Shook, Hardy & Bacon L.L.P.

ISSUE 21 | MARCH 7, 2014

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

Government Task Force Deems Evidence Linking Multivitamins to Cancer Prevention Insufficient

The U.S. Preventive Services Task Force has concluded that evidence is insufficient to determine the effectiveness of taking vitamins and minerals to prevent cardiovascular disease or cancer. "Cardiovascular disease and cancer have a significant health impact in America, and we all want to find ways to prevent these diseases," said Task Force Chair Virginia Moyer. "However, we found that there is not enough evidence to determine whether taking single or paired nutrients or a multivitamin helps to prevent cardiovascular disease or cancer."

The independent panel of experts, which based its determination on five multivitamin studies and 24 studies on individual or paired supplements, also discouraged taking vitamin E and beta-carotene, asserting that evidence shows "no benefit" to taking vitamin E supplements to prevent heart disease or cancer and beta carotene could be harmful because it may increase the risk of lung cancer in people already at risk for developing the disease. "Due to the uncertain benefit of vitamin supplements to prevent cardiovascular disease and cancer, health care professionals should use their best judgment and consider their patient's health history, values, and preferences when having conversations about nutritional supplements," said Task Force Co-chair Michael LeFevre.

Representatives of the vitamin industry, including the Council for Responsible Nutrition (CRN), note that the task force recommendations apply only to healthy adults older than age 50 and are irrelevant to children, women of childbearing age or adults with known nutritional deficiencies. "The report's conclusion that there is '…not enough evidence…' for recommendations in the areas of cancer and cardiovascular disease should not be considered as a lack of benefit as there is a big difference between lack of research and lack of positive results," said CRN Senior Vice President Duffy MacKay. *See CRN News Release*, February 24, 2014; *Task Force News Release*, February 25, 2014.

LEGAL TRENDS
REPORT

ISSUE 21 | MARCH 7, 2014

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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Herbalife Brings Marketing Practices Defense to Capitol Hill

Recently challenged over company business practices by U.S. Sen. Edward Markey (D-Mass.), Herbalife Ltd. executives recently met with congressional staff to tell the company's story and discuss its direct-sales practices. Information about Markey's requests that the U.S. Federal Trade Commission and U.S. Securities and Exchange Commission investigate the nutritional supplements company appears in Issue 19 of this *Report*.

During an interview after the meeting, Herbalife CFO John DeSimone reportedly said, "We're out here just telling our story, educating, being transparent. This was a start to that process." According to a news source, the company, which has compared its practices to those of Avon and Amway, titled its session on Capitol Hill "Direct Selling: An American Tradition." *See The New York Times*, February 20, 2014; *Bloomberg News*, February 21, 2014.

FDA Information Collection Focuses on Dietary Supplements

The U.S. Food and Drug Administration (FDA) has **submitted** a proposed information collection to the Office of Management and Budget regarding the estimated recordkeeping burden for maintaining current good manufacturing practices in manufacturing, packaging, labeling, or holding operations for dietary supplements.

Among other things, FDA notes that the recordkeeping requirements will include establishing written procedures and maintaining records pertaining to personnel; sanitation; calibration of instruments and controls; maintaining, cleaning and sanitizing equipment and utensils and other contact surfaces; production and process controls; quality control; laboratory operations; manufacturing operations; packaging and labeling operations; holding and distributing operations; returned dietary supplements; and product complaints. Comments are requested by March 27, 2014. *See Federal Register*, February 25, 2014.

ICCR Meeting Focuses on Nanomaterials

The U.S. Food and Drug Administration has released three **documents** from the most recent International Cooperation on Cosmetics Regulation (ICCR) meeting, which discussed nanomaterial safety and cosmetics testing regulation. An international group of cosmetics regulatory authorities from the United States, Canada, European Union, and Japan, ICCR seeks to promote regulatory convergence, while maintaining global consumer protection and minimizing barriers to international trade.

One of the documents, titled "Safety Approaches to Nanomaterials in Cosmetics," discusses the ICCR Joint Regulator-Industry Working Group's review of existing safety approaches for the use of nanomaterials in cosmetics

and presents the most recent international consensus on available safety assessments. The other two documents provide an inventory and a table of validated alternatives to animal testing for cosmetic products and ingredients. The next ICCR meeting is slated for July 2014 in Ottawa, Canada.

OEHHA Extends Comment Period on Beta-Myrcene as Carcinogen

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **extended** the comment period on its notice of intent to list beta-myrcene as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). OEHHA took the action at the request of several trade organizations, including the International Fragrance Association. The new comment deadline is March 24, 2014.

OEHHA has proposed adding beta-myrcene—a natural food-plant constituent used as a fragrance in cosmetics, soaps and detergents—to the Prop. 65 list under the authoritative bodies listing mechanism. According to the agency, the National Toxicology Program and several other institutions have concluded that the chemical causes kidney cancer in male rats and liver cancer in male mice. *See OEHHA News Release*, March 4, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Nationwide Class in Fat-Burning Supplement Suit Not Certifiable

A federal court in Florida has denied the plaintiff's motion for class certification in a suit claiming that dietary supplement "VPX Meltdown Fat Incinerator" is ineffective for its advertised purpose and is falsely advertised. *Karhu v. Vital Pharms., Inc. d/b/a VPX Sports*, No. 13-60768 (U.S. Dist. Ct., S.D. Fla., order entered March 3, 2014).

The most significant obstacle to class certification was, according to the court, that the proposed classes—nationwide and New York—were not ascertainable. With direct sales to consumers infrequent, the court noted that the company "does not have a record of the identities of most members of the Proposed Classes." The court also determined that purchasers would have been unlikely to retain purchase receipts, and it was unwilling to "trust individuals to identify themselves as class members through the submission of affidavits," because this would deprive VPX of due process rights and require mini-trials if the company were allowed to contest each individual affidavit. "In short, [the plaintiff] has not suggested any practical means of verifying class membership through existing evidence, and the Court will not allow individuals to identify themselves as class members solely upon a sworn statement."

While the court further determined that the plaintiff had satisfied the prerequisites of Federal Rule of Civil Procedure 23(a)—numerosity, commonality, typicality, and adequacy of representation, it ruled that common issues do not predominate on the Magnuson-Moss Warranty Act, breach of express warranty, unjust enrichment, and unfair trade practices claims for purposes of a nationwide class, because state laws differ and the applicable law would be the law of the state where the product was purchased. Common issues predominated only with respect to the New York subclass under its unfair trade practices statute. Refusing to recast the complaint as a statewide action, the court found that a multistate class action was unmanageable and impractical, thus failing to meet the superiority prong of Rule 23(b)(3).

The court also determined that the plaintiff failed to present a proper Rule 23(b)(2) action for declaratory or injunctive relief, because that relief "takes a back seat to the apparently principal aim of the lawsuit: to recover damages based upon the amount each individual class member paid for an ineffective product." And when a plaintiff seeks both monetary and injunctive or declaratory relief, "a Rule 23(b)(2) class is only appropriate if the monetary relief is merely incidental to the other relief. Monetary relief is 'incidental' when the primary aim of the lawsuit is to obtain a generally applicable group remedy. Group remedies tend to be those pursued by a cohesive class sharing a relevant preexisting legal relationship or common trait, such as race or gender. By way of contrast, the Proposed Classes share no significant preexisting relationships beyond the purchases that form the basis for this suit."

Court Denies Class Certification in Suit Against Boiron

A federal court in California has denied a motion for class certification in a suit alleging that certain Boiron homeopathic products labeled with claims that they can relieve flu-like symptoms deceive consumers because they do not work. *Jovel v. Boiron, Inc.*, No. 11-10803 (U.S. Dist. Ct., C.D. Cal., order entered February 27, 2014).

According to the court, the named plaintiff lacked credibility as to a critical case element—whether he had read the product labels before purchasing the product. The court stated, "Jovel's inconsistent deposition testimony places his credibility in issue on whether he actually relied on Oscillo's label in purchasing the product. If a jury concludes that because of Jovel's prior inconsistent testimony he cannot be believed when he states that he relied on Oscillo's label before purchasing the product, Jovel will jeopardize the interests of all of the other class members."

During his deposition, plaintiff Leonidas Jovel repeatedly testified that he did not read the product label until he finished using the product. He changed his testimony later in the deposition and even "relied on different justifications for why he changed his testimony. First stating that his earlier testimony had been misunderstood, and then later stating that his recollection about

when he viewed the label had been refreshed by a discussion with his counsel." Accordingly, the court ruled that he would not be able to fairly and adequately protect the interests of the class.

The court also denied Boiron's motion for sanctions and vexatious litigation, finding that (i) the evidence was insufficient to show that Jovel's counsel knew when she filed the complaint that he had not read the label before purchasing the product, and (ii) the handful of other cases that Jovel's counsel has filed against Boiron do not appear "to have been filed in bad faith."

"Salon-Only" Claims Re-Filed Against L'Oréal

Within months of a D.C. district court ruling rejecting the final settlement of claims that L'Oréal deceives consumers by labeling some of its products as "salon only" when they are available for sale in mass-market retail stores, the plaintiffs have apparently filed an amended complaint; the court has rescheduled a status conference in the matter for April 25, 2014. *Richardson v. L'Oréal USA, Inc.*, No. 13-0508 (U.S. Dist. Ct., D.D.C., re-filed January 27, 2014). Additional details about the court's initial ruling giving preliminary approval to the settlement appear in Issue 6 of this *Report*. Among other matters, the amended complaint reportedly seeks restitution as well as injunctive relief.

The court had previously rejected the settlement, in part, because injunctive relief was the only remedy that would have been provided to class members. The court agreed with counsel for the Center for Class Action Fairness, representing an objector, that the settlement was not fair in requiring class members to surrender any class-wide claims for damages in exchange for labeling changes, while plaintiffs' counsel would receive nearly $1 million in fees and class representatives would receive $1,000 each. The court also determined that requiring absent class members to release their right to bring any type of class action seeking damages is improper under Federal Rule of Civil Procedure 23(b)(2), which does not give absent class members the right to opt out or entitle them to the best notice practicable. *See Mealey's Class Actions*, February 21, 2014.

Putative Class Claims Supplement's Ingredient Not Beet Derived

A California resident has filed a putative statewide class action against Bluebonnet Nutrition Corp., claiming that the company has misled consumers by advertising its Betaine dietary supplement as derived from beets, when it actually contains betaine hydrochloride, which "can only be created synthetically." *Kochlani v. Bluebonnet Nutrition Corp.*, No. 14-1539 (U.S. Dist. Ct., C.D. Cal., filed February 28, 2014). The complaint includes an image of the product label, which lists betaine hydrochloride as an ingredient.

The plaintiff alleges that he relied on the company's Website, labeling and promotional statements in purchasing a product at a premium price that he thought would have healthful and nutritional benefits, including lowering the levels of homocysteine to reduce the risk of heart disease and stroke. After he purchased and used the product, he apparently learned that the active ingredient was, unlike betaine anhydrous—a safe, beet-derived substance, synthetic and that the recommended intake could burn the stomach lining. Claiming that he was "shocked to learn that Betaine is primarily betaine hydrochloride from synthetic sources, rather than betaine hydrochloride from beets as represented by Defendant," the plaintiff also contends that the company failed to disclose that the ingredient is synthetically created.

Alleging violation of the unlawful, unfair and fraudulent prongs of the California Unfair Competition Law, as well as violation of the False Advertising Law, negligent misrepresentation, and intentional misrepresentation, the plaintiff seeks injunctive relief, including disclosure of the ingredient's source and a public information campaign; a constructive trust and disgorgement; special, general, compensatory, exemplary, and punitive damages; interest; attorney's fees; and costs.

INTERNATIONAL DEVELOPMENTS

German Agency Calls for Aluminum Limits in Cosmetic Products

The German Federal Institute for Risk Assessment (BfR), which advises the country's Federal Ministry of Food and Agriculture on potential health risks of cosmetic product ingredients, has requested that limits be set for the use of aluminum in cosmetics, particularly antiperspirants. Recent studies purportedly demonstrating dermal absorption from aluminum in antiperspirants, lipstick and sunscreen have raised concerns about aluminum toxicity.

According to BfR's recent **risk assessment**, the estimated intake of aluminum from antiperspirants "could possibly lie within the range determined by the European Food Safety Authority as the tolerable weekly intake. As aluminum is also ingested from other sources, such as food, this level could be exceeded by part of the population. To prevent too high an intake of aluminum, excessive use of antiperspirants containing aluminum should be avoided and deodorants that do not contain aluminum salts should be used after shaving or if the skin in the armpits is damaged."

EC Seeks Input on Fragrance Allergens

The European Commission (EC) has **announced** a public consultation on fragrance allergens as part of its response to the Scientific Committee on Consumer Safety's (SCCS's) July 2012 recommendations for tighter regulation

of perfume ingredients. With an aim "to protect consumers against fragrance allergens while preserving the competitive edge of the European fragrance industry," the EC specifically seeks feedback on its proposal to (i) subject substances to new labeling restrictions; (ii) ban the substances HICC, atranol and chloroatranol, which have apparently been found to pose health risks; and (iii) continue studies to establish safe concentration levels for substances of special concern. An estimated 1 to 3 percent of Europeans experience skin allergies evidently caused by fragrances. Comments will be accepted until May 14, 2014.

SCIENCE/TECHNICAL DEVELOPMENTS

Danish Scientists Warn Against Nanosilver

University of Southern Denmark (SDU) researchers have published a study asserting that nanosilver, used in dietary supplements, cosmetics and food packaging, can penetrate human cells and cause damage. Thiago Verano-Braga, et al., "Insights into the Cellular Response Triggered by Silver Nanoparticles Using Quantitative Proteomics," *ACS Nano*, February 10, 2014. Noted for its antibacterial effect, silver in nanoparticle form is often used as a coating in the food and cosmetics industries. When used as a metal, silver does not pose any danger, the researchers said, "but when you break it down to nano-sizes, the particles become small enough to penetrate a cell wall. If nano-silver enters a human cell, it can cause changes in the cell."

"We can confirm that nano-silver leads to the formation of harmful, so called free radicals in cells. We can also see that there are changes in the form and amount of proteins [and] this worries us," said the scientists, noting that cancer and neurological diseases such as Alzheimer's and Parkinson's are characterized by an overproduction of free radicals.

The authors emphasized that their research was conducted on human cells in a laboratory setting, noting that they do not know the amount of human exposure required for the emergence of cellular changes. "We don't know how much is needed, so we cannot conclude that nano-silver can make you sick. But we can say that we must be very cautious and worried when we see an overproduction of free radicals in human cells."

Nanosilver is also sold as a dietary supplement that claims to have an antibacterial, anti-flu and cancer-preventing effect. In the wake of the SDU research, the Danish Veterinary and Food Administration has warned against taking dietary supplements containing nanosilver. *See University of Southern Denmark News Release*, February 27, 2014.

Vitamin E and Selenium Supplements Allegedly Linked to Increased Prostate Cancer Risk

Researchers at the Fred Hutchinson Cancer Research Center in Seattle have published a study allegedly concluding that high doses of selenium and vitamin E supplements may increase the risk of prostate cancer, depending on a man's selenium levels before taking the supplements. Alan Kristal, et al., "Baseline Selenium Status and Effects of Selenium and Vitamin E Supplementation on Prostate Cancer Risk," *Journal of the National Cancer Institute*, February 22, 2014.

The researchers had been running a follow-up trial to the 2005 Selenium and Vitamin E Cancer Prevention Trial (SELECT) prostate cancer prevention study, which was set up to test earlier findings that selenium and vitamin E might reduce the risk of developing prostate cancer. That study, which involved 35,000 men, was stopped in 2008 when researchers found that the men taking the supplements appeared to be at a greater risk of developing aggressive prostate cancer.

Concluding that men who already had high concentrations of selenium in their bodies nearly doubled their risk of aggressive prostate cancer if they took selenium supplements, authors of the current study urge men using these supplements to stop immediately. The new study also revealed that (i) taking vitamin E alone boosted the risk of developing high-grade prostate cancer, but only in men who started the study with low selenium levels; (ii) taking selenium, either alone or in combination with vitamin E, increased the risk of high-grade prostate cancer in men who started the study with high selenium levels, but not in those with low selenium levels; and (iii) among men who did not take either vitamin E or selenium, those who started the study with high selenium levels were no more likely to have developed prostate cancer than men who started it with low selenium levels.

Commonly found in seafood and organ meats, such as liver, selenium is nutritionally essential for humans and plays roles in reproduction, thyroid hormone metabolism and DNA syntheses, as well as protecting against oxidative damage and infection. *See Harvard Health Publications,* February 28, 2014.

FIRM NEWS

SHB-Authored Article Discusses Prop. 65 Issues Facing Cosmetics/Personal Care Products Companies

Shook, Hardy & Bacon Cosmetics & Personal Care Products Senior Associate **Wendy Williams** has authored an **article** appearing in the February 21, 2014, issue of *Law360*.

LEGAL TRENDS
REPORT

ISSUE 21 | MARCH 7, 2014

Titled "Prop 65 Continues to Cause Headaches for Calif. Companies," the article discusses how citizen plaintiffs have focused their efforts on companies that make, distribute and sell cosmetic and personal care products for alleged violations of the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65), which requires warnings to consumers and employees if these products contain chemicals known to cause cancer or reproductive harm. Williams notes that some courts and the governor have found problematic abusive litigation and large attorney's fee awards in Prop. 65 settlements, but reforms have been slow in coming. She concludes with information about upcoming initiatives that could affect chemical listings and litigation under Prop. 65.

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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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