Shook, Hardy & Bacon L.L.P.

ISSUE 19 | FEBRUARY 7, 2014

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

EPA Expands Safer Chemical Ingredient List

The U.S. Environmental Protection Agency (EPA) has added 50 chemicals, including 40 used in fragrances, to its Safer Chemical Ingredient List (SCIL). Created as a resource for manufacturers interested in making safer products and consumers seeking information about chemicals in products, SCIL contains chemicals that meet the criteria of the agency's Safer Product Labeling Program. Writing on *EPA Connect: The Official Blog of EPA's Leadership*, Jim Jones notes that manufacturers can search within each SCIL component class—solvents, fragrances, etc.—to assemble a set of ingredients that satisfies "the performance and customer-appeal characteristics they would like their product to have—including being safer for families and the environment." EPA will continue to update the list with chemicals that meet DfE safer ingredient criteria in key classes such as solvents, surfactants and fragrances. *See EPA Connect Blog*, January 23, 2014.

FDA Cracks Down on Medical Food Manufacturers

The U.S. Food and Drug Administration (FDA) has released a warning letter accusing California-based NVN Therapeutics of illegally selling a prescription drug under the guise of a "medical food," continuing what appears to be a crackdown on the product category. Although FDA warning letters FDA about medical food issues are apparently uncommon, with the agency issuing only 13 since 2001, a recent spate of letters sent to medical food manufacturers suggests that the agency is taking a more active role in enforcing this product category. Since April 2013, FDA has issued four letters citing medical food issues and nearly one-third of all medical food-related warning letters ever issued by FDA have been released during the past nine months.

Under the Orphan Drug Act of 1984, a medical food is defined as a food that is "formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." In

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August 2013, FDA released new draft guidance for medical foods adding that such foods are "intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food."

At issue in the recent warning letter is a product called Glucorein PCOS, whose active ingredients are chlorogenic acid and l-cysteine, and which is marketed as a medical food intended for "dietary management of Polycystic Ovarian Syndrome (PCOS) by reducing the incidence of metabolic syndrome and insulin resistance." Noting that it was unable to find any evidence that patients with PCOS have any medically determined nutrient requirements, FDA wrote, "although there are benefits to these patients obtaining Chlorogenic Acid and L-Cysteine in their diet, there are no established distinctive nutritional requirements or inherent needs for patients with PCOS to have these substances in their diets." As a result of failing to meet the medical food standards, FDA said it considered NVN's product a drug, misbranded under the Federal Food, Drug, and Cosmetic Act. *See RegulatoryAffairsProfessionalsSociety.org*, January 21, 2014; *Nutraingredients-usa.com*, January 22, 2014.

Markey Questions Herbalife Business Practices

U.S. Sen. Edward Markey (D-Mass.) has requested information from Herbalife Ltd., a nutritional supplements company focusing primarily on weight-loss products, about its business practices. In his January 23, 2014, **letter** to the company's U.S. subsidiary, Markey notes that Herbalife bills itself as a multi-level marketing company selling products through a network of distributors, but has the hallmarks of a "pyramid scheme."

Referring to a lawsuit by a former Herbalife distributor making that allegation, Markey reports that some of his constituents have lost their life savings or been otherwise unable to profit from their affiliation with the company. Markey seeks information about the company's system of operations, operations structure, percentage of sales outside its distribution network, and whether the company targets minority or low-income populations to become distributors.

On the same day, Markey also sent letters to the U.S. Securities and Exchange Commission and the U.S. Federal Trade Commission (FTC) calling for investigations into Herbalife's business practices and "questionable" claims. In his **letter** to FTC Chair Edith Ramirez, Markey commended the agency's "recent announcement that it is establishing a new initiative to address 'deceptive claims made by national marketers of fad weight loss products.'" He encouraged FTC to include in its initiative "an examination of the companies' questionable claims about the business opportunities available to people if they distribute certain weight loss products."

The New York Times took note of the senator's investigation, suggesting that it coincided with the efforts of hedge-fund manager William Ackman, who has called Herbalife a fraud and wagered that its stock is worthless. When his rivals started buying the company's stock, Ackman reportedly lost hundreds of millions on paper. He has apparently been lobbying Congress for months in his ongoing campaign against Herbalife. *See Sen. Edward Markey Press Release* and *The New York Times*, January 23, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Plaintiffs Received Refunds, Lack Standing to Pursue Dietary Supplement Class Action

A federal court in California has dismissed putative class claims for breach of warranty and false advertising filed against individuals and a company that manufactures and markets a dietary supplement to treat the symptoms of benign prostate hyperplasia. *Luman v. Theismann*, No. 13-0656 (U.S. Dist. Ct., E.D. Cal., order entered February 4, 2014).

According to the court, the plaintiffs' claims for monetary damages were moot, and thus they lacked standing to bring the lawsuit because the company issued them a refund in response to pre-suit letters required for claims filed under the Consumers Legal Remedies Act. So ruling, the court disagreed that the defendants sought to "pick off" representatives of a putative class to foil the class action. The court also determined that the claims were not "transitory" and thus did not relate back to the date of the complaint's original filing. In the court's view, the defendant "provided relief by sending refunds, thereby obviating the need for plaintiffs to seek through the courts a less efficient resolution of the monetary claims."

As to whether the plaintiffs had standing to bring claims for injunctive relief, the court determined that they did not because they failed to plead that "they continue to be misled by defendants' advertisements" or "any facts indicating they are likely to be misled again. Instead, plaintiffs' allegations that defendants have deceived them suggest that the probability they will be injured again by defendants' alleged deception is infinitesimal." The court was not persuaded by other district courts in the Ninth Circuit that have "permitted consumer class action plaintiffs to pursue injunctive relief despite the lack of a realistic threat of repeated harm." In this regard, the court agreed that it was not within the court's authority "to carve out an exception to Article III's standing requirements to further the purpose of California consumer protection laws." The court ordered the case closed.

$3.2-Million Award Upheld in Wheat- and Gluten-Free Products Dispute

A federal court in Florida has denied the post-trial motions filed by a company that was found in breach of a manufacturing contract for supplying Natrol, Inc. with wheat- and gluten-free dietary supplements that the U.S. Food and Drug Administration (FDA) determined actually contained wheat and gluten; thus the court upheld a jury's verdict on Natrol's counterclaims in excess of $3.2 million. *Nature's Prods., Inc. v. Natrol, Inc.*, No. 11-62409 (U.S. Dist. Ct., S.D. Fla., order entered January 31, 2014). On the basis of FDA's investigation, Natrol was apparently forced to recall the products, cancel all existing purchase orders and destroy recalled "Pro Lab" products. Undisturbed by the court's order was a $750,000 jury award against Natrol for failure to pay invoices as to non-recalled products.

Court Orders More Definite Statement in Hydroxycut Litigation

Following a federal court's refusal to approve the settlement of putative class claims alleging consumer fraud relating to the sale of 14 Hydroxycut-branded weight-loss dietary supplements, the parties elected to proceed on pending motions to dismiss the second amended complaint; the court has denied the motions, but ordered the plaintiffs to file a more definite statement as to the retailer defendants, finding the fraud-related allegations in the second amended complaint insufficient. *In re Hydroxycut Mktg. & Sales Practices Litig.*, Nos. 09-2087, -1088 (U.S. Dist. Ct., S.D. Cal., order entered January 27, 2014).

The manufacturing defendants argued that certain claims should be dismissed because the consumer-fraud statutes of certain states do not allow class actions. They relied on Justice John Paul Stevens' concurring opinion in *Shady Grove Orthopedic Association v. Allstate Insurance Co.*, 559 U.S. 393 (2010), to argue that "the state provisions prohibiting class actions are found within the state consumer protection acts and are therefore so intertwined with the state rights or remedies that application of Rule 23 would violate the Rules Enabling Act." The court disagreed, concluding that Justice Stevens' concurrence did not represent a common denominator in the Court's fractured reasoning. Relying on related Ninth Circuit decisions, the court concluded that state statutory provisions prohibiting class actions are procedural in nature and thus application of Rule 23 to the plaintiffs' claims "does not run afoul of the Rules Enabling Act." The court denied the motion without prejudice; if the Ninth Circuit squarely addresses *Shady Grove*, the manufacturing defendants may file a new motion.

The court agreed with the retailer defendants that the plaintiffs failed to satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b), and found the standard applicable to all of the consumer-protection claims because the plaintiffs alleged a "unified course of fraudulent conduct." The plaintiffs have alleged that the retailer defendants "participated in the advertising and marketing process with Iovate, adopted Iovate's

product representations as their own, and also made their own false and deceptive statements about the products' safety and efficacy." According to the court, the allegations in this regard fail to specify those defendants that made specific representations to which they were exposed.

The court disavowed a reading of *Dorfman v. Nutramax Laboratories, Inc.*, 2013 WL 535040 (S.D. Cal. Sept. 2013), that would hold a retailer defendant who disseminates or repeats deceptive statements liable under California's Unfair Competition Law or Consumers Legal Remedies Act "for statements on product packaging that the retailer did not control." Retailers may be held liable only for displaying additional promotional materials. The court further rejected the theory that the retailers should be held liable as aiders and abettors of the manufacturer because the plaintiffs failed to allege that the retailers knew that the safety and efficacy claims made by the manufacturers were false or deceptive.

Still, to move the case along, the court decided not to dismiss the claims against the retailer defendants, but rather to order the plaintiffs to file a more definite statement. They have 20 days to do so.

$4.2 Million Paid to Man Harmed by Supplements with Anabolic Steroids

According to a news source, a man who claims that his kidneys and liver were destroyed by a dietary supplement produced through small-batch production using imported ingredients, has settled with the manufacturer, distributor and retailer for $4.2 million. *Lineberger v. Max Muscle Mktg., Inc.*, No. 30-2010-00423797 (Cal. Super. Ct.). The "Epio-Flex" supplement that the plaintiff purchased was later allegedly found to be made with two prohibited steroidal compounds—Madol and Superdrol.

His attorney said that the case illustrates the dangers of small-batch production in which sole proprietors fill orders for major manufacturers and wholesalers using contract manufacturers facing little oversight in obtaining their ingredients. Here, the Texas-based contract manufacturer had no standing inventory and filled orders only as needed using ingredients from China.

The Anabolic Steroid Control Act of 1990 reportedly contains a loophole allowing chemical suppliers to adjust their compounds slightly to circumvent the prohibition on any compound that mimics the effects of testosterone. The U.S. Food and Drug Administration (FDA) has apparently found an "alarming variety" of ingredients in body-building supplements, which ingredients are the same or similar to those active in FDA-approved drugs. Some over-the-counter dietary supplements have been found to contain, in addition to steroidal compounds, beta blockers, anti-coagulants, anti-convulsants, and nonsteroidal anti-inflammatory drugs. *See Law360*, February 3, 2014.

Consumer-Fraud Class Action Filed Against Star Scientific

Illinois resident Howard Baldwin has filed a putative nationwide class action against dietary supplement maker Star Scientific and a retailer claiming that its Anatabloc® product cannot deliver on its promised medical benefits. *Baldwin v. Star Scientific, Inc.*, No. 14-0588 (U.S. Dist. Ct., N.D. Ill., E. Div., filed January 27, 2014).

Baldwin bases his claims on the company's alleged failure to prove in clinical trials that the drug can treat inflammation associated with arthritis, Alzheimer's disease, traumatic brain injury, diabetes, and multiple sclerosis. He also relies on the company's purported failure to obtain U.S. Food and Drug Administration approval for its products. Baldwin alleges that he purchased and used the product, relying on the company's representations as to its efficacy, and did not receive any benefit from it. He seeks a full refund for failure to receive the benefit of the bargain. A number of the complaint's allegations concern the alleged relationship between former Virginia Governor Robert McDonnell, his wife and daughter with Star Scientific. Information about related indictments filed against the governor and his wife appear in Issue 18 of this *Report*.

Alleging violations of the unfair competition laws of 37 states, breach of express and implied warranties and unjust enrichment, the plaintiff seeks actual, statutory, punitive, or trebled damages; interest; injunctive relief; attorney's fees; and costs.

Suit Alleges Injury from Weight-Loss Product

According to news sources, a New York resident has filed a personal injury lawsuit against a health food store in Brooklyn, alleging that a weight-loss product it sold her caused insomnia, severe psychotic symptoms, involuntary commitment, and damage to her career in the Army Reserves. *Theodore v. Natural Food Health Ctr.*, No. n/a (Brooklyn Sup. Ct., filed January 6, 2014).

Plaintiff Sainah Theodore claims that she used the product without incident in 2011, but when she began the month-long regimen to get fit for duty in Afghanistan, she acted so bizarrely that she was committed for five days to a mental hospital. Lab testing on remaining Natural Lipo X pills allegedly revealed the presence of laxative and stimulant chemicals not approved for over-the-counter dietary supplements. While Theodore is seeking an undetermined amount of damages, her attorney has reportedly indicated that she sustained up to $21,000 in property losses, a $1,400 ambulance bill and lost wages of $14,000, including potential bonuses she is unlikely to get without duty in an active combat zone. *See N.Y. Daily News*, January 9, 2014; *abcnews.com*, January 13, 2014.

New Lawsuits Allege OxyELITE Pro® Caused Hepatitis

Four new lawsuits have been filed in a federal court in Hawaii by individuals who allege that their use of the dietary supplement OxyELITE Pro® caused their liver failure, hepatitis and related injuries; defendants include USPlabs, company principals and a retailer. *Akau v. USPlabs, LLC; Igafo v.USPlabs, LLC; Ishihara v. USPlabs, LLC;* and *Mattson v. USPlabs, LLC*, Nos. 14-0029, -0030, -0031, and –0032 (U.S. Dist. Ct., D. Hawaii, filed January 23, 2014). Each plaintiff is represented by Wayne Parsons. *See Star Advertiser*, January 26, 2014.

Putative Class Alleges Injury from Weight-Loss Supplements

A Florida resident who allegedly purchased USPlabs' weight-loss supplements when he lived in New Jersey has filed a putative nationwide class action against the company and a retailer alleging that he did not get the benefit of his bargain because the supplements contain the unapproved and allegedly dangerous ingredients Aegeline and DMAA. *Barot v. USPlabs, LLC*, No. 14-0562 (U.S. Dist. Ct., D.N.J., filed January 27, 2014). While the complaint is characterized as an "economic consumer protection action," the plaintiff claims that he "has in the past, and will in the future continue to suffer, damages, including: Physical injury; Loss of wages; Medical expenses; Costs for investigation and repair; and Attorney's fees and costs of suit."

Included in the complaint are references to liver-related injuries allegedly linked to illnesses and a death among Hawaii consumers, as well as product recalls about which the defendants have purportedly "taken no action to provide notice to purchasers." Alleging violation of the New Jersey Consumer Fraud Act, unjust enrichment, breach of implied warranty of merchantability, and violation of the Magnuson-Moss Warranty Act, the plaintiff seeks declaratory and injunctive relief, including a revocation of the defendants' certificate of authority to do business in New Jersey and notice to consumers of the products' alleged dangers; restitution; compensatory, treble and punitive damages; attorney's fees, costs; and interest.

EMERGING TRENDS

Study Asserts That SCPCPA Will Result in Increased Animal Testing

The Coalition for Consumer Information on Cosmetics (CCIC), whose Leaping Bunny Program identifies animal cruelty-free companies, has expressed concern about a recent study suggesting that the Safe Cosmetics and Personal Care Products Act of 2013 (SCPCPA) may result in an increase in animal testing. CCIC cites the January 24, 2014, article "Safety Evaluations Under the Proposed US Safe Cosmetics and Personal Care Products Act of 2013: Animal Use and Cost Estimates," published in the scientific journal *ALTEX*, which studies the language of the SCPCPA to project the amount of animal testing that the law would require.

Concluding that passage of SCPCPA will result "in a minimum of one million animals being used in new required testing and will cost companies between $1.7-$9 billion to perform these tests," a significant increase over current testing costs and numbers of animals used, article co-author Jean Knight states, "in reading the Act, I was surprised to see that it would increase animal testing of cosmetics, since this is counter to the worldwide trend to reduce animal testing. The Act's language can't be easily understood unless you have some background in toxicology, so this impact was flying under the radar. Many Leaping Bunny certified companies were actually supporting the Act, unaware of the implications for animal testing. The article hopefully brings this information onto the radar so that people can make informed decisions."

Observing that the authors of the article "have done a great service in demonstrating that SCPCPA is a regressive bill," CCIC Chair Sue Leary said, "there has been a decisive move in recent years away from cruel and unnecessary animal testing but this bill reverses that. It's hard to imagine why legislators would want to increase animal testing for things like lipstick and shampoo. Consumers certainly don't want this and companies don't either." *See CCIC News Release*, January 27, 2014.

Common Beauty Product Ingredient Apparently Produced by Indian Child Laborers

According to a January 19, 2014, article in *The Sydney Morning Herald*, much of the world's mica, a key ingredient used to add shimmer to beauty products such as eye shadow, nail polish and lipstick, is mined illegally by children in eastern India. In "The Grind and Grief Behind the Glitter," authors Ben Doherty and Sarah Whyte discuss the mica trade in Jharkhand, an impoverished district in eastern India that boasts the world's largest known mica deposits. "The mineral here is easily accessible, high quality and in demand from around the world," the authors write, "but the industry [] is little better than a black market, depending on an unskilled workforce, forced into working for lower and lower prices. Profits are made off the backs of children."

While the government's Bureau of Mines states that India officially produces about 15,000 tons of crude and scrap mica each year, news sources say that the country exported more than 130,000 tons of the mineral in 2011-2012, mostly to China. "The majority of mica mining and trade is illegal," India's Industry Secretary, A.P. Singh, was quoted as saying. Attempts to regulate the mica industry and implement a mica-tracking system have reportedly been ineffective, and government enforcement is lax.

According to news sources, while many beauty product manufacturers reportedly disclose the source of mica used their beauty products and claim that none of their products are associated with child labor, others seem intentionally vague or unwilling to disclose where the mica used in their products was

sourced or identify the suppliers. *See The Sydney Morning Herald*, January 19, 2014; *Grist.org*, January 28, 2014.

INTERNATIONAL DEVELOPMENTS

Toxic Chemicals Allegedly Found in Beauty Products in India

A study conducted by the Pollution Monitoring Lab (PML) at India's Centre for Science and Environment (CSE), has reportedly found excessive levels of hazardous chemicals, including mercury, in nearly one-half of the products tested. Of 73 cosmetic products tested from four different categories, 32 apparently tested positive for mercury, including 44 percent of all skin-whitening creams. Included in the testing were 30 different lipstick products, eight lip balms and three anti-aging creams, many of which tested positive for mercury, chromium and nickel. The samples included both Indian and international cosmetic brands and some herbal products.

CSE compared the levels of heavy metals found with their Acceptable Daily Intake (ADI) limits—the maximum amount of a toxin a person can be exposed to over a lifetime without any appreciable health risk. Because India lacks set ADI limits for mercury, the agency used the ADI set by the U.S. Environmental Protection Agency. The study showed that the whitening creams may contribute up to 71 percent of the ADI for mercury, depending upon the product and its use.

Noting that mercury is banned for use in cosmetics under India's Drugs and Cosmetics Acts and Rules, CSE Director Sunita Narain reportedly called its presence in the products "completely illegal and unlawful" and suggested that, with "lax regulatory requirements that are generally not even enforced, many cosmetics companies are getting away with criminal behavior."

"Our standards for cosmetics are well-defined. We are ensuring that the Drugs and Cosmetics Act is stricter and the companies that do not adhere to these laws will not be in market. To this effect, we have decided to have a dedicated testing laboratory in Chennai," India's Drug Controller General, G.N. Singh said. "The systems are in place and we are working at implementing the rules better." *See LiveMint.com*, January 16, 2014; *Natural News.com*, January 29, 2014.

China Updates Cosmetic Ingredient List

China's Food and Drug Administration has issued a notice inviting comments on a consolidated Inventory of Existing Cosmetic Ingredients in China (IECIC 2014). Last updated in 2003, the previous list contained 3,265 ingredients. The IECIC list includes 8,641 ingredients. Comments will be accepted until February 20, 2014. *See Chemical Inspection and Regulation Service*, January 24, 2014.

India to Remove Mandatory Animal Testing for Soap Products

According to news sources, India will become the second country, after Israel, to end mandatory animal testing of soaps, detergents and household cleaners. The decision evidently followed a Bureau of Indian Standards meeting at which representatives from People for the Ethical Treatment of Animals (PETA) India, MP Maneka Gandhi and members of Parliament pushed for the action. "The tests in which harsh chemicals used to be rubbed onto guinea pigs' abraded skin will be suspended and [] replaced by non-animal testing methods to be followed by a test called the Human Repeated Insult Patch Test," said a PETA India spokesperson, who also noted that official meeting minutes have not yet been released. *See PETAIndia.com*, January 30, 2014.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Antiseptic Mouthwash Allegedly Linked to Heart Attack Risk

A new study conducted by Queen Mary University of London researchers, has reportedly revealed that use of antiseptic mouthwash may lead to an increased risk of heart attack and stroke. Kapil, Vikas, et al., "Physiological role for nitrate-reducing oral bacteria in blood pressure control," *Free Radical and Biology Medicine*, February 2014. The study observed the blood-pressure levels of a small group of healthy individuals who used the commonly prescribed antiseptic mouthwash Corsodyl, which contains 0.2 percent chlorhexidine gluconate by volume. Noting that individuals in the group experienced a rise in blood pressure between 2 and 3.5 units within 24 hours of using the mouthwash, lead researcher Amrita Ahluwalia said that chlorhexidine gluconate can kill "good" bacteria used by the body to create nitrite, a component that controls blood vessel dilation. Even small rises in blood pressure can have "significant impact on morbidity and mortality from heart disease and stroke," she noted.

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Mouthwash products containing chlorhexidine gluconate have been approved by the U.S. Food and Drug Administration to treat gum disease and are available only by prescription. The authors note that the study findings apply only to mouthwashes containing chlorhexidine and warn consumers that other mouthwashes could still produce the same effects as Corsodyl by disrupting the balance of healthy bacteria in the mouth. *See MedicalDaily.com*, January 27, 2014.

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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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