ISSUE 8 | AUGUST 15, 2013

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

Senators Re-Introduce Dietary Supplement Labeling Act

Sens. Richard Durbin (D-Ill.) and Richard Blumenthal (D-Conn.) have re-introduced legislation that seeks to help consumers distinguish between dietary supplements that are safe and those that have potentially serious side-effects or drug interactions. The "Dietary Supplement Labeling Act," would require dietary supplement manufacturers to disclose known ingredient risks and display mandatory warnings if a product contains an ingredient that could cause potentially serious adverse events. Labels would also have to include the batch number to help identify and recall contaminated products. Among other things, the bill would (i) allow the Food and Drug Administration (FDA) to track how many dietary supplements are on the market and what ingredients they contain; (ii) give FDA authority to require that manufacturers provide proof for any potential health benefit claims; and (iii) direct FDA to clarify the distinction between dietary supplements and food and beverage products with additives.

"Though many dietary supplements available today are safe, we can't ignore the growing evidence that there are some in the industry that are taking advantage of the system we have in place to make money selling products they know are harmful," said Durbin. "Regulation of supplements can be improved to protect public health and it starts with making more information available to consumers and the FDA. The bill [provides] common sense steps to make sure supplement risks are printed on the label, products are registered with FDA and manufacturers can back up their big claims." *See Sen. Dick Durbin News Release,* August 1, 2013.

FDA Updates Guidance on Medical Foods

The Food and Drug Administration (FDA) has published draft guidance titled "Frequently Asked Questions About Medical Foods; Second Edition" that provides additional information about the definition, labeling and availability of medical foods—"foods formulated to be consumed or administered orally

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or enterally under the supervision of a physician." The first edition of this guidance was issued in May 2007. Comments will be accepted until October 15, 2013. *See Federal Register,* August 13, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

Plaintiff's Ties to Counsel Preclude Certification of Class

A federal court in California has denied the motion to certify a class of purchasers of Vitamin E products allegedly misrepresented as beneficial to maintain a healthy heart, because the named plaintiff "misremembered" details about her product purchase and had a long-term relationship with class counsel thus putting into question whether she would put his interests above those of the class. *Bohn v. Pharmavite, LLC*, No. 11-10430 (U.S. Dist. Ct., C.D. Cal., decided August 7, 2013).

According to the putative class complaint, scientific studies do not support claims that Vitamin E benefits the heart. The plaintiff sought to certify a 17-state consumer class under California unfair competition law and two single state classes—California and Illinois—under their respective consumer fraud laws. Specifically focusing on the plaintiff's adequacy to represent the class, the court discussed her deposition testimony, including that she purchased the product at Costco in late 2011 as an impulse buy and stopped taking it after a few weeks because she failed to notice any effect. At about the same time, the topic of Vitamin E arose during a dinner involving the plaintiff, her husband, class counsel and his wife, who had been friends for seven to eight years and got together about once a week.

The defendant questioned whether the named plaintiff could have purchased the product in November or December 2011, because it stopped selling the product to Costco in January 2009. The plaintiff then returned to Costco and obtained a receipt, showing that the purchase was made in 2009 and that it was purchased along with a different supplement than she had remembered when testifying. She conceded that she "misremembered when she made her purchase, who she was with, and what else she bought, but that she 'is [still] certain' she purchased the Vitamin E product and had read and relied upon the 'helps maintain a healthy heart' statement in making her purchase."

According to the court, the plaintiff's inconsistent testimony raised two issues: whether she actually relied on the heart health statement, when the product label also included statements about antioxidants and support of the immune system; and "she appears to have based her initial testimony on a memory that reconstructed the relevant events around her discussions with [counsel] and the filing of this suit, when, in fact, the purchase took place nearly three years prior." The court was also concerned that her credibility would be "a significant issue at trial, undermining the interest of the classes." The plaintiff's

close personal relationship with counsel only exacerbated these problems. In this regard, the court stated, the friendship and weekly gatherings "suggest that Plaintiff may have, at best, unduly relied on her close friend, or, at worst, have no real interest in prosecuting this action other than to assist her close friend in recovering a sizeable fee award relative to the small individual recoveries of the class members."

Putative Class Alleges Fraudulent Scheme Against Mona Vie

A New Jersey resident has filed a complaint on behalf of a putative statewide class against Mona Vie, Inc., alleging that the company engages in a fraudulent scheme through a multi-level system of purportedly independent distributors to sell its 25-ounce beverages at an inflated price—$45—by claiming that it can provide an array of "benefits to nearly every known medical condition." *Pontrelli v. Mona Vie, Inc.*, No. 13-4649 (U.S. Dist. Ct., D.N.J., filed August 1, 2013). Alleging violation of the New Jersey Consumer Fraud Act, fraud and unjust enrichment, the plaintiff seeks injunctive relief, restitution, actual and punitive damages in excess of $5 million, interest, attorney's fees, and costs.

The complaint alleges that the man behind the alleged scheme, Dallin Larsen, conducted a similar "super juice" enterprise that resulted in Food and Drug Administration scrutiny and unsold inventory poured into a landfill under the agency's supervision. The plaintiff contends that she saw and relied "upon advertisements, representations and statements made by Defendants or other Scheme members about the alleged health benefits of drinking Mona Vie Products. The advertisements, representations and statements which were relied upon by Plaintiff resulted from the Mona Vie Scheme described herein and were embraced either tacitly or expressly by Defendants." She alleges that she used the product and did not experience any of the advertised benefits. According to the plaintiff, the alleged scheme allows Mona Vie to distance itself from its "independent distributors" who are exposed to testimonials about the products' purported benefits during conventions and then, with insufficient training or knowledge, make a frenzy of misleading, false and "outlandish" product representations. The complaint states, "Defendants are veterans of the multi-level-marketing game which has plagued consumers for decades throughout this country."

ITC Rejects Patent Packaging Claim Against Liquor, Toy and Cosmetic Importers

In the first investigation subject to a pilot program, the International Trade Commission (ITC) has agreed with an administrative law judge (ALJ) that a company alleging infringement of its patents for laminated packaging by the importers of liquor, toys, wine, electronics, and cosmetics failed to show that it had a domestic industry that would be harmed by the alleged infringement. *In re Certain Prods. Having Laminated Packaging & Components Thereof*, No.

337-TA-874 (ITC, decided August 6, 2013). Several alleged infringers, including L'Oréal, were terminated from the investigation before it was resolved on the basis of settlement agreements with claimant Lamina Packaging Innovations, Inc. of Longview, Texas.

ITC has the authority to bar imports of products deemed harmful to a domestic industry and announced earlier this year that it would test expedited procedures in cases alleging unfair practices in import trade. Under the program, ITC identifies potentially dispositive issues and directs the assigned ALJ to rule on those issues early in an investigation through expedited fact-finding and an abbreviated hearing limited to those issues. While ITC upheld the ALJ's determination that the complainant did not satisfy the economic prong of the domestic industry requirement, it reversed the ALJ's findings that ITC may have violated the Administrative Procedure Act by failing to publish information about the pilot program ahead of time and directing the issuance of an initial ALJ determination within 100 days in this case.

Lamina reportedly objected to the expedited proceeding and indicated before ITC ruled that the company would consider taking an appeal to the Federal Circuit Court of Appeals. According to some commentators, who have watched the case closely, early action on threshold dispositive issues, such as whether a patent holder has invested in factories or hired a significant workforce thus establishing a domestic industry, could deter litigation filed by companies referred to as "patent trolls" or "patent assertion entities" that are in the business of buying and asserting patents and do not themselves use the patents to make things. *See ITC News Release*, June 24, 2013; *AmLaw Litigation Daily*, July 10 and August 12, 2013.

Court Allows Most Banana Boat Sunscreen Claims to Proceed

Dismissing the plaintiff's breach of warranty claims with leave to amend, a federal court in California has determined that she may pursue her remaining putative class allegations in consumer fraud litigation filed against the companies that distribute, market and sell the Banana Boat® SPF 85-110 collection of sunscreen products. *Corra v. Energizer Holdings, Inc.*, No. 12-1736 (U.S. Dist. Ct., E.D. Cal., order entered August 2, 2013). The plaintiff claims that the combination of SPF values higher than 50 on product labels, a premium price and representations that these products provide superior UVB protection misleads consumers because "SPF values over 50 provide no additional clinical benefit to consumers."

The defendants sought to dismiss the claims as preempted under federal law. The court disagreed, finding that the plaintiff does not claim that the SPF 85-110 ratings alone are per se false or misleading; rather, that the defendants marketed the products beyond simply providing an SPF rating thus misleading "consumers into purchasing more expensive, higher SPF-rated

products even though, according to Plaintiff, these products did not provide proportionally greater protection than less expensive, lower SPF-rated products. If Plaintiff were to prevail under [California's consumer fraud laws], Defendants' SPF labeling duties would remain unchanged." The court also found that primary jurisdiction did not bar it from deciding the claims, which raise the types of factual questions "routinely committed to the courts."

The court rejected the defendants' challenge to the plaintiff's standing as to products she did not purchase, agreeing with a Northern District of California case holding that a plaintiff may bring claims on behalf of putative class members where the product she purchased is sufficiently similar to the products not purchased. Here, the plaintiff alleged that they contained virtually identical active ingredients and were marketed in "virtually the same manner."

As to the defendants' argument that the plaintiff failed to provide the required pre-suit notice under the Consumers Legal Remedies Act, the court found that because the operative complaint—the first amended complaint—was filed more than 30 days after the original complaint, accompanied by copies of the notice letter dated the same day, was filed, sufficient notice had been provided and she was entitled to pursue damages.

False Ad Claims for Glucosamine Products Withstand Challenge

A federal court in California has denied the defendants' motion to dismiss a putative class action alleging that health-related representations about their dietary supplements containing glucosamine, chondroitin and "MSM" are false and misleading because scientific evidence refutes these assertions and the products do not provide the relief and benefits advertised. *Hazlin v. Botanical Labs., Inc.*, No. 13-0618 (U.S. Dist. Ct., S.D. Cal., order entered August 8, 2013).

According to the court, the claims were not preempted because they are not based on either an interpretation or violation of the Food, Drug, and Cosmetic Act; instead, they allege violations of state law. The court also rejected the defendants' argument that the plaintiffs' claims rely on a "lack of substantiation" theory, which is non-cognizable. While the plaintiffs allege that the defendants lack competent and reliable scientific evidence to substantiate their health-benefit representations, they also cite 23 studies that purportedly refute the product claims and render them false. Agreeing with the plaintiffs that the defendants invited the court to weigh the evidence cited in support of the plaintiffs' allegations, the court found that the defendants' challenge to the alleged facts does not constitute insufficient pleading and does not warrant dismissal on that basis.

The court further declined to rule at this stage that the plaintiffs lacked standing to pursue claims based on representations they did not see and therefore did not rely on when purchasing the products. According to the court, while the district courts in California are split on the issue, the majority

was persuasive, and "whether Plaintiffs may pursue claims based on representations they did not see is more appropriately addressed on class certification, not a motion to dismiss."

Watchdog Group Calls for IRS Investigation of Star Scientific

Political watchdog group Citizens for Responsibility and Ethics in Washington (CREW) recently requested that the Internal Revenue Service (IRS) investigate whether Virginia Governor Robert McDonnell (R) and his wife, Virginia Attorney General Kenneth Cuccinelli (R), and Star Scientific, Inc. violated tax laws by failing to report as gifts or income certain payments and gifts made to the state officials. According to CREW, during the past two years, the governor and his wife received at least $166,150 in payments, goods and services from Star Scientific CEO Jonnie Williams Sr., a trust that he controls and the company. The McDonnells in return allegedly promoted Anatabloc®, a dietary supplement that CREW claims is critical to Star Scientific's success, given losses over 10 years and about $29 million in 2012 alone.

Williams has reportedly cooperated with prosecutors conducting a public corruption probe. He will apparently be able to provide insight into whether the governor and his wife took official action in exchange for gifts ranging from shopping trips, vacations, a Rolex watch, money for their daughter's wedding, and a purported loan. Star Scientific has, according to a news source, informed investors that it is also facing a securities investigation. At one time, the attorney general was allegedly one of those investors and also received some $19,000 in goods and services from Williams and Star Scientific, including a box of Anatabloc® valued at more than $6,500. While CREW acknowledges that the state officials have amended their financial disclosure forms, it asks the IRS to determine whether and how the cash and goods were reported on their tax returns. *See CREW Press Release*, July 23, 2013; and *The Washington Post,* August 3, 2013.

Claims Against Weight-Loss Supplement Maker Dismissed with Leave to Amend

A federal court in Florida has dismissed without prejudice a number of claims in a putative class action alleging that Vital Pharmaceuticals, Inc., which makes and markets the dietary supplement VPX Meltdown Fat Incinerator®, has deceived consumers by claiming that it burns fat thus helping with weight loss. *Karhu v. Vital Pharms., Inc.*, No. 113-60768 (U.S. Dist. Ct., S.D. Fla., order entered August 9, 2013). While the court ordered that a second amended complaint be filed no later than August 19, it dismissed with prejudice the plaintiff's claim that the defendant breached an implied warranty of merchantability for lack of privity—a direct relationship between the parties.

The court notes that the plaintiff included in his first amended complaint information about the demand made on the company to cease making fat burning and comparison ad claims by the National Advertising Division (NAD) of the Council of Better Business Bureaus. The plaintiff also apparently cited a warning from one of the company's scientists who said that Meltdown ingredients Synephrine and Synephrine HCl "are as useless as a screen door on a submarine." Dismissing the complaint in its entirety because it was a "shotgun pleading" that did not indicate which facts applied to which causes of action, the court addressed the parties' arguments to guide preparation of subsequent pleadings.

Among other matters, the court rejected the defendant's claim that the complaint did not contain sufficient factual content to support the claims in that it relied exclusively on the NAD's findings. According to the court, other factual allegations supported the claims. The court also refused to apply the primary jurisdiction doctrine, finding that its ruling on the claims would not interfere with either the Food and Drug Administration or Federal Trade Commission's regulatory scheme. The court further determined that the action could proceed under Florida's Uniform Trade Practices Act because the alleged fraudulent conduct took place in Florida, which is the company's place of incorporation and where its principal place of business is located. The defendant had argued that the law should not apply because the plaintiff purchased and consumed the product in New York. The court concluded that the Florida law may apply to non-Florida residents "if the offending conduct took place predominantly or entirely in Florida."

Personal Injury Suit Claims Diet Supplement Caused Stroke

An Illinois resident alleging that she had a stroke after taking a Thyro-Drive® weight-loss dietary supplement has reportedly sued the companies that made and distributed the product and the store manager who gave it to her. *Bauer v. 1st Phorm Int'l*, No. 13-L-0390 (St. Clair Cnty. Ct., Ill., filed July 26, 2013).

Claiming that she was a 36-year-old with no history of stroke or cardiovascular problems, plaintiff Catherine Bauer alleges that she went to a Supplement Superstore to purchase weight-loss supplements she had used in the past, but store manager Jordan Pea discussed another product, claimed to be the best on the market, with her. "Defendant Pea failed to discuss safety, warn of any potential side effects, or provide any detailed instructions or warnings on use," according to the complaint. "Instead, defendant Pea provided plaintiff with free samples of the drug in a clear, plastic bag. The bag contained a small piece of paper that described the color of the pills and instructed the user to take with water and a meal. No other warnings or information were given."

Bauer claims that she took the pills as directed and the next day "woke up with extreme weakness on the left side of her body and slurred speech."

Purportedly diagnosed with a stroke, the plaintiff alleges and seeks damages for product liability, negligence, breach of warranty, misrepresentation by omission, fraud, and violations of the Illinois Consumer Fraud Act. She also apparently seeks damages for "disfigurement, conscious pain, suffering, mental anguish, mental suffering, embarrassment, shame, loss of enjoyment of life, loss of association, loss of earnings, loss of profits, [and] loss of salary." *See Courthouse News Service*, August 6, 2013.

EMERGING TRENDS

Biotech to Develop Medical Food for Diabetes

MicroBiome Therapeutics (MBT), a biotech firm co-founded by Whole Foods Market Chair John Elstrott, has reportedly asked consumer health care firms about developing medical foods which contain a novel ingredient that claims to improve blood glucose control and metabolic function in people deemed pre-diabetic and those diagnosed with type 2 diabetes.

According to news sources, MBT's lead product, NM504, which contains a proprietary combination of prebiotic fiber, beta glucan and a berry extract, has been shown in rodent studies to beneficially alter the balance of gut microflora, increase insulin sensitivity, improve oral glucose tolerance test results, lower overnight fasting blood glucose levels, and improve lipid profiles. The product is currently in a clinical trial for the management of insulin sensitivity and blood glucose levels in patients with type 2 diabetes, as well as in a pilot clinical study as adjunctive therapy to the diabetes drug metformin. *See CenterWatch.com,* August 7, 2013; *Foodnavigator-usa.com,* August 12, 2013.

INTERNATIONAL DEVELOPMENTS

Lipsticks Found in Manila Contain Toxic Chemicals

Environmental watchdog EcoWaste Coalition has reportedly found lipsticks containing excessive levels of hazardous chemicals, including arsenic, lead and mercury, in Manila. Based on its analysis of 45 samples of 22 brands of lipsticks, EcoWaste stated that 13 of the products contained dangerous chemicals that exceeded the Association of Southeast Asian Nations (ASEAN) Cosmetics Drive's limits of 5 parts per million (ppm) for arsenic, 20 ppm for lead and 1 ppm for mercury.

Stating that exposure to toxic metals can cause reproductive defects, developmental maladies, neurological and behavioral difficulties, endocrine disorders, and cancer, EcoWaste has urged cosmetics manufacturers to replace toxic metals and other chemicals of concern with non-hazardous

substitutes. The group has also asked manufacturers to disclose product ingredients and impurities on labels and requested that the government revise ASEAN's limits for heavy metals in cosmetics.

Additional details about contaminated lipstick appear in Issue 2 of this *Report*. *See EcoWaste Coalition News Release,* August 14, 2013.

Counterfeit Colgate-Palmolive Goods Seized in Kenya

The Kenyan anti-counterfeit agency, in collaboration with Interpol, has reportedly intercepted a container of counterfeit Colgate-Palmolive brand soap and beauty products at the port of Mombasa. Originating in China and on transit to the Democratic Republic of Congo, the container evidently contained 2,976 pieces of Pharmapur soaps, 3,600 pieces of high mercuric iodine extra Clair soap and 129,816 pieces of medisoft soap, with a total estimated value of €100,000 ($132,460). According to sources, the products contain hazardous chemicals used for skin bleaching that purportedly cause skin cancer. "We are investigating to ascertain the real owner of the products so that we can take the necessary action on them," said Mombasa County Anti-counterfeit Officer Casper Oluoch. "We shall not allow anyone to trade on counterfeits. We are alert and will not allow any counterfeits into our country." According to the agency, most counterfeits are declared as transit goods to evade verification. Evidently, the goods have not been claimed. *See allafrica.com,* August 1, 2013.

EC Seeks Input on Hydrated Formaldehyde

The European Commission (EC) has announced a public consultation on methylene glycol, or hydrated formaldehyde, a substance often present in cosmetics, particularly hair-straightening products. According to EC, although restrictions on formaldehyde use in cosmetic products exist per Directive 76/768/EEC, Annex III, entry 13 (concerning formaldehyde in nail hardeners) and in Annex VI, entry 5 (concerning formaldehyde and paraformaldehyde used as preservatives), use of methylene glycol is not explicitly included, and the agency would like it banned from these products. Responses to the consultation will be accepted until September 27, 2013.

EFSA Announces Public Consultation on Manganese

The European Food Safety Authority (EFSA) has launched a public consultation on draft guidance issued by the agency's Panel on Dietetic Products, Nutrition and Allergies (NDA) for manganese dietary reference values for adults, infants and children and pregnant and lactating women. According to NDA, because there was "insufficient evidence available to derive an Average Requirement and a Population Reference Intake," an Adequate Intake of 3 mg/day was proposed. The agency will accept comments on the guidance until September 13, 2013.

EFSA Approves Reduced Cholesterol Claims of Artichoke Extract Supplement

A French firm has secured approval from the European Food Safety Authority's (EFSA's) Panel on Dietetic Products, Nutrition and Allergies (NDA) for its artichoke leaf extract-based herbal formulation, Limicol®, that evidently can reduce cholesterol. Stating that limited evidence backed claims that any of the "other food constituents in Limicol®, including policosanols and artichoke leaf extract, exert an LDL-cholesterol-lowering effect in humans on their own and that at the proposed conditions of use no evidence has been provided for an LDL-cholesterol-lowering effect of any of the food constituents in Limicol®, or as to how the ingredients individually or in any combination could contribute to the claimed effect," the panel nevertheless determined that a "cause and effect relationship" has been established between the consumption of the combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d-α-tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate in in Limicol®, and a reduction in blood LDL-cholesterol concentrations.

EU Seeks Comments on Nanosubstances Used in Sunscreens

The European Union's (EU's) Scientific Committee on Consumer Safety (SCCS) has announced a public consultation on three nanosubstances—2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl) phenol), titanium dioxide and zinc oxide—that are used as ultraviolet filters in sunscreens and skin whiteners. According to SCCS opinions on the ingredients, use of the nano form of the substances in cosmetics such as sunscreens should generally be subject to the same maximum concentrations as the substances at standard scale—10 percent for 2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) and 25 percent for both titanium dioxide and zinc oxide. SCCS expressed some reservations, however, including that titanium dioxide nanoparticles should not be used in powders or sprays and that some types of titanium dioxide nanoparticles should not be used because they can penetrate the skin. The panel will accept comments until September 6, 2013. *See Bloomberg BNA Product Safety & Liability Reporter,* August 1, 2013.

EU to Review Non-Animal Skin Allergen Test

According to news sources, a new, non-animal skin testing method will be submitted to the European Union (EU) Reference Laboratory for alternatives to animal testing (EURL ECVAM), the organization that officially approves methods for chemical testing required by European government regulation.

Developed by Michigan-based CeeTox, Inc. and funded in part by People for the Ethical Treatment of Animals (PETA), the non-animal testing method uses

a 3-dimensional, human-derived skin model that evidently can accurately replicate key traits of normal human skin, thus replacing the need to use guinea pigs or mice. Although non-animal tests and tests that reduce the use of animals are required by some European regulations and encouraged in many countries, no formally validated and regulatory adopted non-animal tests to identify compounds that cause "skin sensitization," reportedly exist. *See PETA News Release,* August 6, 2013; *Bloomberg BNA Product Safety & Liability Reporter,* August 12, 2013.

Meanwhile, EURL ECVAM has issued a **request** for public comments on its latest recommendations concerning two alternative test methods, the Direct Peptide Reactivity Assay and the Cell Transformation Assay. Comments will be accepted until September13, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Study Alleges Link Between Perfume and Autism

A recent **paper** from researchers at the South Carolina Center for Biotechnology proposes that perfume and cosmetics may play a role in the development of autism spectrum disorders (ASDs), which reportedly affect one out of 88 children. Omar Bagasra, et al., "Role of Perfumes in Pathogenesis of Autism," *Medical Hypotheses,* June 2013. Claiming that "there is little irrefutable evidence that pesticides, water born chemicals, or food preservatives play critical roles in inducing the genetic mutations associated with known intellectual deficiencies that have been linked to [ASD]," the authors assert that autism is not an inherited disease as commonly believed, but is caused by the "highly mutagenic, neurotoxic, and neuromodulatory chemicals" found in perfumes and cosmetics. They also claim that the reason why perfumes and chemicals purportedly contain such chemicals is because of a "giant loophole in the Federal Fair Packaging and Labeling Act of 1973," which evidently exempts fragrance producers from having to disclose perfume ingredients on product labels.

The researchers reportedly studied 17 name-brand products containing 38 different unidentified chemicals, including many that are known carcinogens and mutagens that can cause damage during human fetal brain development.

Meanwhile, critics of the paper, including the Cosmetic, Toiletry & Perfumery Association (CTPA), claim that it lacks credibility and that the data do not support the authors' hypothesis that chemicals in perfumes are mutagenic or that they can be linked to ASD. "It is a legal requirement that each cosmetic product must undergo a robust safety assessment before it is placed on the

market," Emma Meredith, head of scientific and technical services at CTPA reportedly said. "If a substance is not safe it is banned from use in cosmetic products—and this would most certainly include any substance classified as 'highly mutagenic.'" *See EmaxHealth.com,* August 4, 2013*; Cosmeticsdesign-europe.com,* August 9, 2013.

DMAA Cleared as Cause of Soldiers' Deaths

A safety review panel formed by the U.S. Army and Department of Defense (DOD) has issued a report which concludes that although DMAA (1,3-dimethlyamylamine) did not evidently cause the deaths of four soldiers who died with the ingredient in their bloodstreams, the substance still poses potential health risks and should remain banned from military stores. The report was released by DOD's Human Performance Research Center and covers a two-year study of DMAA that began in 2011 after the soldiers' deaths.

The safety panel concluded that despite a high apparent usage of DMAA among service members (as high as 15 percent), the substance, at the manufacturer-recommended doses, poses a low risk of serious harm for most healthy service members. "The existing evidence does not conclusively establish that DMAA-containing substances are causally-associated with adverse medical events," noted the report. "However, a consistent theme among the studies is that DMAA use potentially affects cardiovascular function, just as other sympathomimetic stimulants. Without further rigorous study designs developed to evaluate the safety of DMAA, especially in patients with concomitant use of other substances, co-morbid conditions and high frequency use, the magnitude of the association of DMAA with adverse medical events is uncertain."

Most manufacturers and marketers of DMAA-containing products have either stopped producing such products or reformulated them to be DMAA-free after the Food and Drug Administration warned in 2012 that the substance was not legal in dietary supplements and was subject to a subsequent class action lawsuit. Additional details appear in Issues 5 and 7 of this *Report. See NaturalProductsInsider,* August 7, 2013.

Meanwhile, supplement manufacturer BPI Sports, LLC, has reportedly discontinued advertising claims for three of its products, one of which contains DMAA, after the claims were challenged by the Council for Responsible Nutrition. One of the products, Go Performance Pre-Training Powder, made the following claims: "Stronger than 13 DMAA" and "Hits You Harder. Lasts Longer. Crazy Energy. Zero Crash." Evidently, BPI Sports did not attempt to support the claims with evidence and instead pulled the claims from products

and marketing materials and told the National Advertising Division that the company does not intend to make such claims in the future. *See truthinadvertising.org,* August 9, 2013.

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LEGAL TRENDS REPORT

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