive, but some will apparently remain available through practitioners. The ban took effect in the United Kingdom on May 1, 2014.

While the directive became active in April 2011, its implementation has varied throughout EU's member states. The UK Medicines and Healthcare products Regulatory Agency (MHRA) indicated that some 300 products have been approved under the directive's standards, giving consumers a wide range of products to choose from.

According to a news source, ATCM claims that the sell-through period was ambiguous and that assumptions about shelf-life for the products should have been a matter of 4-5 years rather than 18-24 months. In a statement commenting on ATCM's putative legal action, the head of the Alliance for Natural Health International said, "The MHRA and Department of Health have now created a very uncertain future for products sold in the UK that are neither eligible for the [directive registration]—that even the European Commission considers not fit for its originally intended purpose—and those that benefited previously from exemption under the now defunct Section 12(2) of the 1968 Medicines Act." *See NutraIngredients.com*, April 30, 2014.

INTERNATIONAL DEVELOPMENTS

EC Outlines Position on U.S. Cosmetics Cooperation

As part of ongoing efforts between the United States and European Union to iron out details of the proposed Transatlantic Trade and Investment Partnership, the European Commission (EC) has **published** a position paper on cosmetics, outlining the continent's plan for greater standardization in trading between the countries.

Published alongside position papers on chemicals, pharmaceuticals, motor vehicles, and clothing, the EC's suggestions for cosmetics emphasize regulation and testing as key areas of improvement. Specifically, the agency proposes that EU and U.S. regulators work together to (i) recognize each other's lists of permitted or banned substances; (ii) recognize each other's Good Manufacturing Practices; (iii) develop and use alternatives to animal testing; (iv) harmonize methods and requirements for testing products;(v) align each other's requirements for labeling; and (vi) work more closely together in the International Council on Cosmetics Regulation.

EC Announces Public Consultation on Transparency Measures for Nanomaterials

As part of its Communication on the Second Regulatory Review on Nanomaterials, the European Commission (EC) has launched a public consultation on an impact assessment to "identify and develop the most adequate means to increase transparency and ensure regulatory oversight on nanomaterials."

According to the agency, the impact assessment will examine different policy options aimed at gathering information or generating new information on the presence of nanomaterials and products containing nanomaterials on the market. Data generated from the impact assessment will be used to address (i) why and to what extent there is an information gap; (ii) whether and on what scale this poses a problem; and (iii) what benefits additional information could bring and at what costs. Comments will be accepted until August 5, 2014.

The Commission also plans to hold a June 30, workshop in Brussels, Belgium, to discuss the preliminary results of a study supporting the impact assessment on transparency measures for nanomaterials.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Nanomaterials Linked to Workplace Injury

In what is apparently the first of its kind, a recent case study has allegedly attributed a U.S. chemist's health problems to her exposure to nanomaterials in the workplace. W. Shane Journeay, et al., "Occupational handling of nickel nanoparticles: A case report," *American Journal of Industrial Medicine*, May 8, 2014. According to researchers, a 26-year-old chemist who created polymers and coatings containing nickel nanoparticles, developed throat congestion with postnasal drip, facial flushing and skin sensitivity to metals within one week of exposure—periodically weighing and measuring small amounts of nickel nanoparticles without using protective measures—to the ingredient. Her symptoms apparently continued even after she stopped working with the material and moved to another floor, and did not improve until she moved to a lab that does not handle metal chemistry work.

Observing that this is the "first well-documented case" of a worker handling nanoparticles in a U.S. manufacturing facility developing serious health effects, study co-author Shane Journeay suggests that the study may be "the tip of the iceberg" and states that he has received numerous emails from medical workers at occupational health and safety clinics who have seen similar cases. With little data available on the impacts on human health of a wide range of nanomaterials in use, Journeay cautions that "workers are using these materials, and the health effects are completely unknown."

According to industry experts, nanomaterial safety is complicated by such factors as (i) ordinary materials such as nickel or titanium have extraordinary properties at the nano scale and more research on the health effects of the new materials is needed; and (ii) requirements for handling these materials in the workplace do not exist. *See Occupational Safety & Health Reporter*, May 15, 2014.

Study Finding Health Benefits of Omega-3s Had Significant Flaws, Researchers Say

A recent review has reportedly identified several flaws in the widely cited 1970s study which found that diets rich in omega-3 fatty acids could help fight coronary artery disease (CAD). George J. Fodor et al., "'Fishing' for the origins of the 'eskimos and heart disease' story. Facts or wishful thinking? A review," Canadian Journal of Cardiology, April 2014. In the original study, Danish researchers examined the diet of Greenland eskimos and linked the high amount of fish oil to the purportedly low incidence of CAD. A team of researchers has reexamined the original study as well as more recent studies on the eskimo population and found that eskimos actually suffer CAD at the same rate as Caucasians. The 2014 study identifies several reasons why the original study's source for CAD rates in the Greenland eskimos—the annual reports produced by Greenland's chief medical officer—were likely insufficient, including poor reporting rates, inaccessibility of doctors and inaccurate records. The researchers also found that eskimos have very high rates of mortality due to strokes. "Considering the dismal health status of eskimos," said lead researcher George Fodor, "it is remarkable that instead of labeling their diet as dangerous to health, a hypothesis has been construed that dietary intake of marine fats prevents CAD and reduces atherosclerotic burden." *See Elsevier*, May 1, 2014

Study Examines Skin Cancer Risk of Nail Salon UV Lights

A recent **study** conducted by researchers at Georgia Regents University's Medical College of Georgia has allegedly found that as few as eight sessions under the ultraviolet lamps used in many nail salon dryers may be enough to cause DNA damage to the skin, increasing the risk of skin cancer. The researchers measured the amount of UVA and UVB light emitted from 17 different light units from 16 salons with a wide range of bulbs, wattage and irradiance emitted by each device, and concluded that while a single nail polish drying session under one of the lamps would not expose a person to a potentially cancer-causing amount of UVA light, precautions should be taken, including using sunscreen on the hands or UVA-protective gloves to limit both cancer risk and premature skin aging. *See Scientific American*, May 6, 2014.

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CONFERENCES

Global Cosmetic Compliance Summit to Focus on International Regulation

Scheduled for May 27-29, 2014, in Amsterdam, the Netherlands, the Global Cosmetic Compliance Summit will convene manufacturers, distributors and other industry stakeholders to discuss cosmetic regulations around the world. Among the topics slated for discussion are navigating the opportunities and challenges of exporting products to China; entering the Japanese market; advertising in Asian markets; adapting to marketing restrictions across multiple regions, including the United States; understanding the South African market; and assessing the global ramifications of new European standards. ■

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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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