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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FDA to Take Closer Look at Antibacterial Soap

The U.S. Food and Drug Administration (FDA) has issued a proposed rule that would require manufacturers of antibacterial hand soaps and body washes to demonstrate that their products are safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infections. Under the proposal, if companies do not demonstrate such safety and effectiveness, these products would need to be reformulated or relabeled to remain on the market. The action is part of an ongoing agency review of antibacterial active ingredients and would not apply to hand sanitizers, wipes or antibacterial products used in health-care settings.

Noting that although many consumers generally view antibacterial products as effective tools to help prevent the spread of germs, FDA cites a lack of evidence that they are any more effective at preventing illness than washing with plain soap and water and observes that some data suggest that long-term exposure to certain active ingredients used in antibacterial products—for example, triclosan (liquid soaps) and triclocarban (bar soaps)—could pose health risks such as bacterial resistance or hormonal effects.

"New data suggest that the risks associated with long-term, daily use of antibacterial soaps may outweigh the benefits," said FDA Microbiologist Colleen Rogers. "There are indications that certain ingredients in these soaps may contribute to bacterial resistance to antibiotics, and may have unanticipated hormonal effects that are of concern to FDA." Rogers also asserts that laboratory tests that have historically been used to evaluate the effectiveness of antibacterial soaps do not directly test the effect of a product on infection rates. That would change with FDA's current proposal, which would require studies that directly test the ability of an antibacterial soap to provide a

clinical benefit over washing with non-antibacterial soap. Additional details about FDA's commitment to assess the safety and efficacy of these products appear in Issue 15 of this *Report. See FDA News Release,* December 16, 2013; *Federal Register,* December 17, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

Putative Class Cries Foul in "Organic" Personal-Care Products Litigation

Responding to Hain Celestial Group Inc.'s motion for summary judgment in a putative consumer-fraud class action alleging that the company wrongfully markets its Avalon Organics® and Jason brand products as "organic," the plaintiffs have asked the court to overlook the resolution of an administrative proceeding which concluded that the company's labels did not represent the products as organic. *Brown v. The Hain Celestial Group, Inc.*, No. 11-3082 (U.S. Dist. Ct., N.D. Cal., opposition filed December 6, 2013). The matter will be considered during a February 6, 2014, hearing before the court.

According to the plaintiffs, Hain failed to disclose to the plaintiffs or court the existence of a state investigation involving its alleged violation of the California Organic Products Act (COPA) until the company argued in its motion that the proceeding bars the plaintiffs' claims. And even if the court decides to consider the California Department of Public Health (CDPH) letter absolving the company of misconduct, the plaintiffs argue that it does not preclude them from pursuing claims based on more than product labels; the plaintiffs have alleged in addition that the company's advertising and marketing is false and misleading.

They also contend that the administrative action lacked the procedural safeguards necessary for the agency proceeding to preclude judicial proceedings. The plaintiffs state in this regard, "There were no submissions in opposition to Hain's letters, no hearing regarding the Products' compliance with COPA, no discovery, and no sworn testimony (or, for that matter, any testimony). In short, CDPH's inquiry lacked any of the quasi-judicial protections required for an agency proceeding to bar judicial claims. Moreover, since they were completely unaware of the pendency of the inquiry until after it had concluded, Plaintiffs had no opportunity to participate in CDPH's investigation and thus cannot have their claims barred by the outcome of CDPH's investigation."

The plaintiffs further take issue with the company's argument during the course of litigation, "while the CDPH inquiry was pending," that "the United

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States Department of Agriculture had 'exclusive jurisdiction' over organic claims on the Products and that the Products had been sold for nearly twenty years 'without objection' by state or federal authorities." They contend that waiver and equitable estoppel doctrines "are designed to prohibit this type of duplicitous conduct. Moreover, Hain's repeated violations of its disclosure and discovery obligations regarding its involvement with CDPH warrant barring Hain from relying on the fruits of its misconduct."

Federal Court Orders Seizure of Domain Names as Sanction in Chanel Infringement Suit

A federal court in Massachusetts has granted Chanel, Inc.'s motion for sanctions more than five years after the company prevailed in trademark-infringement litigation against Jian Yao and has ordered Yao to transfer 16 domain names to Chanel's control. *Chanel, Inc. v. Jian Yao,* No. 07-30032 (U.S. Dist. Ct., D. Mass., order entered December 12, 2013). Yao apparently used the sites to sell counterfeit Chanel products. The court also ordered Yao and any employees, agents or subsidiaries to stop using Chanel trademarks and "any confusingly similar trademarks." According to a news source, Chanel secured a permanent injunction and $3.8 million in statutory damages, plus attorney's fees, costs, and investigative fees against Yao in 2008, but the counterfeit sales allegedly continued. *See The National Law Journal*, December 13, 2013.

Court Narrows Claims in L'Oréal Wrinkle Cream MDL

A multidistrict litigation (MDL) court in New Jersey has dismissed with prejudice consumer fraud claims filed against L'Oréal to the extent that a "host of putative class" plaintiffs seek to assert unjust enrichment under New Jersey law which does not allow the cause of action where the plaintiffs purchase their products from third parties. *In re L'Oréal Mktg. & Sales Practices Litig.*, MDL No. 2415 (U.S. Dist. Ct., D.N.J., order entered December 9, 2013). In all other respects, the court will allow claims that the company misled consumers about the results provided by its wrinkle-cream products to proceed.

Among other matters, the court rejected the company's argument that the plaintiffs lacked standing as to 14 products that the named plaintiffs did not purchase, noting that it would address the inquiry at the class certification stage because (i) the basis for each claim is the same for the products purchased and those not purchased, (ii) the products are closely related, and (iii) the defendant is the same. The court also found that the plaintiffs had pleaded their fraud claims with the requisite particularity.

New Yorker Sues Snooki and Dietary Supplement Company

A New York resident has filed a putative class action against a company and individuals, including reality TV star and media personality Nicole Polizzi, a/k/a Snooki, alleging that the marketing and promotion of Zantrex-3 weight-loss products is false and misleading. *Brady v. Basic Research, L.L.C.*, No. 13-7169 (U.S. Dist. Ct., E.D.N.Y., filed December 16, 2013). Snooki is allegedly paid to endorse the product and does so across various media, including her Facebook and Twitter accounts.

According to the complaint, the product's main ingredient is "a dangerously large dose of caffeine which the U.S. Food and Drug Administration has determined is not safe or effective for weight control or appetite suppression." The plaintiff does not claim that she experienced any ill effects from using the product, but contends that she relied on the defendants' purported misrepresentations that she could lose weight without diet and exercise to purchase the product and would not have purchased it had she known that the misrepresentations were false. She contends that some of the defendants have long been associated with "peddling useless dietary supplements and over-the-counter products without any scientific support." She also challenges the study on which the defendants rely to establish the "effectiveness" of the product; it apparently included 30 subjects only 25 of whom completed the study.

Seeking to certify a nationwide class and statewide subclass of consumers, the plaintiff alleges violation of the Magnuson-Moss Warranty Act, breach of express warranty, negligent misrepresentation, fraud, and unjust enrichment. She seeks compensatory and punitive damages, interest, restitution, injunctive relief, attorney's fees, and costs.

EMERGING TRENDS

Counterfeit Estée Lauder Products on the Rise in San Francisco

The U.S. Department of Homeland Security (DHS) has reportedly uncovered an increasing number of counterfeit make-up manufacturing rings selling products that contain high concentrations of metals and carcinogenic ingredients normally banned from use in cosmetics. In particular, the agency notes that a large number of products falsely labeled Make-Up Art Cosmetics (MAC), a line manufactured by an Estée Lauder subsidiary, have turned up in San Francisco area flea markets and on Craig's List and Facebook. Many of the counterfeit products are manufactured in China, which evidently supplies 80 percent of all fake cosmetics, and when worn, allegedly cause intense allergic reactions. As part of its pursuit of rings of MAC cosmetics counterfeiters in the

Bay area, DHS reportedly recovered fake versions of the beauty products as part of a $1-million haul of counterfeit goods in Newport Beach, California, in 2012. *See Cosmeticsdesign.com,* November 27, 2013.

INTERNATIONAL DEVELOPMENTS

France Assesses First Year of Mandatory Nanomaterial Reporting

France's Ministry of Ecology, Sustainable Development and Energy (MEDDE) has published an assessment based on the mandatory reporting of nanomaterials, a requirement that took effect January 1, 2013, revealing that some 500,000 metric tons of nanomaterials—280,000 produced in France and 220,000 imported—were introduced on the French market in 2012. With goals of better understanding nanoparticle substances and providing improved traceability as to their use, the new rule requires companies that manufacture, import and/or distribute a substance with nanoparticle status in an amount of at least 100 grams per year, to submit an annual report with substance identity, quantity and use information. As of June 30, 2013, more than 930 reporters submitted more than 3,400 statements concerning substances placed on the French market. According to MEDDE, more than 1,000 common products contain nanomaterials, including cosmetics and sunscreens and "their recent development and [] growing use make it desirable to improve knowledge of these substances."

Industry experts note that the data likely reflect only a partial picture of the market for nanoparticle substances due to the novelty of the rule and the multiplicity and diversity of stakeholders, and advise that the data for this first year of reporting be taken with caution. MEDDE reportedly plans to release a second version of the report by January 2014. *See BloombergBNA.com*, *and Centre for NanoBioSafety and Sustainability News Release*, December 6, 2013.

Cosmetics Europe Urges Ban on Preservative in Skin Care Products

Cosmetics Europe, a European cosmetics trade association, has issued an industry-wide recommendation to discontinue use of the preservative methylisothiazolinone—also known as MI or MIT—in leave-on skin cosmetics and personal-care products. Noting that the action is made in the interests of consumer health and in response to recent clinical data that purportedly show an increase in adverse skin reactions to the ingredient, the association concluded that the discontinuation of MIT use in leave-on skin products including cosmetic wet wipes would result in "a significant decrease" in the incidence of sensitization to this ingredient. Cosmetics Europe suggests that industry "does not await regulatory intervention under the Cosmetics Regulation, but that it takes voluntary action in implementing this change as soon as feasible." *See Cosmetics Europe News Release,* December 12, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Animal Study Reveals How Vitamin D May Help MS Patients

A new study, conducted in mice by researchers at Johns Hopkins University School of Medicine and partially funded by the National Institutes of Health, has reportedly revealed that vitamin D may benefit people with multiple sclerosis (MS), an autoimmune disorder apparently caused when the immune system wrongly attacks a person's own cells. Although the study results, published in *Proceedings of the National Academy of Sciences,* have not been confirmed in humans with the disease, scientists note that they may help better explain how the disease works, how to treat it and why certain people are more prone to developing it.

Because the disease is more prevalent in regions of the world farthest from the equator where there is less sunshine—the main natural source of vitamin D, researchers have long-suspected a link between the disease and sun exposure. "With this research, we learned vitamin D might be working not by altering the function of damaging immune cells but by preventing their journey into the brain," said lead researcher Anne Gocke. "If we are right, and we can exploit Mother Nature's natural protective mechanism, an approach like this could be as effective as and safer than existing drugs that treat MS."

For the study, Gocke and her colleagues simultaneously gave mice the rodent form of MS and a high dose of vitamin D, observing that this protected the mice from showing disease symptoms. The study team remarked that with the clinical trial on vitamin D supplementation ongoing, no one is certain whether it will actually work to prevent or slow the progression of MS in humans. "But this new research," study co-author Peter Calabresi said, "can offer the opportunity to study samples taken from participants to see whether vitamin D is having the same effect on human cells as it appears to be having in mice." *See Johns Hopkins School of Medicine News Release,* December 5, 2013.

Health Experts Claim Multivitamins Are a Waste of Money

A recent **editorial** authored by British and U.S. medical doctors and scientists in response to three new studies on vitamin and mineral supplementation, concludes that "supplementing the diet of well-nourished adults. . .has no clear benefit and might even be harmful." Eliseo Guallar, et al., "Enough Is Enough: Stop Wasting Money on Vitamin and Mineral Supplements," *Annals of Internal Medicine,* December 17, 2013. Representing the University of Warwick in the United Kingdom, Johns Hopkins University School of Medicine and the American College of Physicians, the group's editorial is based on three studies—published in the same journal issue—that examine the effects of multivitamins on preventing heart attacks and cancer and improving cognitive function in men older than 65.

The first study, a meta-analysis of 27 studies covering more than 450,000 participants, found that taking multivitamins had no beneficial effect on preventing cardiovascular disease or cancer. A second study examined 6,000 elderly men and found no improvement on cognitive decline after 12 years of taking supplements, and a third study revealed no advantage of supplements among 1,700 heart patients studied over an average of five years. "The message is simple," write the authors. "Most supplements do not prevent chronic disease or death, their use is not justified, and they should be avoided." The team also claims that an average western diet is sufficient to provide the vitamins the body needs. "These vitamins should not be used for chronic disease prevention. Enough is enough." The authors also noted that specifically, antioxidant, folic acid and vitamin B supplements seem to hold no benefits, and beta carotene, vitamin E and high doses of vitamin A could potentially be harmful.

"The [vitamin and supplement] industry is based on anecdote, people saying 'I take this, and it makes me feel better,'" said Edgar Miller, one of the editorial's authors and a professor of medicine and epidemiology at Johns Hopkins University School of Medicine. "It's perpetuated. But when you put it to the test, there's no evidence of benefit in the long term. It can't prevent mortality, stroke or heart attack."

Critics note that the populations examined—one group included physicians with no health problems—are not reflective of the American population, which may not get ample nutrients and vitamins from their diets. "There's always a nontrivial minority that's actually getting a questionable level of some micronutrients. So multivitamins are a backstop against our poor diet," said University of California Berkeley Professor Gladys Block.

The Natural Products Association claimed that "the authors' hypothesis is flawed in that multivitamins are not intended to cure chronic disease or prevent death solely on their own. They are designed to address nutrient deficiencies, and to aid in the general health and well-being of consumers. Multivitamins are not meant to serve as the answer to all of life's ailments; they are, however, an important piece of the puzzle in leading a healthy lifestyle."

Meanwhile, an unrelated **study** of adults in the Midwest has reportedly revealed that the use of certain dietary supplements, including coenzyme Q10, fish oil and echinacea, was associated with changes—both positive and negative—in diastolic and systolic blood pressure.

Catherine McCarty, et al., "The use of dietary supplements and their association with blood pressure in a large Midwestern cohort," *BMC Complementary and Alternative Medicine,* November 28, 2013. Noting that "these results should not be interpreted as causal, nor can the direction of the association be assumed to be correct because the temporality of the association is

unknown," the researchers wrote that "despite these limitations, these data are intriguing and suggest areas for further research, where sufficient evidence does not already exist, into potential dietary supplements that could be used to lower BP [blood pressure] or for which use should be cautioned in people with hypertension." *See Natural Products Association News Release* and *Huffington Post,* December 16, 2013; *CNN.com,* December 17, 2013.

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LEGAL TRENDS REPORT

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