

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS
• DIETARY SUPPLEMENTS
• NUTRACEUTICALS



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FIRM NEWS

Crampton Prepares U.S. Chamber ILR Report on Legal Trends in Latin America

Shook, Hardy & Bacon Global Product Liability Partner William Crampton has [prepared](#) a U.S. Chamber Institute for Legal Reform (ILR) report titled “Following Each Other’s Lead: Law Reform in Latin America” that “reviews some of the significant trends in Latin America that could significantly affect potential defendants.”

According to Crampton, change in one country is often adopted regionally, thus changes to procedural rules and the adoption of class-action mechanisms in Brazil have established a model that others have followed. He describes the reforms, both adopted and pending, in some detail. While acknowledging that access to justice could be improved in some countries by creating a class action mechanism, Crampton argues that “it is fair and appropriate to oppose class action systems that change the meaning of justice under the guise of creating access to it.” He recommends that the business sector participate in the discussion “to ensure that a level playing field is maintained for both plaintiffs and defendants.”

INSIDE GOVERNMENT

House Approves Sunscreen Ingredient Bill

The U.S. House of Representatives has approved by voice vote a bill ([H.R. 4250](#)) intended to speed up the review of the safety and effectiveness of nonprescription sunscreen active ingredients. It was forwarded to the Senate on July 29, 2014, where an identical bill (S. 2141) has been pending since March. The “Sunscreen Innovation Act” would impose certain timeframes on a generally recognized as safe and effective (GRASE) review of these ingredients and require a GRASE determination within 300 days of the application’s filing. The proposed order making that determination would be subject to public review and comment.

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EPA Announces NY Superfund Landfill Treatment for Cosmetics Chemical

According to the U.S. Environmental Protection Agency (EPA), additional technology will be added to the existing treatment plant at a New York Superfund site to “further address the long-term treatment of the chemical 1,4 dioxane, a stabilizer and solvent that is also a component of some cosmetics, detergents and shampoos.” The treatment plant was constructed and is operated by the two companies responsible for the landfill’s purported contamination between 1952 and 1968. The waste deposited there included “industrial solvents, waste oils, polychlorinated biphenyls (PCBs), scrap materials, sludge and solids,” EPA said. “Volatile organic compounds and other hazardous substances have seeped out of the landfill and contaminated the groundwater. PCBs have also moved downstream, causing contamination of sediment and several species of fish in and near Nassau Lake.”

A carbon filtration system currently in place has apparently been “effectively removing 1,4-dioxane,” and it will be the primary treatment method for the chemical until the new treatment technology is functioning. There is no discharge limit for the chemical, but the state requires quarterly monitoring, and the National Toxicology Program has included it in the “reasonably anticipated human carcinogen” category. EPA and the responsible companies apparently “agreed that adding the specialized treatment is the best long-term treatment option for 1,4-dioxane.” Environmental concerns raised by the chemical have apparently caused some companies to re-formulate their products, and EPA’s new treatment option at the Dewey Loeffel Landfill Superfund site could be applied to other treatment facilities. *See EPA News Release, July 21, 2014; Cosmeticsdesign.com, July 22, 2014.*

LITIGATION AND REGULATORY ENFORCEMENT

Vitamin Supplements Can Be Medical Treatment, Eighth Circuit Says

The Eighth Circuit has sided with Sun Life Assurance Co. of Canada in a lawsuit alleging that the insurance company improperly denied the plaintiff long-term disability benefits for taking vitamin A supplements at the direction of his doctor to slow the progression of his retinitis pigmentosa, which the company said qualified as medical treatment under its pre-existing condition clause. [*Kutten v. Sun Life Assurance Co. of Can., No. 13-2559 \(8th Cir., order entered July 21, 2014\).*](#)

Sun Life’s long-term disability policy specifically excluded coverage for pre-existing conditions, which it defined as receiving “medical treatment, care or services, including diagnostic measures” or taking “prescribed drugs or medications.” Under the direction of his doctor, the plaintiff took 15,000 units each day of a non-prescribed, over-the-counter vitamin A palmitate supplement, and, when Sun Life denied his request for benefits, he sued. The district

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court held that Sun Life abused its discretion in construing the clause to apply to the use of supplements, finding that the company's broad interpretation of "medical treatment" rendered portions of the clause meaningless and internally inconsistent.

The Eighth Circuit disagreed, dismissing the plaintiff's close reading of the pre-existing condition clause to differentiate between supplements and medical treatment because "[f]ocusing on such semantics misses the larger purpose of the clause." The court found that "[t]he supplements are 'medical' in the sense that they prevented or alleviated the progression of [the plaintiff's] retinitis pigmentosa. Further, [the plaintiff's] daily supplement regimen constituted a 'treatment' because it was the 'manner,' in fact the only manner, by which [the plaintiff] could 'care for' his condition."

A dissenting judge argued that vitamin supplement use does not constitute medical treatment because supplements are over-the-counter, and Sun Life's expansive interpretation of the clause could be dangerous. "Any time a medical official gave advice it would be considered medical treatment," he wrote. "Even simple things such as getting eight hours of sleep a night, brushing one's teeth, exercising thirty minutes a day, or taking an aspirin for a headache would be encompassed by this interpretation." He also said that "Sun Life's pre-existing condition clause was poorly drafted—which is its own fault—and thus should not be allowed to change the clause by argument in court."

"Double Shot" Weight Loss Supplement Maker to Pay \$500,000 for Deceptive Claims

Manon Fernet and her company 7734956 CANADA, doing business as Freedom Center Against Obesity, have agreed to pay \$500,000 to the U.S. Federal Trade Commission (FTC) to settle charges that they deceived customers by claiming that their product, Double Shot pills, would cause substantial weight loss quickly and without diet and exercise changes. *FTC v. 7734956 CANADA*, No. 14-2267 (U.S. Dist. Ct., Md., N. Div., order entered July 21, 2014).

Through its direct advertising, the company claimed that Double Shot users could eat plates of food and absorb only a fraction of the calories by taking a blue pill that burned fat and a red pill that blocked calories. It purported to support these claims through the endorsement of a doctor who served as the director of weight loss research at the Freedom Center Against Obesity, the name the company gave to its fulfillment house. In addition to the \$500,000 payment, the settlement requires the defendants to document in detail any studies conducted to support their health claims, and it enjoins them from manufacturing or selling weight loss products, making misleading claims about Double Shot pills or misrepresenting scientific study results.

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RICO Putative Class Action Dismissed Against GNC Corp. and Gencor Nutrients

A California federal court has dismissed with prejudice a putative class action alleging that GNC Corp., Gencor Nutrients and several individuals defrauded consumers by manipulating scientific data on the health effects of the herbal extract fenugreek and Gencor's commercial version, Testofen. *O'Toole v. Gencor Nutrients*, No. 14-3754 (U.S. Dist. Ct., C.D. Cal., order entered July 23, 2014). Finding that the plaintiffs failed to demonstrate that California could exercise personal jurisdiction over the non-resident individual defendants, co-founders of defendant Direct Digital, the court first dismissed the claims against them.

The court then dismissed each of the remaining claims in turn. The plaintiffs alleged that Gencor and GNC violated the Racketeer Influenced and Corrupt Organizations (RICO) Act based on mail and wire fraud, but the court pointed out that the plaintiffs did not explain "the who, what, where, and when" of the allegations. The breach of warranty claims also fail, the court found, because the plaintiffs did not allege reliance, causation and injury. The court then dismissed all remaining claims because they rested on the allegation that Gencor's clinical trial failed to use the "Bonferroni correction," which corrects for several dependent or independent statistical tests. The plaintiffs argued that, according to the report attached to their complaint, this failure amounted to an invalidation of the study's results. The court disagreed, finding that the report actually contradicted the plaintiffs' argument, and dismissed the remaining actions with prejudice.

Federal Court Certifies Nationwide Class Action Against Homeopathic Co.

Less than four months after a federal court in California certified a nationwide class in litigation alleging that the makers of homeopathic products advertised as safe and effective misled consumers because "homeopathy is pseudoscience" and the products do not work, another California court has certified another nationwide class bringing essentially the same claims. *Allen v. Hyland's Inc.*, No. 12-1150 (U.S. Dist. Ct., C.D. Cal., order entered August 1, 2014). Information about the April ruling appears in Issue [23](#) of this *Report*. The court refused to certify the plaintiffs' "100% Natural" theory—that is, that consumers were misled by this labeling when the products allegedly contain synthetic or artificial ingredients—because they had failed to demonstrate "that 'natural' has a definite meaning that would exclude any of the ingredients at issue, nor had they demonstrated that class members relied on the 'natural' labelling statements at issue."

The court rejected a challenge to one of the plaintiff's experts finding that, while he lacked expertise on homeopathy, he has substantial training and experience in medicine and the treatment of disease generally and was qualified to offer opinions as to the medical or scientific underpinnings of homeopathy in general based on a recent literature review. The court

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also rejected the defendants' argument that California law could not be constitutionally applied to out-of-state class members, because they had not sufficiently briefed the matter. According to the court, they relied on conclusory statements about the "markedly different laws of the 50 states" and "also failed to provide case-specific analysis as to the second and third prongs of the governmental interest test, relying instead on *Mazza*. Courts in this Circuit have repeatedly rejected such wholesale reliance on *Mazza* as insufficient to meet the defendant's burden under the governmental interest test."

Rejecting the defendants' argument that the proposed class is not sufficiently ascertainable, the court disagreed that self-identification requires corroborating evidence because "the identity of class members need not be known at the time of class certification." The court also found persuasive the court's ascertainability analysis in the other homeopathy product class action. The court further found that the plaintiffs met the numerosity, commonality and typicality requirements of Rule 23, with one exception. One of the plaintiffs, who was the only one to purchase two specific products, testified that she could not recall if she had seen the product labels before buying them. Thus, she was not typical of the class members with respect to these products, and the motion for class certification was denied as to ClearAc and Poison Ivy/Oak Tablets.

Regarding the adequacy of the plaintiffs to represent the class, the court rejected claims that they were inadequate because they had been solicited by counsel on a Website, some of them had sought refunds or rebates, counsel did not actually contact them about the litigation until after the defendants filed a motion to dismiss the original complaint, and most of them had not reviewed or verified the complaint's allegations before it was filed. Counsel were deemed adequate despite claims that they lured in plaintiffs with advertising, were jockeying with other attorneys to become lead counsel, had a conflict of interest because they were representing plaintiffs in parallel litigation, had demonstrated that their "true intention is to secure a fee," and did not conduct a sufficient pre-filing investigation.

The court found that the plaintiffs had failed to demonstrate standing to seek class-wide relief for the fraud-based Unfair Competition Law claims as to two products—Colic Tablets and Leg Cramps with Quinine—due to a lack of actual reliance on the allegedly deceptive or misleading statements. But, because the "record supports a finding that all class members were exposed to the same alleged misleading statements by Defendants," the court ruled that the plaintiffs demonstrated that these claims were subject to class-wide proof. In this regard, the court stated, "It strains credulity to suggest that a 'significant portion of the general consuming public or of targeted consumers' do not rely—at least *in part*—on representations about the products' uses and effectiveness on product packaging when buying the products."

The court allowed class certification of the plaintiffs' breach of warranty and implied warranty of merchantability claims, ruling that an exception to vertical privity applied.

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Court Dismisses Hi-Tech Pharmaceutical's Request for Declaratory Judgment

A Georgia federal court has dismissed Hi-Tech Pharmaceutical's action seeking a declaratory judgment relating to U.S. Federal Trade Commission (FTC) product-advertising substantiation requirements, finding that Hi-Tech was merely attempting to collaterally attack an enforcement action that imposed \$40 million in sanctions, required product recalls and limited the company's advertising practices. *Hi-Tech Pharm. v. FTC*, No. 13-4306 (U.S. Dist. Ct., N.D. Ga., Atlanta Div., order entered July 23, 2014).

FTC initially sued Hi-Tech, National Urological Group and three individuals in 2004, alleging that they made unsubstantiated claims about weight-loss supplements Benzedrine, Fastin, Lipodrene, and Stimerex-ES. In 2008, the court enjoined the defendants from advertising their products without reliable scientific evidence, and in 2013, at FTC's urging, the court found the defendants in contempt of the injunction for circulating advertisements with claims that violated the court's order. Hi-Tech then filed an action for "a narrow and specific declaratory judgment relating to the 'competent and reliable scientific evidence' substantiation standard for advertising claims." The company argued that the action for declaratory judgment was not a collateral attack on the enforcement action but merely a request for clarification, but the court agreed with FTC and dismissed the case for lack of subject-matter jurisdiction.

Claims Trimmed in ACT Mouthwash False-Advertising Lawsuit

A Florida federal court has dismissed without prejudice claims that Chattem breached implied warranties by falsely advertising its ACT mouthwash as "remineralizing" tooth enamel. *Foster v. Chattem*, No. 14-346 (U.S. Dist. Ct., M.D. Fl., order entered July 23, 2014). The court denied the company's motion to dismiss claims of unjust enrichment and violation of Florida's Deceptive and Unfair Trade Practices Act, rejecting Chattem's argument that it did not deceptively advertise ACT mouthwash because a reasonable consumer would not differentiate between "rebuilding" and "remineralizing" enamel.

The plaintiff's warranty claims failed, the court said, because she was not in privity with Chattem. "[S]ome courts have held that direct contact between a purchaser and a manufacturer satisfied the privity requirement at the pleadings stage; however, direct contact in that sense refers to personal contacts between the purchaser and a representative of the manufacturer, not merely some contact between the purchaser and the manufacturer's product or advertising," the court noted.

New Class Action Filed Against Guthy-Renker

Claiming that she has lost one-third of her hair after using Guthy-Renker LLC WEN Cleansing Conditioner hair-care products, a Florida resident has filed a putative nationwide class action in a California federal court, alleging strict

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products liability, breach of warranty, failures to warn and test, as well as consumer fraud. *Friedman v. Guthy-Renker LLC*, No. 14-6009 (U.S. Dist. Ct., C.D. Cal., filed July 31, 2014).

The complaint includes what are alleged to be a small sample of numerous blog and other Website statements from WEN conditioner purchasers making the same comments about hair loss that continued even after use of the product ceased. It further asserts that "YouTube features numerous videos also documenting hair loss caused by WEN Cleansing Conditioner." The plaintiff claims that the company not only failed to warn about the product defects, but "actively concealed customers' comments concerning hair loss, by blocking and/or erasing such comments from the WEN Facebook page." She also alleges that the company makes false statements on which she relied about the "gentle nature of the product" including that it can be used every day.

To bolster claims that the defendant knew about the hair-loss problems, the plaintiff contends that after she complained about the product to the U.S. Food and Drug Administration, the company contacted her and posed "two dozen comprehensive questions concerning Plaintiff's use of WEN Cleansing Conditioner. Discovery in this litigation will undoubtedly demonstrate that Defendant formulated these questions long ago and has repeatedly used them with complaining consumers." She also alleges that she was contacted by the company's apparent insurer and claims, "Rather than address this systemic problem, Defendant is apparently attempting to payoff consumers on the cheap, sweep this problem under the rug and continue its lucrative business selling its defective WEN Cleansing Conditioner." The plaintiff claims that the company has not recalled the product.

In addition to a request to certify a nationwide class, the plaintiff seeks to certify a Florida subclass. She requests actual, general, special, incidental, statutory, and consequential damages, including the costs of efforts to regain hair and mask the effects of hair loss. She also seeks injunctive relief requiring the defendant to replace the conditioner with non-defective products or provide an "appropriate curative notice regarding the existence and cause of the defect."

Beauty Blogger with L'Oréal Line Sued for Copyright Infringement

Ultra Records and Ultra International Music Publishing (UIMP), a record label and a music publisher, have filed a lawsuit in California federal court against beauty blogger and popular YouTube personality Michelle Phan accusing her of using the companies' music in her beauty videos without permission. *UIMP v. Phan*, No. 14-5533 (U.S. Dist. Ct., C.D. Cal., filed July 16, 2014). Ultra and UIMP, which produce dance music, allege that "Phan, without license, authorization or permission from Plaintiffs, has embarked on a wholesale infringement of Plaintiffs' musical compositions and recordings" by using their music in videos she uploaded to YouTube and to her own Website.

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A spokesperson for Phan has said that Ultra agreed to allow her to use its music in her videos and that Phan plans to file counterclaims against the record label and publishing company. On YouTube, Phan has almost 7 million subscribers, and her most popular video has accumulated more than 55 million views in four years; her online popularity has led to a position as Lancôme's official video artist and her own L'Oréal cosmetics line. Noting this success, Ultra's complaint has alleged the infringing use of its music in 55 of Phan's videos—with some videos featuring more than one alleged infringement—and requests \$150,000 per infringement, as well as an injunction and attorney's fees. *See BBC*, July 22, 2014.

INTERNATIONAL DEVELOPMENTS

Canada to Continue Monitoring Some Azo Basic Dyes

The Canada Departments of the Environment and of Health have [issued](#) a notice proposing that, after assessing 33 azo basic dyes, which are found in an array of products including cosmetics and hair dyes, just 14 warrant further monitoring. Because human and environmental exposures to the dyes are regarded as low, they do not meet statutory toxicity criteria. Still, monitoring is recommended because some of the substances have been identified as having a high potential of carcinogenicity or genotoxicity. The draft screening assessments will be open for public comment until September 24, 2014. *See Canada Gazette*, July 26, 2014.

Corporate Messaging Overtakes Ancient Beauty Secrets

A recent *New York Times* article discusses how countries that were previously isolated from global commerce are beginning to see changes in consumer trends as "corporate messaging seems to be making headway." A case in point is Myanmar, where Burmese men, women and children have for centuries used thanakha, a yellowish paste derived from ground tree bark, to improve their complexions and protect their skin from the sun. Multinational cosmetic companies, relying on pervasive advertising have apparently made inroads, particularly among the young who think that "wearing thanakha makes you look like a villager." Some thanakha manufacturers have sought to compete with the cosmetics appearing in modern department stores by packaging the traditional product as a ready-made powder. But some of these products have allegedly been found to contain heavy metals and lead, leading to government warnings. It remains to be seen if its use will withstand the allure of more modern cosmetic formulations; many continue to believe that thanakha enhances personal appearance in addition to providing skin-care benefits. *See The New York Times*, July 28, 2014.

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EMERGING TRENDS**Body Shop Reviews Home Party Policies in Response to Youth Marketing Complaint**

Responding to complaints that at least one Body Shop consultant may have used dubious tactics to pressure young teenage girls to host home sales parties for the company's cosmetics products, a spokesperson has reportedly indicated that the company is reviewing its party policies to ensure that existing rules requiring hosts to be 18 and attendees younger than 16 be accompanied by a parent or guardian are followed by self-employed company consultants.

A July 9, 2014, *MailOnline* article by journalist Shona Sibary describes in some detail how her 13-year-old daughter ended up begging for money over the phone during one such party, which a consultant said the girls had "won" after "liking" the company on Facebook. While Sibary expected that her daughter would be eating cake and dancing during the party, it was actually a high-pressure sales presentation for popular products that the girls could not afford. As Sibary explains, "Once it was Tupperware. Now women up and down the country are selling everything from vintage jewellery to scented candles to friends and family. We're adults: we know the difference between a genuine knees-up and flogging exercise, but children don't." According to the company, "Due to this unusual incident we are reviewing our party policies to prevent this happening again." See *Cosmeticsdesign-Europe.com*, July 17, 2014.

SCIENTIFIC/TECHNICAL DEVELOPMENTS**Study Suggests Creams with Food Ingredients Could Trigger Allergies**

Researchers led by Australia's Monash University Director of Allergy, Immunology and Respiratory Medicine Robyn O'Hehir have reportedly shown that "natural" cosmetic products targeting dry skin often contain allergenic ingredients, such as goat's milk, cow's milk, nut oils, and oats, and their use could increase the risk of developing a food allergy. Astrid Voskamp, et al., "Goat's cheese anaphylaxis after cutaneous sensitization by moisturizer that contained goat's milk," *The Journal of Allergy and Clinical Immunology: In Practice*, June 2014. The research highlights the experience of a 55-year-old woman who reportedly had a life-threatening reaction from consuming goat cheese, which the researchers say was triggered by her repeated use several months earlier of a moisturizer containing goat's milk. O'Hehir said, "While unlikely to be a problem for most people, application of these [products] to broken or eczematous skin may lead to a severe allergic reaction when the food is next eaten. To ensure allergies don't develop, if you have eczema, it's important to use skin care that is bland and avoid agents capable of sensitization, especially food." See *Monash University News Release*, June 19, 2014.

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Monell Center Studies Asthmatic Reactions to Cognitive Odor Expectations

Philadelphia, Pennsylvania-based Monell Chemical Senses Center has published new research suggesting that “simply believing that an odor is potentially harmful can increase airway inflammation in asthmatics for at least 24 hours following exposure.” Jaén Cristina & Pamela Dalton, “Asthma and odors: The role of risk perception in asthma exacerbation,” *Journal of Psychosomatic Research*, July 2014. The goal of the study, involving 17 subjects characterized as moderate asthmatics, was to “investigate how beliefs about an odor’s relationship to asthmatic symptoms could affect the physiological and psychological responses of asthmatics.” Those told that the odor to which they would be exposed was potentially harmful “rated it as more irritating and annoying as compared to those who thought it might be therapeutic.” Airway inflammation apparently increased immediately among those believing it to be harmful and remained elevated for 24 hours. Conversely, the Monell researchers found “[t]here was no increase of inflammation when the odor was characterized as therapeutic, even in individuals who described themselves as sensitive to perfumes and other odors.” The odor used was phenylethyl alcohol, often described as rose-smelling, but deemed a “pure” odorant because it has no associated physiological irritant qualities. See *Monell Chemical Senses Center News Release*, July 22, 2014.

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