

## LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS  
• DIETARY SUPPLEMENTS  
• NUTRACEUTICALS



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### INSIDE GOVERNMENT

#### Interagency Committee Issues Progress Report on Animal-Testing Alternatives

The U.S. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) has [issued](#) its 2012-2013 biennial progress report. Composed of representatives from 15 U.S. federal regulatory and research agencies that either generate or use toxicological and safety-testing information, ICCVAM was tasked when created in 2000 with fostering new regulatory test methods that would reduce the use of animals in toxicology testing while upholding scientific quality and protecting human and animal health, and the environment.

According to the report, many of its recommendations have not been used for regulatory decision making during its first 15 years, so ICCVAM has taken a new approach under which partner agencies will drive its activities and its scope will expand "to provide bioinformatics and computational toxicology support to the DNTP [Division of the National Toxicology Program] overall and the DNTP's Biomolecular Screening Branch." ICCVAM is still developing new operating procedures and planning future activities under the approach. See *NTP News*, August 4, 2014.

### LITIGATION AND REGULATORY ENFORCEMENT

#### Sixth Circuit Affirms 5-Hour Energy Trademark, Trade Dress Ruling

A Michigan federal district court did not err in ruling against N2G Distributing and Alpha Performance Labs on Innovation Ventures, LLC's (IV's) trademark and trade dress infringement claims relating to its 5-hour ENERGY (FHE) mark, the Sixth Circuit has determined. [Innovation Ventures, LLC v. N2G Distributing, Inc., No. 12-1635 \(6th Cir., order entered August 14, 2014\)](#). After a jury found that N2G had intentionally infringed IV's trademark and trade dress with several products, including its 6 Hour Energy product, and awarded IV \$1.75 million in damages, N2G appealed on several points.

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IV filed its initial complaint in 2008 and won a preliminary injunction against N2G, which pulled 6 Hour Energy from the market and released Pure Energy, a similar product with similar trade dress. IV then amended its complaint to add Pure Energy, and N2G discontinued it and released another similar product—a cycle that continued until IV's complaint alleged that eight of N2G's products infringed its trademark and trade dress. The jury agreed that N2G's products were infringing, and the district court issued a permanent injunction on selling the products. IV later discovered that N2G continued to supply the enjoined products to its customers; on motion to the court, N2G was held in contempt of the injunction and ordered to destroy the products or face fines of \$1,000 per day of noncompliance.

N2G appealed to the Sixth Circuit, arguing that the district court erred in denying its motion for a new trial. The circuit court disagreed, finding that a jury could reasonably conclude that infringement occurred based on the evidence presented. "[T]he jury could use their eyes and see that Defendants' products use similar marks," the court noted, and found further that "[t]he jury heard ample evidence that an 'ordinary consumer who would consider buying' FHE could likely be confused by the marks on Defendants' products." The court also rejected N2G's fair use defense that it was merely a descriptive name, pointing out that the company's owner "testified that he had no basis for claiming that his products gave 7, 7+, or 14 hours' worth of energy. A jury could infer that Defendants did not intend to describe what their products did when Defendants weren't sure of that themselves."

N2G also challenged the Safe Distance Rule, the principle that allows courts to enforce permanent injunctions in intellectual property cases by ensuring that the infringer changes its trademarks and trade dress to be "so far removed from any characteristic of the plaintiff so as to put the public on notice that the two are not related" without subjecting the parties to new trademark contests if the defendant fails to sufficiently change its infringing use. N2G argued that the rule should not be applied in trademark cases brought under the Lanham Act, but the Sixth Circuit dismissed the argument, noting the history of success across jurisdictions in applying the rule in Lanham Act cases.

### **Ninth Circuit Removes Illegal Acai Total Burn Scheme from FTC Enforcement Action**

The Ninth Circuit Court of Appeals has ruled that a man under Federal Trade Commission (FTC) scrutiny for more than a decade for fraudulent business practices did not directly participate in the online marketing of Acai berries and thus partially reversed a district court grant of summary judgment to the FTC as to the "Acai Total Burn Scheme." [\*FTC v. Kimoto, No. 11-18023 \(9th Cir., decided August 15, 2014\)\*](#). According to the court, while Kyle Kimoto allegedly controlled the company that set up a number of schemes for which

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he was responsible, including lines of credit, government grant connections and work-from-home enterprises, due to his incarceration when the Acai Total Burn Scheme was planned and launched, the evidence to support his personal involvement in it in violation of the FTC Act was lacking.

The schemes were all the same and allegedly involved false testimonials, hidden “upsells” for additional programs with “free trial” periods and recurring monthly charges that were “exceedingly difficult” to cancel, because the company needlessly transferred “customers to different websites or phone numbers, even though all of the calls ended up in the same service center.” By the time FTC shut down each scheme, the vast majority of subscribers, “after considerable effort on their parts,” had cancelled the subscriptions.

Upholding the lower court’s findings as to the defendant’s involvement in the other schemes, the court rejected his argument that individuals cannot be held liable under the Electronic Fund Transfer Act and also ruled that the injunction imposed was appropriately tailored to his bad acts. In this regard, the court stated, “Kimoto has also consistently engaged in variations on the same deceptive marketing scheme, which in its latest iteration alone, has defrauded consumers of more than \$29 million. As the record reveals, the common elements employed in each of the frauds concocted by Kimoto [are] easily transferable both to new product lines and to new modes of communication with consumers.”

**Dial Corp. Seeks Class Cert. in Anti-Competition Suit Against News Corp.**

A group of consumer packaged goods companies (CPGs), including personal-care-products company Dial Corp., has filed a motion for class certification in New York federal court in a lawsuit against News Corp. alleging that the company has shut the CPGs out of the market for in-store advertising services, including coupon dispensers, shopping cart advertisements and coupon books inserted in newspapers. *Dial Corp. v. News Corp.*, No. 13-6802 (U.S. Dist. Ct., S.D.N.Y., motion filed August 11, 2014). The complaint alleged that News Corp. used its dominant position in the market to overcharge customers of its News America Marketing FSI Inc. and News America Marketing In-Store Services LLC units through both exclusive and staggered retailer contracts. The proposed class includes “United States CPGs that have purchased in-store promotions from News at any time on or after April 5, 2008,” because each class member purchased in-store services from News and has the same legal claims against it, argues the plaintiffs’ group, which includes several food manufacturers as well as Spectrum Brands, which sells batteries, appliances, hardware, and home and garden and pet supply products.

**Forum to Focus on Aluminum in Cosmetics, Foods, Water, Drugs, Packaging**

The Germany-based Federal Institute for Risk Assessment (BfR) will [host](#) its 15<sup>th</sup> consumer protection forum—"Aluminum in Everyday Life: A Health Risk? Intake of Aluminum from Food, Cosmetics and Other Consumer Products"—on November 26-27, 2014, in Berlin-Marienfelde. Experts will provide information on the current state of research so that stakeholders may begin to answer questions such as (i) "How much aluminum do we intake via food, drinking water, drugs, packaging and cosmetic products?"; (ii) "Are there reasons to believe that aluminum intake is a cause of Alzheimer's disease or breast cancer?"; and (iii) "Should contact with aluminum be reduced, and if so, what are measures that individual consumers can take?" The event will be interpreted and broadcast via live streaming.

**Man Sentenced to Prison in UK for "Herbal" Supplements with Prescription-Only Ingredients**

According to the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), a Barnet man has been sentenced to 16 weeks in prison for selling an "herbal" erectile dysfunction product that reportedly contained tadalafil, the active ingredient in Cialis®. The 58-year-old had been cautioned in 2009 for possession with intent to supply Jia Yi Jian, "a fake 'herbal' product which actually contained up to four times the dose of erection drug tadalafil and more than four times the dose of withdrawn slimming medicine sibutramine," and received a 32-week suspended sentence in 2010 after he was stopped at Heathrow Airport with more than 50,000 tablets of "Herbal Viagra." Most recently, he was caught with more than 5,000 tablets hidden in boxes labeled as "Diet tea." The Wood Green Crown Court has sentenced him to eight weeks in prison for breach of his suspended sentence and another eight weeks for placing unlicensed medicine on the market without authorization, in addition to a fine of £600 for court costs. *See MHRA Press Release*, August 15, 2014.

**Gluten-Free Claims Increase in UK Beauty Industry**

U.K. beauty industry watchers have reportedly noted an increase in the number of products highlighting their "gluten-free credentials" on product labels, and some believe that the trend will only accelerate given consumer interest in a gluten-free lifestyle. Coeliac UK has indicated, however, that "gluten will only cause a problem if you eat it; it cannot be absorbed through the skin," and that the level ingested, for example from lip balm or lipstick, would be insufficient to cause problems. Some companies have not adopted the labeling because they are unconvinced that gluten content in cosmetic products is relevant to most consumers.

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Pravera Ltd. Founder Graeme Hume, whose company distributes the Lavera brand in the United Kingdom, noted that “even those who are allergic to gluten in food can often tolerate it in skincare formulations” and, because only so much information can be included on packaging, the company has decided not to address gluten content on its labeling. Other producers, such as Aubrey, are using gluten-free symbols, finding that consumers are looking for this type of mark on a product. Au Naturel Director of Operations Gianni Quaglieri was quoted as saying, “Some people feel that if they are gluten intolerant they don’t want to have anything to do with gluten. We’re giving them the option and offering that service if they’re looking for a gluten-free product—it’s a question of making your own mind up really.” See *Natural Products News*, August 12, 2014.

### Cosmetics Website Focuses on Nano-Ingredients

Independent Website CosmeticOBS-L’Observatoire des Cosmétiques has [published](#) an August 11, 2014, dossier titled “Nanoparticles: the file,” which compiles a variety of information, including the current status of EU regulatory requirements, the latest research on the purported effects on human health of nanomaterials in cosmetic and personal-care products, and consumer alerts relating to nanoparticles in sunscreens issued by nongovernmental organizations around the world.

Among other matters, the dossier also reports that nanoparticles can be found in organic sun-care products. Appended to the dossier are links to 26 additional articles related to the topic.

### Banned Cosmetics Turning Up in Philippines Markets

According to a public-interest organization in the Philippines, traditional Pakistani eye cosmetics that have been prohibited in Canada, Europe and the United States because they contain heavy metals such as lead have been found in retail establishments in the Philippines. The cosmetics, known as “kajal,” “kohl” or “surma” have apparently been subject to recalls elsewhere and were most recently at issue in a U.S. Food and Drug Administration Import Alert that warned, “[T]he use of these colors may present a hazard to health because of their heavy metal content.” The alert also noted, “[T]he risks associated with exposure to lead are especially serious for children, who are particularly susceptible to absorbing lead from the environment.” EcoWaste Coalition National Coordinator Aileen Lucero said, “These eye cosmetics were subjected to various product recalls abroad and should not be sold here. Local consumers who use them should be duly alerted of the health hazards posed by such cosmetics.” See *EcoWaste Coalition News Release*, August 17, 2014.

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**Russia Searches Oriflame Offices in Tax Probe**

In an ongoing tax investigation spanning several years, Russian police searched the Moscow offices of Swedish cosmetics company Oriflame and seized documents related to unpaid tax allegations reportedly amounting to \$84 million (3 billion rubles) from 2006 to 2010. Russia is one of Oriflame's two largest markets in its direct-to-customer sales, and the company has stated that it pays a high tax rate in Russia. "Several independent local and international experts have confirmed that Oriflame's tax practices are in accordance with applicable local and international legislation," the company said in a statement. "The event came as a complete surprise to the company as it has been fully co-operating with the authorities since the beginning of the investigation." See *Oriflame Press Release* and *Law360*, August 5, 2014.

**EMERGING TRENDS****New Test Unveiled to Quickly Detect Mercury in Skin-Lightening Creams**

California Department of Public Health (CDPH) scientists have reportedly identified a new method of screening product samples to determine mercury contents in skin-lightening creams. According to Gordon Vrdoljak of CDPH, some of the creams have been found to contain mercury levels as high as 210,000 parts per million (ppm) despite the U.S. limit of 1 ppm. "If people are using the product quite regularly," he said in an August 13, 2014, press release from the American Chemical Society (ACS), "their hands will exude it, it will get in their food, on their countertops, on the sheets their kids sleep on."

The new method reportedly involves a machine that employs a technique called total reflection x-ray fluorescence, which apparently runs between 20 or 30 samples each day, while a previous technique could take several days to show results, said Vrdoljak. The ACS press release noted that mercury can successfully lighten skin—which may explain the lightening products' popularity—but may, at excessive exposure levels, cause several health problems, including kidney damage, headaches, fatigue, depression, and lower cognitive functioning. The skin-lightening creams are apparently popular in Asia, Central America, Africa, and the Middle East, and American visitors to those regions may bring the products back with them for personal use. See *ACS Press Release*, August 13, 2014.

**Questions Raised over Triclosan Safety**

*Bloomberg News* has published a wide-ranging overview of the use of triclosan in consumer products, the most recent concerns raised by scientists studying its purported endocrine-disrupting and carcinogenic effects, as well as regulatory initiatives, including Minnesota's recent ban on its use in most

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consumer retail products. Details about the state law and the 2013 launch of a U.S. Food and Drug Administration (FDA) safety review of anti-bacterial ingredients including triclosan appear in Issue [25](#) of this *Report*.

According to the *Bloomberg* article, titled “Cancer-Linked Colgate Total Ingredient Suggests Flaws in FDA Review Process,” the summaries of toxicology studies that Colgate submitted to FDA in the 1990s to secure approval of the ingredient in its toothpaste came to light only when the agency released them in response to a Freedom of Information Act request and then posted them on its Website. Scientists asked to review the material reportedly question whether FDA’s approval should stand given more recent research allegedly showing adverse effects of triclosan on animals at low doses. And *Bloomberg* expresses concern that the approval process relies on “company-backed science to show products are safe and effective.”

Noting that a number of companies, including Avon Products Inc., have voluntarily reformulated products such as hand soaps to remove triclosan, the article reports that it is used in nearly 200 products, ranging from rugs to pet-food dispensers. It also reports that consumers have become increasingly wary of chemicals as advocacy organizations publish lists ranking the purported toxicity of various products. As to FDA’s review of triclosan, the article reports that the agency proposed issuing a monograph on the safety of antibacterial ingredients in 1974, but that they were grandfathered in existing substances with no safety testing under a 1976 law. “The FDA, four decades after its first promise, has yet to issue a ruling on whether triclosan is safe or effective in soaps,” the article states. The agency has apparently promised to deliver the monograph by 2016, but will not revisit its decision about use of triclosan in toothpaste unless it has “a good reason to do that.”

Meanwhile, the Cosmetic, Toiletry and Perfumery Association (CTPA) has issued a Q&A article addressing “scare stories” on triclosan to assure consumers that it is safe for use in cosmetic and personal-care products. The article acknowledges a study finding traces of the chemical in the urine of pregnant women and in some umbilical cord blood, but notes that the study does not show the levels to be harmful or to cause adverse effects and, in fact, that the authors admit that triclosan is readily flushed from the body. The association also reports that Europe, which strictly regulates the safety of cosmetic products, has supported its use in toothpastes, hand and body soaps, shower gels, deodorants, face powders, blemish concealers, nail cleansers, and mouthwashes. See *Bloomberg BNA Product Safety and Liability Reporter*<sup>™</sup>, August 11, 2014; *CTPA News Release*, August 12, 2014.

**Researchers Link Phthalates to Endocrine Disruption**

University of Michigan School of Public Health researchers have conducted a study that explores “relationships between urinary concentrations of 13 phthalate metabolites and serum total T levels among men, women, and children when adjusting for important cofounders and stratifying by sex and age.” [John Meeker & Kelly Ferguson, “Urinary Phthalate Metabolites Are Associated with Decreased Serum Testosterone in Men, Women, and Children from NHANES 2011-2012,” \*Journal of Clinical Endocrinology & Metabolism\*, July 2014.](#) Phthalates are found in plastics and some personal-care products. The researchers found reduced levels of circulating testosterone associated with increased phthalate exposure in certain populations, including boys ages 6-12 and men and women ages 40-60. Of the 13,431 subjects screened in the 2011-2012 NHANES cycle, only the 2,208 participants with both T and phthalate metabolite levels were included in this study.

The researchers found that women ages 40-60 with increased phthalate concentrations were associated with a 10.8- to 24-percent decline in testosterone levels, while boys ages 6-12 with increased concentrations of metabolites of a phthalate known as DEHP had a 24- to 34.1-percent decrease in testosterone levels. Study co-author John Meeker said that the findings “may have important public health implications, since low testosterone levels in young boys can negatively impact reproductive development, and in middle age can impair sexual function, libido, energy, cognitive function and bone health in men and women.” *See Endocrine Society Press Release, August 14, 2014.*

According to a news source, the U.S. Centers for Disease Control and Prevention (CDC) withdrew certain data released in July 2014 from NHANES 2011-2012, indicating that it had discovered an error in sampling weights. Among the biomonitoring data corrected in updated tables posted to the CDC Website were measurements of exposure to phthalate metabolites. Because the data corrected involved information released long after this paper was prepared and peer-reviewed, it is unlikely that the observed associations would be affected. *See Bloomberg BNA Product Safety & Liability Reporter™, August 18, 2014.*

**Cellulose Nanoparticles Synthesized with “Green” Methods**

Iranian researchers have reportedly found an environmentally friendly way to synthesize cellulose nanoparticles, useful in personal-care products such as conditioners, from waste cotton fibers. Tayyebeh Fattahi Mei-Abadi et al., “Spherical cellulose nanoparticle preparation from waste cotton using a green method,” *Powder Technology*, July 2014. The processes used were described

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by the lead author as enzyme hydrolysis and ultrasound methods. Noting that acidic hydrolysis is most often used to produce cellulose nanoparticles, lead researcher Tayyebah Fattahi Mei-Abadi said, "This method is not in agreement with environmental issues, and it leaves byproducts. But in this research, enzyme hydrolysis method was used, which enables the production of nanoparticles under mild condition without any environmental damage, and it does not require specific equipment. In addition, ultrasonic process was carried out with low energy in a short period, which makes cost-effective the production of cellulose nanoparticles through this method." *See Fars News Agency, July 29, 2014.*

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