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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FDA Investigates Connection Between Weight-Loss Supplement and Liver Failure

The Food and Drug Administration (FDA), Centers for Disease Control and Prevention and Hawaii Department of Health (DOH) have launched an investigation into an increasing number of reports of liver failure allegedly linked to use of the dietary weight-loss supplement OxyELITE Pro, manufactured by the Dallas, Texas-based USPlabs LLC. According to FDA, 29 cases of acute non-viral hepatitis with an unknown cause have been identified in Hawaii. Eleven of the 29 cases have been hospitalized with acute hepatitis, two cases have received liver transplants, and one person has died. Hawaii DOH reported that at least 24 of the patients said that they had used OxyELITE Pro during the 60 days before they became ill.

FDA is reviewing patient medical records and histories as well as analyzing the composition of product samples collected from some of the patients. The agency is also inspecting the facilities where the product is made and reviewing production and product distribution records. In response to USPlabs' claims that counterfeit versions of OxyELITE Pro have been circulating throughout the United States, FDA also plans to investigate whether counterfeit products may be linked to any of the hepatitis cases.

In the meantime, FDA indicated in an October 11, 2013, letter to USPlabs CEO Jacob Geissler that a dietary ingredient known as aegeline could have played a role in the illnesses and warned that it is not aware of any "history of use or other evidence of safety establishing that aegeline will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of OxyELITE Pro []."

FDA has advised consumers to stop using any dietary supplement product labeled as OxyELITE Pro while the investigation continues, and USPlabs has stopped distributing the product. According to a USPlabs statement, "The cluster of liver issues in Hawaii is a complete mystery and nothing like this has ever been associated with OxyELITE Pro in all of the years our products have

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been in the market. We know of no credible evidence linking OxyELITE Pro to liver issues. The ingredients have been studied for safety, are consumed in the food supply and widely used in dietary supplements. The studies and consumption history show no negative liver issues." *See USPlabs LLC News Release,* October 8, 2013; *Natural Products Insider,* October 14, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

Court Excludes Defense Expert in FTC Challenge to Supplement Ads

A federal magistrate judge in California has ruled unreliable and inadmissible the expert testimony proffered by the defendant in a Federal Trade Commission (FTC) lawsuit alleging that the company, its owners and officers deceptively advertised two dietary supplements by claiming they effectively treat diabetes and insulin resistance. ***FTC v. Wellness Support Network, Inc.,* No. 10-4879 (U.S. Dist. Ct., N.D. Cal., order entered October 4, 2013)**.

According to the court, the expert, a "Clinical Professor of Medicine with extensive experience in the study and treatment of diabetes," failed to (i) address the specific allegedly false advertising claims in his report, (ii) show that the medical community embraced his methodology, including his exclusive consideration of "positive clinical studies" to support his opinions on diabetes treatments, or (iii) adequately support the arbitrary hierarchy he created to describe the level of "clinical effectiveness" of the ingredients used in the defendant's products. As to the latter, the court noted that the expert apparently relied on Food and Drug Administration (FDA) "medical foods" regulations to support his classification system, thus underlining its irrelevance and lack of grounding in scientific principles. In this regard, the court said, "Even assuming WSN's products were considered medical foods by the FDA—a question the Court need not reach—the degree of regulation they would be subjected to by the FDA simply is not relevant to the issues of this case."

Kentucky Court Allows Defective Hair Smoothing Product Claims to Proceed

A federal court in Kentucky has denied the defendants' motions to dismiss in a putative class action alleging that Unilever U.S., Inc.'s Suave® "Professionals Keratin Infusion 30 Day Smoothing Kit" is falsely labeled as a safe, smoothing hair care product because it, in fact, caused consumers to lose their hair and burned their scalps. ***Naiser v. Unilever U.S., Inc.*, No. 13-395 (U.S. Dist. Ct., W.D. Ky., Louisville Div., order entered September 30, 2013)**. The product was recalled in May 2012, but the company allegedly continued to advise consumers that it was safe and was recalled "due to consumer misunderstanding of the product's appropriate use and application."

The court found that the plaintiffs' breach of warranty, consumer protection law violation, negligence, strict liability, and unjust enrichment claims were sufficiently pleaded, based in large part on the ruling of an Illinois federal court considering similar claims. *Reid v. Unilever U.S., Inc.*, 2013 WL 4050194 (N.D. Ill. Aug. 7, 2013). Unilever contended that the label statements about smoothing were nonactionable puffery and that other label statements about varying product effects as well as label warnings made it clear to consumers that the product was a hair straightener with the "same chemicals used in perming to alter hair shape and texture." The court disagreed, saying it could not make this determination as a matter of law at this stage of the proceedings. The company also argued that a lack of privity doomed the claims, but the court agreed with the plaintiffs that Kentucky law allowed claims against manufacturers who sell their products through retailers where their "alleged written, express warranties were clearly intended for the product's consumers."

While the court agreed with the defendants that Kentucky law requires a plaintiff to prove that a safer, feasible alternative design was available to the manufacturer when it made the product, it found that this element could be inferred from the plaintiffs' allegations that the defendants "advertised that the hair product contained no formaldehyde, despite the fact that it contained a formaldehyde-releaser. The Court finds that from this allegation, it can be inferred that a safer alternative design exists: namely, a product containing no formaldehyde or formaldehyde-releaser." The court further allowed the unjust enrichment claim to proceed as an alternative cause of action.

In a related development, California plaintiffs have reportedly filed similar litigation, seeking class certification, cancellation of purportedly unconscionable releases, and damages for negligence, gross negligence, breach of warranty, deceptive advertising, unjust enrichment, and violations of the Magnuson-Moss Warranty Act and business and consumer laws. *Wells v. Unilever U.S., Inc.*, No. 13-4749 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed October 11, 2013). One of the named plaintiffs alleges that her hair started "melting" as soon as she applied the product. According to a news source, the complaint states that the company failed to disclose that "the treatment contains an ingredient or combination of ingredients that causes significant hair loss upon proper application. The active ingredient in the treatment, thioglycolic acid, including its salts and esters, is the same active ingredient that is used in hair depilatories and some hair perming solutions." *See Courthouse News Service*, October 15, 2013.

Court Rules Organic Food Standards Inapplicable to Personal Care Products

A federal court in California has denied the motion to dismiss filed by Kiss My Face, LLC in a putative class action contending that the company misleads

consumers by labeling its personal care products as "obsessively organic"; among other matters, the court determined that national organic standards applicable to agricultural commodities or products do not preempt the claims because they do not regulate cosmetics or personal care products. *Dronkers v. Kiss My Face, LLC*, No. 12-1151 (U.S. Dist. Ct., S.D. Cal., order entered September 26, 2013).

Kiss My Face asserted that the plaintiff's claims, premised on the labeling requirements of the U.S. Department of Agriculture's (USDA's) national organic program (NOP), were expressly or impliedly preempted by NOP standards. The company also argued that they should be dismissed or suspended under the primary jurisdiction doctrine and that the plaintiff had not sufficiently pleaded his fraud-based claims.

As to preemption, the court was unswayed by the defendant's reliance on USDA policy statements permitting cosmetic, body care and personal care products containing agricultural ingredients to be certified under the NOP because "[t]he policy statement and recommendations are informal agency actions lacking a rulemaking or adjudicatory process." And observing that neither the National Organic Standards Board nor USDA was currently involved in rulemaking on the issue, the court found the primary jurisdiction doctrine inapplicable. While the court agreed that the heightened pleading standard of Federal Rule of Civil Procedure 9(b) applied, it further determined that the plaintiff had adequately pleaded his fraud-based claims.

Final Approval Given to Toothpaste Settlement

A federal court in New Jersey has certified a class of those who purchased Crest Sensitivity toothpaste relying on advertising promises of "Relief Within Minutes" and given final approval to a settlement of claims that these promises were false and unsubstantiated. *Rossi v. The Proctor & Gamble Co.*, 11-7238 (U.S. Dist. Ct., D.N.J., decided October 3, 2013). While the company admitted no wrongdoing, it agreed to pay $4 to each class claimant, up to $700,000 in attorney's fees and expenses in addition to the class benefits, and $1,500 to each named plaintiff. Noting that just one individual objected to the settlement and rejecting his concerns for their conclusory nature, the court found the settlement fair, reasonable and adequate.

Putative Class Sues Supplement Maker, Claims Product Ineffective

A California resident has filed a putative statewide consumer-fraud class action against the company that makes Natrol Glucosamine Chondroitin supplements and promotes them as products that can "Help[] Rebuild Cartilage Tissue" and contain "Clinically Tested Ingredients to Promote Optimal Joint Flexibility, Lubrication, Mobility and Comfort." *Dao v. Natrol, Inc.*, No. 13-2433 (U.S. Dist. Ct., S.D. Cal., filed October 9, 2013). According to the

complaint, scientific studies confirm that these products "have no efficacy at all: that they are ineffective in the improvement of joint health, provide no benefits related to the reduction of pain in human joints, and they do not protect cartilage from breakdown."

The plaintiff alleges that she relied on the product labeling to purchase a bottle for $25 and did not obtain the promised relief. While she does not claim damages for physical harm, she contends that she lost money and would not have purchased the product if she had known it would not work. The complaint details the many studies published since 1999 indicating that the main ingredients in the defendant's products are no more effective than placebos. Alleging violations of the Consumers Legal Remedies Act and Business & Professions Code, as well as breach of express warranty, the plaintiff seeks damages, restitution and disgorgement, injunctive relief including a corrective advertising campaign, attorney's fees, and costs.

Advertising Self-Regulation Watchdog Issues Compliance Warning

The Advertising Self-Regulation Council's (ASRC's) Accountability Program has issued a compliance warning as part of its educational outreach to address how Website operators should fulfill their obligation to provide notice to consumers that information about their browsing activity is being collected by third parties for use in generating "interest-based ads." The warning "explains the responsibilities of first parties to provide website enhanced notice on every page where they permit third parties to collect information for interest-based advertising or when they themselves transfer such data to unrelated third parties." The Accountability Program will begin enforcing the requirements January 1, 2014. Administered by the Council of Better Business Bureaus, ASRC is the advertising industry's self-regulator. *See ARSC Press Release*, October 8, 2013.

NAD Issues Recommendations on Mascara and Supplement Ads

While the Advertising Self-Regulation Council's National Advertising Division (NAD) has found that Procter & Gamble Co. can support express advertising claims for Covergirl® "Clump Crusher" mascara, including "200% more volume" and "The new curved brush crushes clumps as it builds volume," it recommended that the company cease artificially enhancing its model's eyelashes. NAD suggested that P&G either stop using artificial lash enhancements or alert consumers that "the images depict the volume achieved when CC Mascara is used together with lash inserts." The company found the recommendations reasonable and said it would take them into account in future advertising.

NAD has also recommended that Supragenix, LLC discontinue certain advertising claims related to its "CB-1 Weight Gainer" dietary supplement. The company reportedly decided not to provide substantiation for claims, since abandoned, that its product is "the only Safe and Effective All-Natural weight gain supplement"; the "only" solution "to gain weight, bulk up, or add some sexy curves"; and "[t]he #1 solution for rapid weight gain." NAD determined that discontinuing the claims was necessary and appropriate and that they should not be used in further advertising; it also recommended that the company cease claiming (i) "Average weight gain of 9.4 lbs. in only 4 weeks," (ii) "stimulates appetite and slows metabolism," and (iii) "CB-1 produces an actual increase in body mass that you keep when you stop taking it, not just temporary water weight." The company reportedly challenged NAD's findings, but said it would modify its claims to conform to the industry self-regulatory watchdog's decision. *See ASRC Press Release*, September 27 and October 7, 2013.

Israeli Cosmetics Co. Sues Amazon for Trademark Infringement

According to a news source, Dead Sea Premier Laboratories, which makes cosmetics and beauty products sold throughout the world, has filed a lawsuit in the Tel Aviv District Court alleging that Amazon infringes its trademarks and copyrights by selling current, out-of-date and imitation products, using the company's trademarks and product images without authorization. The Tel Aviv-based company claims that Amazon does not request trademark owners of products to approve when resellers post details of product offerings on Amazon's online retail site. This practice, Dead Sea Premier alleges, allows anyone to sell products whether or not authorized to do so by the manufacturer.

The company reportedly contends that it has not granted Amazon permission to use its trademarks and intellectual property and that Amazon has failed to remove infringing material from its Website when asked to do so. Seeking a provisional amount of compensation—some US$168,000—Dead Sea Premier asks the court to order an accounting to determine the full extent of Amazon's profit from using the company's name and products. *See Jewish Business News*, October 15, 2013.

Indian Lawyer Seeks Improvements to Personal Care Product Packaging

In a petition filed before the Bombay High Court, activist-attorney Geetanjali Tapan Dutta has reportedly challenged the methods that multinational companies use to seal their personal care, hygiene and cosmetic products. She contends that improper sealing risks contamination, especially during transit, and can result in allergies and skin diseases or reactions. She was quoted as saying, "I have seen many times when shop owners or walk-in

customers casually pick up products like deodorants and perfumes from the shelves and put them back again. So, the consumer actually gets less of the product they have paid for. Also, there are chances of contamination which can be dangerous." Among the companies named as respondents are Hindustan Unilever, Procter & Gamble and Colgate Palmolive (India). Dutta has also named certain government agencies and asks the court to intervene to ensure the adoption of rules and guidelines requiring that these products be sealed. *See Economic Times*, October 2, 2013.

Dove Hair Care Ads Pulled in Australia, ASA Found Ethics Breach

After Australia's Advertising Standards Authority (ASA) upheld a complaint about a Dove Hair Care ad claiming that "90% of Kiwi women recommend" the product, Unilever Australasia was reportedly forced to pull the ad campaign from the air. The complainants sought the company's evidence for making the claim, and the company responded by showing it had conducted a survey of 221 "New Zealand women aged between 25 and 55 with dry, damaged or split hair" and that 90.9 percent of them "either agreed or strongly agreed that they would recommend Dove Hair Care products to a friend or family member."

According to the Complaints Board, "the likely consumer take out from the statement '90% of Kiwi women recommend Dove Hair Care' would be that 90% of all New Zealand women would recommend Dove." Thus, the board found that the ad was likely to mislead or deceive consumers and breached ethics rules requiring truthful presentation of information and a principle stating that all ads "should be prepared with a due sense of social responsibility to consumers and to society." Unilever has reportedly indicated that it was prepared to revise the ad to say "90% of Kiwi women who tried Dove Hair Care recommend it." *See The New Zealand Herald*, October 4, 2013; *msn.co.nz*, October 5, 2013.

EMERGING TRENDS

Philadelphia Children's Hospital Bans Dietary Supplements

The Children's Hospital of Philadelphia (CHOP) has removed most dietary supplements from its list of approved medications due to regulatory, safety and efficacy concerns. The move reportedly makes CHOP the first hospital in the nation to place such a ban. Noting that vitamins and dietary supplements are essentially unregulated and "there is no sound information about adverse side effects, drug interactions, or even standard dosing for the vast majority of them," Sarah Erush, pharmacy clinical manager and a member of the hospital's Therapeutic Standards Committee, said that "administering these medications—particularly to children with serious health complications— is

unethical when the risks are unknown, and when there are alternative treatments that have been proven in clinical trials to be safe and effective."

The hospital will allow a limited list of vitamins and nutrients to be used with regard to certain medical conditions. To be included on the list, products must follow guidelines similar to those for FDA-approved medications and demonstrate proven safety and efficacy data in pediatric patients.

Under the new policy, parents or guardians will be asked upon admission whether the patient is taking any medication or supplements, and the attending nurse or physician will review the hospital's policy discouraging the use of supplements and inform parents or guardians of the potential risks associated with the supplement—contamination, mislabeling, interactions with medications, or potential unforeseen adverse effects. To use supplements not on the approved list, parents or guardians will be required to sign a waiver stating that they agree to be responsible for providing the product. *See Children's Hospital of Philadelphia News Release,* October 8, 2013.

Cosmetics Theft Threatens Dutch Beauty Industry

A recent study by Utrecht University researchers has reportedly revealed that cosmetics theft by gangs of Eastern European criminals is "one of the biggest issues" affecting the Dutch beauty industry. Among the items generally targeted are Maybelline mascaras, L'Oréal shampoos and brand-name razor blades, which are re-sold on the Dutch black market. Observing that they appear to work in highly organized groups, researcher Dina Siegel, speaking to officials and criminals in Lithuania, Poland, Romania, and Bulgaria, said that the thieves use prepared aluminum bags to steal the beauty products, which are generally not protected as well as other types of goods. Siegel also implied that although cosmetics theft in the Netherlands is a "really big industry," neither Dutch nor Eastern European police have made the issue a priority. *See Cosmeticsdesign-europe.com,* September 20, 2013.

INTERNATIONAL DEVELOPMENTS

EU Initiative Promises Better Cruelty-Free Predictions of Cosmetic Toxicity

The European Commission (EC) and the European trade association Cosmetics Europe have undertaken the Notox **study**, one of six SEURAT-1 (Safety Evaluation Ultimately Replacing Animal Testing) research projects that aim to advance research in the field of alternative testing methods for long-term systemic toxicity and "develop non-animal and human relevant testing methods for safety assessment using *in vitro* human cell cultures and *in silico* computer models."

The five-year study will reportedly use experiments on human cells to develop computer models and algorithms to show the long-term effects of chemicals on the body. The predictions are expected to help replace animal testing by providing a different source of testable predictions and allowing products such as make-up, soap or toothpaste to be tested without using living organisms. A consortium of international research teams comprising scientists from 11 academic institutions and research laboratories will work on the project. *See notox-sb.eu,* October 7, 2013.

Australian Oversight Agency Reviewing Goods with Caffeine and Oxedrine

The Therapeutic Goods Administration (TGA) of Australia's Department of Health has issued a monitoring **communication** to advise consumers and health professionals that it is "undertaking a comprehensive review of the safety of therapeutic goods containing both caffeine and oxedrine." These ingredients are apparently used in energy supplements, appetite suppressants and weight- loss products. TGA contends that use of the products as recreational stimulants "could create significant health risks, especially if used in combination with illicit drugs or other stimulants." Among the purported adverse events that have been reported to TGA are teenagers experiencing "serious cardiovascular toxicity" when using products with these ingredients along with alcohol and caffeinated energy drinks. Other reported effects include fainting, increased heart rate, raised blood pressure, stroke, and heart attack. TGA suggests that parents address these issues with their teenage children and that all consumers read product labels carefully to moderate caffeine intake.

EC Seeks Input on Phenoxyethanol and O-phenylphenol

The European Commission's (EC's) Scientific Committee on Consumer Safety (SCCS) has announced the availability of assessment **studies** from the French ANSM (National Agency for Medicines and Health Products Safety) on phenoxyethanol and o-phenylphenol—often used as preservatives in cosmetics products. Specifically, ANSM concluded that (i) the maximum authorized concentration of phenoxyethanol for use as a preservative (currently 1 percent) should be lowered to 0.4 percent in cosmetic products for children younger than three; (ii) phenoxyethanol should not be used in products intended for the diaper area; and (iii) the maximum authorized concentration of o-phenylphenol (0.2 percent) when used as a preservative in cosmetic products is considered unsafe. SCCS seeks data regarding "all toxicological end-points and an indication on the suggested concentration safe limits for these ingredients." The panel will accept comments until December 9, 2013.

EFSA Approves Folate Supplement

The European Food Safety Authority (EFSA) has concluded that the supplement Quatrefolic® is safe for human consumption and may be added for nutritional purposes to food supplements as a source of folate—an ingredient purported to reduce the risk of neural tube defects in infants. Derived from methyltetrahydrofolate and glucosamine salt, Quatrefolic® evidently features high water solubility, improved bioavailability, long-lasting stability, established safety, and higher formulation flexibility, and can overcome existing limits of previous methyl derivative reduced folates. It was approved as a New Dietary Ingredient by the U.S. Food and Drug Administration in 2010. *See Gnosis Group News Release,* October 3, 2013; *newhope360,* October 4, 2013.

China to Consider Revision to Animal-Testing Regulation

The Chinese government reportedly intends to revise its main cosmetics regulation which, unchanged since 1990, requires that every new cosmetic product formulation intended for sale in China be animal-tested in a government laboratory before sale to Chinese consumers. Although Chinese authorities have not officially made a commitment to use animal-testing alternatives, they have apparently invited industry representatives and other interested parties to review the cosmetics regulation and have stated that they "do not object in principle" to accepting animal-testing alternatives.

Despite China's booming cosmetics industry, worth an estimated $22 billion, its animal test-based regulatory framework has reportedly created an increasing divide between the Chinese market and the growing number of countries that have banned cosmetic testing on animals. Some manufacturers have pledged not to sell products in China until the animal-test requirement is removed.

Animal rights groups such as Humane Society International (HSI), which launched its Be Cruelty-Free China campaign earlier this year, have publicly welcomed China's action, and HSI toxicology experts have prepared a report for the China Food and Drug Administration that highlights opportunities to reduce longstanding scientific and trade barriers. These include accelerating China's acceptance of internationally recognized non-animal methods for safety testing and aligning China's animal-testing policy with that of Europe, Israel and India, where such testing is banned for cosmetic products and ingredients.

"We hope that China will align its cosmetics policy with Europe and other regions where cosmetics animal testing has already been abandoned, so that Chinese consumers can benefit from the cruelty-free cosmetics they clearly want and Chinese companies are free to sell their new cosmetics lines in the

cruelty-free EU market," said HIS Director of Research and Toxicology Troy Seidle. *See Humane Society International News Release,* September 30, 2013; *livescience.com,* October 11, 2013.

EC Issues Opinions on Two Hair Dyes

The European Commission's (EC's) Scientific Committee on Consumer Safety (SCCS) has approved the use of henna—a natural material derived from dried and powdered leaves of the plant *lawsonia inermis*—as a cosmetic hair dye.

Noting that its assessment was based on specific batches of henna that contained a maximum lawsone content of 1.4 percent, SCCS stated that, when formulated and applied as indicated under functions and uses (100g Henna powder mixed with 300ml of boiling water), henna is safe for consumers. Henna extracts with different compositions and the use of henna as a body-paint were not assessed.

SCCS also assessed the use of 2-chloro-p-phenylenediamine in hair dye formulations for eyebrows and eyelashes and determined that, due to the lack of a proper *in vivo* test for gene mutation induction, the agency cannot establish its genotoxic potential and therefore it is not considered safe for consumer use.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Multivitamins May Protect Women with Invasive Breast Cancer

A recent study has reportedly revealed that postmenopausal invasive breast cancer patients who take multivitamins with minerals on a regular basis have a 30 percent lower rate of death when compared with those who do not take the supplement. S. Wassertheil-Smoller, et al., "Multivitamin and Mineral Use and Breast Cancer Mortality in Older Women with Invasive Breast Cancer in the Women's Health Initiative," *Breast Cancer Research and Treatment,* October 2013. Calling the evidence "tentative but intriguing," lead author Sylvia Wassertheil-Smoller, said that "multivitamin/mineral supplements may help older women who develop invasive breast cancer survive their disease."

Using a database of 161,608 postmenopausal women aged 50 to 79 from the Women's Health Initiative (WHI) Clinical Trials and the WHI Observational Study, 7,728 participants diagnosed with invasive breast cancer during the WHI were followed for an average of seven years after their diagnosis. After enrolling in the WHI and during repeated follow-up visits, all participants provided information about their health including whether or not they had taken a multivitamin/mineral supplement at least once a week during the prior two weeks. Nearly 38 percent of the 7,728 women who developed invasive breast cancer during the WHI study used multivitamins and mineral

supplements, and the majority took them before being diagnosed with breast cancer, the research showed. A comparison of mortality rates revealed that women with invasive breast cancer who took the supplements were 30 percent less likely to die from their cancer than women with invasive breast cancer who did not take the supplements. The scientists noted that a reduced risk of death remained even when factors such as race/ethnicity, weight, depression, alcohol use, physical activity, age at breast cancer diagnosis, and diabetes were taken into account.

"Controlling for these other factors strengthens our confidence that the association we observed—between taking multivitamin/mineral supplements and lowering breast-cancer mortality risk among postmenopausal women with invasive breast cancer—is a real one," said Wassertheil-Smoller. "But further studies are needed to confirm whether there truly is a cause-and-effect relationship here. And our findings certainly cannot be generalized to premenopausal women diagnosed with invasive cancer or to other populations of women." *See Science Daily,* October 9, 2013.

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LEGAL TRENDS REPORT

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