Shook, Hardy & Bacon L.L.P.

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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FTC Targets Weight-Loss Products, Companies to Pay $34 Million for Misleading Consumers

As millions of American consumers begin the new year with weight-loss resolutions, the U.S. Federal Trade Commission (FTC) held a January 7, 2014, press conference to announce enforcement initiatives against companies which promise that their products, including food additives, skin cream and dietary supplements, can produce slimming results with little effort.

FTC Bureau of Consumer Protections Director Jessica Rich discussed the start of "Operation Failed Resolution," which is a part of FTC's effort to stop misleading claims related to weight-loss products. FTC reported four enforcement actions, challenging a variety of weight-loss advertising campaigns, that will recover approximately $34 million for consumers. Under the settlements reached with product makers, only the false claims will be prohibited, not the products themselves.

FTC has issued new guidance for media outlets for the identification of false weight-loss advertising. Titled "Gut-Check: A Reference Guide for Media on Spotting False Weight-Loss Claims," the guidance contains an online tutorial and written materials that the media can use to identify the seven claims that experts and evidence have shown are always false.

Those claims are (i) causes weight loss of 2 pounds or more per week for a month or more without dieting or exercise; (ii) causes substantial weight loss no matter what or how much the consumer eats; (iii) causes permanent weight loss even after the consumer stops using the product; (iv) blocks the absorption of fat or calories to enable consumers to lose substantial weight; (v) safely enables consumers to lose more than 3 pounds per week for more than four weeks; (vi) causes substantial weight loss for all users; or (vii) causes substantial weight loss by wearing a product on the body or rubbing it into the skin. If any one of the seven claims are found in advertisements, they are likely deceptive, and FTC recommends that such marketing be rejected by the media.

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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FTC has also **provided** guidance for consumers of products and services advertised for weight loss, urging them to carefully evaluate advertising claims for weight-loss products.

FTC **summarized** each proposed settlement as follows:

Sensa Products, LLC

The marketers of Sensa® will pay $26.5 million to settle charges that they deceived consumers with unsupported weight-loss claims and misleading endorsements. Sensa marketed flavored powder to sprinkle on food by promising weight loss without any change to diet or exercise. The company claimed that the powder enhanced food's smell and taste, making the user feel fuller faster. FTC charged Sensa Products LLC, its parent company, CEO Adam Goldenberg, and Sensa® creator Alan Hirsch.

In addition to alleging deceptive advertising, FTC also claimed that the defendants failed to disclose that consumers were compensated for their endorsements with payments of $1,000-$5,000 and trips to Los Angeles. FTC further alleged that Hirsch made expert endorsements not supported by scientific evidence and misrepresented the company's role in a study. Under the order, Sensa is barred from misrepresenting any scientific evidence and is also prohibited from making (i) weight-loss claims unless the company has two adequate and well-controlled human clinical studies to support the claims or (ii) any other health-related claim unless it is supported by competent and reliable scientific tests, analyses, research, or studies. While the order imposes a $46.5-million judgment against the defendants, Sensa will be required to pay only $26.5 million of the total judgment due to its inability to pay.

L'Occitane, Inc.

FTC has reached a settlement regarding L'Occitane's allegedly deceptive claims that its Almond Beautiful Shape® and Almond Shaping Delight® skin creams are clinically proven to slim the body. The company claimed that the creams could trim 1.3 inches in just four weeks and fought cellulite. It also claimed that the creams were clinically proven to visibly refine and reshape the silhouette, as well as tone the body. L'Occitane has agreed to pay $450,000 for consumer redress as a part of the settlement. The proposed settlement bans L'Occitane from claiming that the cream causes substantial weight loss unless supported by two adequate well-controlled human clinical studies; requires that any claim that a drug or cosmetic reduces or eliminates cellulite or affects body fat or weight be backed by competent and reliable scientific evidence; and prohibits the company from misrepresenting the results of any test, study or research, or that the benefits of a product are scientifically proven.

HCG Diet Direct

FTC alleges that HCG Diet Direct and its director Clint Ethington falsely promised that their liquid homeopathic hCG drops would cause rapid weight loss, and they have agreed to a settlement that would bar such claims. The company sold a diluted liquid form of hCG, the hormone produced by the human placenta, that has been falsely promoted as a weight-loss supplement. According to the complaint FTC filed in an Arizona federal court, consumers were instructed to use the drops in conjunction with a very low-calorie diet program—500 to 800 calories per day—that the defendants claimed was safe. The company also allegedly posted testimonials on its Website without disclosing that the customers "had received free products, had been paid, or were related to Ethington."

FTC and the Food and Drug Administration jointly issued warning letters in November 2011 to HCG Diet Direct and six other companies advising that their hCG products were mislabeled and that it was unlawful under the FTC Act to make weight-loss claims that were not supported by reliable scientific evidence. The proposed settlement bars the defendants from claiming that any dietary supplement, food or drug causes weight loss or that consumers who use the product can expect the same result as endorsers unless the claim is non-misleading, and unless they have two adequate and well-controlled human clinical studies to substantiate their claims. The order imposes a $3.2-million judgment, which has been suspended based on the defendants' inability to pay.

LeanSpa, LLC

FTC settled claims against LeanSpa for some $7 million. In December 2001, FTC and Connecticut officials charged the company with using fake news Websites to promote their acai berry and "colon cleanse" products, making deceptive weight-loss claims and telling consumers they could receive free product trials by paying the normal cost of shipping and handling. Consumers actually paid $79.99 for the trial and for recurring monthly product shipments that were allegedly difficult to cancel. The proposed settlement prohibits the defendants from billing consumers for products or services by automatically charging them on a recurring basis unless they opt out; bars the defendants from falsely claiming that any product can cause rapid and substantial weight loss without diet or exercise; and requires LeanSpa to have at least two human clinical trials to support any weight-loss claims it makes about the products it sells. This summary was prepared by Shook, Hardy & Bacon Associate Nazish Shabbir.

FDA Warns Against Concussion Supplement Claims

The U.S. Food and Drug Administration (FDA) has issued an alert warning consumers to avoid dietary supplements marketed with claims to prevent, treat or cure concussions and other traumatic brain injuries (TBIs) because the claims are not backed with "scientific evidence that the products are safe or effective." The alert identified one manufacturer, the Virginia-based Star Scientific, Inc., which FDA accused in a December 20, 2013 warning letter (summarized elsewhere in this *Report*) of illegally marketing its anti-inflammatory product, Anatabloc, as effective in treating TBIs.

Calling such products "untested, unproven and possibly dangerous," the agency cites a growing body of research which indicates that if concussion victims resume strenuous activities—such as football, soccer or hockey—too soon, they risk a greater chance of having a subsequent concussion. "As amazing as the marketing claims here are, the science doesn't support the use of any dietary supplements for the prevention of concussions or the reduction of post-concussion symptoms that would enable one to return to playing a sport faster," said Daniel Fabricant, director of FDA's Division of Dietary Supplement Programs.

The agency has also criticized manufacturers of exploiting increasing public interest in concussion injuries as research about head trauma in athletics allegedly linking repeated concussions to brain problems later in life continues to mount. FDA stated that it would monitor the marketplace for products with similar fraudulent claims and will take appropriate regulatory action to protect the public health. "We can't guarantee you won't see a claim about TBIs. But we can promise you this: There is no dietary supplement that has been shown to prevent or treat them," said FDA National Health Fraud Coordinator Gary Coody. "If someone tells you otherwise, walk away."

FDLI Compares U.S. and EU Cosmetics Regulation

The December 11, 2013, issue of the Food and Drug Law Institute's (FDLI's) *Food and Drug Policy Forum* offers a comparative analysis of cosmetics regulation in the United States and the European Union (EU). Titled "Is it Time for Harmonized Cosmetics Standards? A Comparison of U.S. and E.U. Cosmetics Regulation" the analysis highlights increasing safety concerns regarding cosmetics regulation and maintains that the EU has responded with stricter standards and more regulatory requirements than the U.S. Food and Drug Administration (FDA) has the authority to implement. Despite citing recent efforts by congress to pass legislation that would broaden FDA's authority over cosmetics, the authors assert that there is "no reason to expect Congressional action in the near future." Among other things, the authors recommend that (i) an international standard for cosmetic manufacture and safety be established, similar to the International Conference on Harmonization

standards for pharmaceutical development and clinical trials; and (ii) FDA assess and expand its list of substances banned from use in cosmetics; and (iii) Congress authorize FDA to require cosmetics manufacturers to register, submit ingredient lists and report adverse events. *See FDLI News Release*, December 11, 2013.

Committee Urges EPA to Warn Pregnant Women About Environmental Exposures

As part of its ongoing effort to educate the public about the importance of preventing and reducing harmful environmental exposures before and during the prenatal period, the Environmental Protection Agency's (EPA's) Children's Health Protection Advisory Committee (CHPAC) has asked the agency to publicly disseminate its **document** titled, "Preparing for the Nine Months that Last a Lifetime." Noting that the chemicals in food, cosmetics, clothing, and cleaning supplies—many of which have not been tested for their impacts on human health—can be passed on to babies through the placenta and breast milk, CHPAC specifically urges health care providers to advise pregnant women to "reduce the use of products with fragrances (for example perfumes and air fresheners) as they may contain phthalates."

LITIGATION AND REGULATORY ENFORCEMENT

Court Rejects Neutrogena's Preemption Argument

A federal court in California has denied Neutrogena Corp.'s motion to dismiss a putative class action alleging that the company misleads consumers by using phrases such as "100% naturally sourced sunscreen ingredients" in the products' principal display panels. *Fagan v. Neutrogena Corp.*, No. 13-1316 (U.S. Dist. Ct., C.D. Cal., order entered January 8, 2014). According to the court, the company's preemption argument fails because if, as alleged, the language is misleading "then state law liability based on the product labels merely creates a damages remedy for violation of state law requirements that '"parallel," rather than add to, federal requirements.'"

The court also rejected Neutrogena's contention that the claims were barred under the primary jurisdiction doctrine, finding that the Food and Drug Administration "has affirmed that 'proceedings to define the term "natural" [in the context of cosmetics] do not fit within [its] current health and safety priorities.'" The company's challenge to the sufficiency of the allegations met a similar fate, with the court finding that the disputed phrase was subject to multiple interpretations and could not be interpreted one way as a matter of law. The court further determined that *Williams v. Gerber Products Co.*, 552 F.3d 934 (9th Cir. 2008), foreclosed the company's argument that any ambiguity in the language is "dispelled by the explicit list of ingredients elsewhere on the product."

JPML Consolidates Glucosamine Lawsuits

The U.S. Judicial Panel on Multidistrict Litigation (JPML) has transferred to a Maryland district court six putative consumer-fraud class actions pending before federal courts in four states against companies that make or sell supplements containing glucosamine and chondroitin. *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig. (No. II)*, MDL No. 2491; *In re Nutramax Cosamin Mktg. & Sales Practices Litig.*, MDL No. 2498 (J.P.M.L., orders entered December 17, 2013).

According to JPML, the scientific issues—whether clinical studies demonstrate that these ingredients do not provide the advertised joint-health benefits—will require "extensive expert discovery" and "one or more *Daubert* hearings" thus making centralization the best way to prevent duplicative discovery and inconsistent pretrial rulings, as well as to conserve litigant and court resources. Thus the panel rejected the plaintiffs' contentions that the actions were few, common factual issues were not "especially complex" and counsel had agreed to avoid duplicative pretrial activity.

Class Settlement Finalized in Glucosamine Suit, Attorney's Fees Slashed

A federal court in Illinois has given final approval to the settlement of class claims against NBTY, Inc., Rexall Sundown, Inc. and Target Corp. requiring the companies, which continue to stand by their glucosamine products and efficacy claims, to establish a guaranteed settlement fund of $2 million and make certain labeling changes. *Pearson v. NBTY, Inc.*, No. 11-7972 (U.S. Dist. Ct., N.D. Ill., E. Div., order entered January 3, 2014).

Among other matters, the agreement requires that the company cease making certain product claims while revising others and adding the phrase "individual results may vary" to product labels. Among the claims that Rexall agreed to stop using were "renew[s]," "help[s] renew," "repair[s]," "help[s] repair," "rebuild[s]," and "help[s] rebuild cartilage." Any other statements including these terms will be modified using terms such as "support[s]" or "protect[s] cartilage."

Settlement objectors challenged the attorney's fees awarded to class counsel, and, while the court refused to find that the settlement was not fair and reasonable on this basis, it reduced the fee and expenses award from $4.5 million to $1.9 million, to reflect a lodestar with no multiplier. According to the court, this reduces the award from 22.3 percent of the total settlement fund of $20.2 million—an amount that included total funds available to the class had all of them filed claims, i.e., the "constructive fund," notice costs and requested counsel fees—to 9.6 percent. The court took the action, "[d]ue to the low actual relief secured for the Class and lack of other meaningful benefit

to compensate the Class for past injuries." The court declined to impute a monetary value to the injunctive relief obtained because it was "difficult to ascertain" and did not directly benefit the class members.

Court Dismisses Challenge to "Natural" Cosmetics Labeling with Prejudice

A federal court in California has dismissed putative class claims that Hain Celestial Group, Inc. misleads consumers by labeling its Alba Botanica® cosmetics line with the word "natural." *Balser v. Hain Celestial Grp., Inc.*, No. 13-5604 (U.S. Dist. Ct., C.D. Cal., decided December 18, 2013). According to the court, "it is undisputed that 'natural' is a vague and ambiguous term."

While the plaintiffs alleged that "natural" means "existing in or produced by nature; not artificial," the court found their definition "implausible as applied to the products at issue: shampoos and lotions do not exist in nature, there are no shampoo trees, cosmetics are manufactured. Thus Plaintiffs cannot plausibly allege they were deceived to believe shampoo was 'existing in or produced by nature.'" The court observed that the defendant actively defines what "natural" means on its Website by stating "We make natural, 100% vegetarian personal care products . . . . This means we don't use parabens, sulfates, or phthalates." The company also lists on its Website those ingredients not used in its Alba Botanica® products, and its product labels "include an explanation explaining what natural ingredients are added, what ingredients are excluded and a complete list of all ingredients."

In the court's view, "Read as a whole, no reasonable consumer would be misled by the label 'natural.'" Because the complaint's defects could not be cured by amendment, the court dismissed it with prejudice.

FDA Issues Warning to Star Scientific for Antabloc and CigRx Products

The U.S. Food and Drug Administration (FDA) has **warned** former Star Scientific, Inc. CEO Jonnie Williams that the company makes therapeutic claims for its Antabloc dietary supplement, thereby rendering the product a drug subject to FDA approval under the Food, Drug, and Cosmetic Act. The company has reportedly been linked to an investigation into the conduct of outgoing Virginia Governor Robert McDonnell (R) and his wife, Virginia. Details about the executive couple's alleged involvement with the company appear in Issue **8** of this *Report*.

In its December 30, 2013, warning letter, FDA also focuses on the ingredient antabine in two of the company's products, Antabloc and CigRx, stating that they were promoted as dietary supplements before the ingredient was "authorized for investigation as a new drug under an investigational new drug application (IND)." Under the law, "a dietary supplement that contains a new dietary ingredient shall be deemed adulterated" unless the ingredient has

been present in the food supply "as an article used for food in a form in which the food has not been chemically altered" or it has a history of safety "and, at least 75 days before being introduced or delivered for introduction into interstate commerce" the manufacturer provides FDA "with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe."

The company has acknowledged receiving the warning letter and claims that anatabine is "a substance naturally occurring in various plants." According to Star Scientific, it is "responding to the letter and has already advised the agency that it intends to work cooperatively to resolve these issues, including undertaking a review of the Company's websites." FDA highlights company Website statements about the supplements and their ability to alleviate symptoms or treat a variety of diseases, including ulcerative colitis, multiple sclerosis, Alzheimer's disease, and traumatic brain injury.

Press reports indicate that Williams has resigned his position with the company, and it is now led by Michael Mullan, who formerly headed the Roskamp Institute, a senior living facilities developer. Meanwhile, federal prosecutors reportedly indicated, after meeting with the McDonnell's legal team, that they would delay charging the couple in connection with the alleged gift scandal. *See The Washington Post*, December 18, 2013; *NaturalProductsInsider.com*, December 31, 2013.

INTERNATIONAL DEVELOPMENTS

China Changes Mandatory Animal Testing Requirements

After a six-week public consultation on a November 2013 draft notice, the China Food and Drug Administration (CFDA) has issued a final **notice** outlining details pertaining to the removal of mandatory animal-testing requirements for certain domestically manufactured cosmetic products. Among other things, the new rules state that manufacturers of "non-special use cosmetics" such as shampoo or perfume, will no longer be required to provide samples of new products to the government for animal testing and will instead be allowed to conduct their own product risk assessments using ingredient safety data and the results of non-animal test methods, provided the test methods are deemed scientifically valid by the European Union. In addition, cosmetics with skin-whitening and skin pigmentation reduction claims have been re-classified as special-use cosmetics (anti-freckle category), effective December 16, 2013. Additional details about China's phase out of mandatory cosmetics animal testing appear in Issue **14** of this *Report*. *See CFDA News Release*, December 16, 2013; *ChemLinked*, December 23, 2013.

Meanwhile, on December 31, 2013, South Korea's Ministry of Food and Drug Safety issued a policy formally recognizing alternatives to animal testing for "functional cosmetics" such as sunscreens and anti-wrinkle creams. Although the new policy does not ban the use of animal testing for functional cosmetics, but offers non-animal testing as an option, industry experts call the action a major shift in Korean policy concerning functional cosmetics. *See ChemLinked*, January 3, 2014.

India to Consider Ban on Importing Animal-Tested Cosmetics

Following the June 2013 decision to prohibit the testing of domestically produced cosmetics and their ingredients on animals (details about which appear in Issue 6 of this *Report*), India's Drug Technical Advisory Board (DTAB) has reportedly recommended that the country's Drugs and Cosmetics Rules also be amended to prohibit imported cosmetics tested on animals. *See OneGreenPlanet.org.*, December 30, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Vitamin E May Slow Functional Decline of Alzheimer's Disease

A recent study has purportedly revealed that daily supplements of vitamin E—known for its antioxidant properties—may help to slow the functional decline of people with mild to moderate Alzheimer's disease and may help reduce the amount of care these patients need. Maurice Dysken, et al., "Effect of Vitamin E and Memantine on Functional Decline in Alzheimer Disease," *The Journal of the American Medical Association*, January 1, 2014. Sponsored by the U.S. Department of Veteran's Affairs (VA), the study followed 613 patients from 14 VA medical centers across the country given one of four treatments—20 mg of the Alzheimer's medication memantine, 2000 international units of vitamin E, a combination of vitamin E plus memantine, or a placebo.

Although vitamin E did not delay cognitive or memory deterioration in any of the groups, the study revealed that patients who received the vitamin E had a 19-percent reduction in functional decline, compared with patients who received the placebo. The researchers noted that this is the equivalent to a "clinically meaningful delay in progression" of 6.2 months. Study results also showed that patients who received vitamin E needed two fewer hours per day of caregiver assistance.

The main outcome measure was a test of how well the patients could perform activities of daily living such as dressing and feeding themselves. Previous studies have reportedly shown the use of vitamin E to be effective in patients with severe Alzheimer's disease, however, the use of vitamin E has apparently not been studied in patients with a mild to moderate form of the disease.

Noting that a delay of this size in the disease's progression can have a "significant impact" on quality of life for patients and their family members, lead researcher Maurice Dysken said that "it could be very meaningful for someone with early Alzheimer's who is still functioning at a high level, and for his or her caregivers, to have a delay of six months in the progression of the disease over about a two-year period."

In response to concerns about prior research that reportedly suggested an increase in the risk of death associated with vitamin E supplementation, Dysken reported that no such effect was seen in the VA study. "We looked at that very carefully as we designed the study protocol and the patients were monitored very closely throughout the trial." He noted that no patients in the trial, including those with existing heart disease, appeared to do any worse on vitamin E, compared with their peers in the other treatment groups.

Many experts, including the authors, note that the study does not mean that high-dose vitamin E should be taken by everyone with dementia or by people hoping to prevent it. "While this study into the link between vitamin E intake and reduction in functional decline is of interest, it is by no means conclusive." *See MedicalNewsToday.com*, January 1, 2014; *Veteran's Health Administration News Release*, January 6, 2014.

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