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SPOTLIGHT

JAMA Study and Editorial Call for Improvements in Cosmetic Regulation and Surveillance

In response to a study analyzing adverse events for cosmetics and personal care products, the *Journal of the American Medical Association* (*JAMA*) *Internal Medicine* has published an editorial calling for new registration and active surveillance of such products and arguing that waiting for self-reporting to alert regulators of potential problems raises serious and important questions about the safety of cosmetic and health-related products.

After the U.S. Food and Drug Administration (FDA) made its Center for Food Safety and Applied Nutrition's Adverse Event Reporting System (CFSAN) repository publicly available in 2016, researchers at Northwestern University Feinberg School of Medicine extracted the entire CFSAN data file—including all voluntary submissions from consumers and healthcare providers—and categorized all cosmetic-related adverse events by FDA-designated product class. Michael Kwa, et al., "Adverse Events Reported to the US Food and Drug Administration for Cosmetics and Personal Care Products," June 26, 2017. The researchers found a total of 5,144 adverse events reported to FDA from 2004 to 2016, with hair care, skin care and tattoo products the most frequent cause of reports. They then assessed the problems in reliance on the current system of self-reporting, noting as an example that the manufacturer of WEN by Chaz Dean hair conditioner products received more than 21,000 adverse reports about alopecia and scalp irritation before FDA learned of the

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problem through 127 direct consumer complaints registered in CFSAN.

The study also referred to FDA's "profound disappointment" with the industry's draft legislation to modernize cosmetics regulation and noted that Sen. Dianne Feinstein (D-Calif.) has twice introduced the Personal Care Products Safety Act, which would grant authority to FDA to recall unsafe products, mandate manufacturer reporting of adverse events and require a yearly safety review of selected ingredients. The researchers concluded, "Better cosmetic surveillance is needed given [the products'] ubiquity and a lack of premarket approval pathway. Unlike devices, pharmaceuticals and dietary supplements, cosmetic manufacturers have no legal obligation to forward adverse events to the FDA . . . the first step to improve cosmetic safety is broader reporting, especially from manufacturers."

JAMA Internal Medicine's publication of the research study letter was accompanied by an editorial in which the organization called for greater regulatory oversight of cosmetics and health-related products. Without such oversight, public health is dangerously dependent on voluntary reporting, and where "there is insufficient regulatory oversight, a few unscrupulous people or companies will exploit the vulnerable public for profit," the authors say. "Without a legal requirement for the cosmetics industry to collect or report adverse events or even register marketed products, the FDA must wait for clues to accumulate from voluntary reports suggesting that a product may not be as completely safe as presumed. For example, in 2007, toothpaste made in China that included diethylene glycol, a solvent related to conventional antifreeze, was found for sale in a few discount stores in the United States. The discovery was made possible because the FDA had been alerted to look for these products by other countries that had first recognized the adulteration problem." *See JAMA Internal Medicine*, June 26, 2017.

The authors concede that U.S. attitudes toward government regulation are ambivalent. "We want to be safe and be able to use products without injuring our health, but we do not want products to become more expensive or take longer to reach the market simply to clear regulatory hurdles that achieve no useful goals," they write. But when adverse events are only voluntarily self-reported, the authors point out there is simply no way to determine the severity or even the validity of a potential safety problem. Moreover, they say FDA's oversight authority for cosmetics is stuck at the levels first established in 1938, when the Food, Drug and Cosmetic Act was enacted to prevent adulterants such as mercury, lead, carbolic acid and radium from being added to products and ensure proper labeling of ingredients.

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ABOUT SHOOK

Shook, Hardy & Bacon attorneys counsel consumer product manufacturers on FDA, USDA and FTC regulatory compliance and risk management issues, ranging from recalls and antitrust matters to facility inspections, labeling, marketing, advertising, and consumer safety. We help these industries develop early legal risk assessments to evaluate potential liability and develop appropriate policies and responses to threats of litigation or product disparagement.

The firm's lawyers also counsel manufacturers on labeling audits and a full range of legal matters such as U.S. and foreign patent procurement; licensing and technology transfer; venture capital and private financing arrangements; joint venture agreements; patent portfolio management; research and development; risk assessment and management; records and information management issues and regulations; and employment matters, including confidentiality and non-compete agreements.

The editorial recommends that first, Congress should provide FDA with an adequate budget to fulfill its existing responsibilities, noting the agency is "vastly underresourced for even the very limited responsibilities it currently has for the safety of cosmetics." Second, they urge Congress to require manufacturers to register marketed cosmetic products; without such data, they say, FDA has no way to determine "the universe of products to which customers are exposed." And finally, they call for development of "efficient, cost-effective active surveillance" of cosmetics similar to those for medical drugs and devices.

"The oversight of cosmetics can be modernized without creating an inappropriately burdensome regulatory process," the editorial concludes. "Using these new tools to collect and analyze the right kinds of empirical data, we can achieve the high levels of safety people in the United States have a right to expect."

LEGISLATION, REGULATIONS & STANDARDS

ERSP Refers Supplement-Endorsement Complaint to FTC

The Electronic Retailing Self-Regulation Program (ERSP) has announced that it intends to refer direct-response advertising for two garcinia cambogia weight-loss products to the Federal Trade Commission (FTC) because the marketer, Mayfair Industries, failed to respond to an ERSP inquiry. The initial inquiry involved claims related to reported celebrity endorsements by Megyn Kelly, Melissa McCarthy, Carrie Underwood and Wendy Williams as well as claims that the product "accelerate[d] weight loss by at least 40%" and could prevent the production of fat.

GLOBAL

Canada Set to Ban Plastic Microbeads in Personal Care Products

Canada has published Microbeads in Toiletries Regulations, a ban on the use of plastic microbeads in cosmetics and natural-health products that will purportedly "prevent the release of plastic microbeads from toiletries that wash down household drains and contribute to plastic pollution in our oceans, rivers and lakes." The regulation applies to microbeads five millimeters or smaller and will take effect January 1, 2018.

LITIGATION

ECJ Rules Against Glucose Supplement Maker on Sugar Health Claims

The European Court of Justice (ECJ) has ruled that a German dietary-supplement maker's claims about its glucose tablets were "contradictory and ambiguous" and encouraged consumption of sugar. *Dextro Energy GmbH & Co. KG v. Commission*, No. C-296-16 (E.C.J., order entered June 8, 2017). Dextro Energy claimed in advertising that glucose is the "elixir of life for the brain" that "contributes to normal energy-yielding metabolism during exercise" and delivers a "faster supply of energy to the brain for an immediate cognitive boost." The company appealed the European Commission's refusal to authorize health claims for its products; in March, the EU's General Court upheld the decision of the Commission.

In its ruling, the ECJ refused to authorize Dextro Energy's health claims, finding that the claims encourage consumption of sugar despite the recommendations of international authorities to reduce sugar intake, and concluded, "[N]one of the arguments put forward by that company can succeed."

Blistex Dispenser Design is Not Deceptive, Court Rules

An Illinois federal court has dismissed a putative class action alleging fraud and unjust enrichment against the maker of Blistex Medicated Lip Ointment, concluding the plaintiff failed to "allege a plausible claim that defendant's packaging was deceptive or misleading." *Hillen v. Blistex*, No. 17-2074 (N.D. Ill., order entered July 5, 2017). The plaintiff claimed that the "uniquely designed" shape of the dispenser "trapped" at least one-quarter of the product within its tube. The court first concluded that her "wasteful packaging" claim was sufficient to establish standing.

Turning to the substantive claims, the court held that the complaint did not plausibly allege deception. The plaintiff conceded that "reasonable consumers" of personal care products would expect some product to remain in the packaging. "Plaintiff does not contend that the tubes of Medicated Lip Ointment she purchased contained less of the product than the net weight stated on the label. Nor does she claim to have been surprised by the shape of the tube . . . the alleged deception, in plaintiff's view, is that the dispenser's hard plastic tip 'appears to be solid, even though it is hollow,'" the court found. "Put simply, plaintiff's disappointment in defendant's tube design does not establish

deception, nor does it transform defendant's accurate labeling of the product's net weight into fraud by omission." If "the manufacturer supplies the amount of product stated," the court said, "whatever difficulty there is in extracting 100 percent of the product" does not constitute unjust enrichment.

Plaintiff Alleges "Heightened" Risk of Product Injury Violates Civil Rights Act

The maker of Just For Men® hair color faces a putative class action alleging that "target marketing" of its Jet Black color product and failure to disclose an alleged increased risk of physical injury to African-American users violate federal civil rights law. *Stringer v. Combe,* No. 17-3192 (N.D. Cal., filed June 5, 2017). The plaintiff asserts that the Jet Black color shade is targeted towards African-Americans because the exterior packaging features an African-American model and product spokespersons include prominent African-American sports figures.

According to the complaint, Just For Men® dyes contain the coloring agent p-Phenylenediamine (PPD), a substance identified by the U.S. Product Safety Commission as a "strong sensitizer." The complaint alleges that PPD can cause allergic reactions and has been linked to other conditions, including renal failure and coma. The plaintiff asserts that the Jet Black shade contains 17 times more PPD than lighter shades targeted to white consumers and that the "sensitization rate" of African-Americans to PPD is five times higher than that of whites. Further, the plaintiff alleges Just For Men® failed to warn African-American consumers of the "significantly heightened propensity for severe physical injury or that the Jet Black color shade was unreasonably dangerous."

The plaintiff argues that as long as the product carries a "generic" safety warning, the U.S. Food and Drug Administration (FDA) cannot take action against the manufacturer because Just For Men® products are classified as coal-tar dyes under the Food, Drug and Cosmetic Act and thus exempt from FDA approval. Claiming violations of the Civil Rights Act and California consumer-protection laws, the plaintiff seeks compensation for non-economic losses, punitive and exemplary damages, restitution, disgorgement and attorney's fees.

Putative Class Action Alleges Ginkgo Biloba Fails to Provide Advertised Health

Benefits

The plaintiffs in a putative class action filed in California federal court assert that a Ginkgo biloba supplement advertised as increasing brain and memory function has no effect on "improvement of brain function, treatment of memory problems or cognitive health." *Petkevicius v. NBTY*, No. 27-1152 (S.D. Cal., filed June 8, 2017). The plaintiffs filed suit against three manufacturers of Ginkgo biloba supplements—NBTY, Nature's Bounty and Rexall Sundown—alleging that product advertising and labeling claiming the products help support "healthy brain function," "mental alertness" and "memory, especially occasional mild memory problems associated with aging" are misleading and deceptive.

The plaintiffs assert that numerous scientific studies, including two published in the *Journal of the American Medical Association*, have concluded that users of the supplement receive no significant benefit and that the manufacturers' claims are not supported by research. Further, the plaintiffs assert that a study by the National Toxicology Program concluded that Ginkgo biloba extract caused thyroid and liver cancers in rats and mice. Alleging violations of California and New York consumer-protection laws, plaintiffs seek class certification, compensatory and punitive damages and attorney's fees.

Lawsuits Call Glucosamine, Chondroitin Products "Worthless"

Two putative class actions filed against the makers of glucosamine and chondroitin supplements allege that none of the products' ingredients can affect joint health and are therefore "worthless." *Seegert v. Rexall Sundown*, No. 17-1243 (S.D. Cal., filed June 19, 2017); *Yamagata v. Reckitt Benckiser*, No. 17-3529 (N.D. Cal., filed June 19, 2017). Represented by the same attorneys in both suits, the plaintiffs allege that Rexall Sundown's Osteo Bi-Flex and Reckitt Benckiser's Schiff Move Free dietary supplements are marketed and labeled with claims that the products improve joint health and comfort for consumers with osteoarthritis.

According to the plaintiffs, randomized clinical trials conducted by the National Institutes of Health and published in the *New England Journal of Medicine* show "no significant difference" between treatment groups and placebo groups. The complaints also cite the European Food Safety Authority, which has purportedly concluded that no cause-and-effect relationship has been established between use of glucosamine and chondroitin and reduced rates of cartilage degeneration or improved joint health.

Further, plaintiffs allege that the American Academy of Orthopaedic Surgeons has recommended against prescribing glucosamine or chondroitin for patients with osteoarthritis, reportedly finding that neither have "any clinical benefit in patients." Claiming violations of California consumer-protection laws, the plaintiffs seek class certification, restitution and disgorgement, corrective advertising, damages and attorney's fees.

Court Allows Fake Aloe Vera Suit to Proceed

A Illinois federal court has refused to dismiss a projected class action against Dollar General stores, holding that the labeling of the company's "DG Body Soothing Aloe Gel" gave rise to an express warranty that the product did contain aloe vera leaf extract. *Lambert v. Dollar General*, No. 16-11319 (N.D. Ill., order entered June 16, 2017). The plaintiffs allege that the product label listed aloe barbadensis leaf extract among its ingredients and stated the product was "made with aloe vera," but product testing apparently indicated the product contained neither aloe vera nor any of its chemical markers. Two additional claims—for breach of implied warranty and violation of the Illinois Consumer Fraud act—were dismissed without prejudice.

Plaintiff Claims Liver Detox Supplement Exploits Consumers' "Profound Ignorance"

Now Health Group faces a proposed class action alleging that advertising for its Liver Detoxifier & Regenerator is false and misleading. *Lau v. Now Health Grp.*, No. 17-3992 (E.D.N.Y., filed July 5, 2017). The plaintiff argues that the "concept of detoxification," while legitimate in a medical setting to treat poisoning or overdose, is now used by supplement makers as a non-scientific marketing ploy to "treat a nonexistent condition." The complaint asserts that Now Health Group exploits the "profound ignorance" of consumers who think that toxins accumulate in the body, arguing that "[a]nyone whose liver actually requires detoxification should be in the emergency room, not scouring pharmacy shelves for the Product." Alleging violations of New York consumer-protection laws and fraud, the plaintiff seeks class certification, restitution and disgorgement, damages and attorney's fees.

Lawsuit Alleges "Potentially Dangerous" Iodine Levels in Kelp Supplement

A plaintiff has filed a putative class action against the maker of a kelp supplement alleging its levels of iodine exceed U.S. Food and Drug Administration (FDA) regulations and are "potentially dangerous." *Noonan v. Progressive Labs.*, No. 2017-CH-8233 (Ill. Cir. Ct., Cook Cty., filed June 13, 2017). The complaint alleges that the label on the Kelp Original Formula supplement manufactured by Progressive Laboratories states that each capsule contains 500 micrograms of iodine, but testing apparently indicates capsules contain as much as 960 micrograms, or "approximately 190% of the listed amount." The plaintiff also asserts FDA regulations specify that "due to safety concerns, the amount of iodine contained in a kelp supplement may not exceed 225 mcg of iodine" in a daily serving. The complaint argues that high intake of iodine can cause some of the same symptoms as iodine deficiency as well as thyroiditis and thyroid papillary cancer. Claiming violations of state consumer-protection laws, the plaintiff seeks class certification, damages, restitution and attorney's fees.

Consumer Claims Natrol Biotin Supplement Has No Health Benefit

A consumer has filed suit against Natrol alleging the company's biotin product is "unneeded, superfluous and will not provide any benefits" to its users. *Jensen v. Natrol*, No. 17-3193 (N.D. Cal., filed June 5, 2017). The plaintiff alleges she bought the product because of the label's representations that the product "promotes healthy hair and nails" but later learned that healthy adults need only 30 micrograms of biotin per day while Natrol's biotin products contain from 5,000 to 15,000 micrograms per dose. The complaint asserts that "these mega-dose amounts are far beyond any conceivable range that would ever be beneficial." Claiming violations of California consumer-protection laws, the plaintiff seeks class certification, restitution and disgorgement, corrective advertising and attorney's fees.

Plaintiff Dismisses Garcinia Cambogia Putative Class Action Against Vitamin Shoppe

A California plaintiff has voluntarily dismissed a putative class action filed in May 2017 against Vitamin Shoppe Inc. alleging the company's garcinia cambogia extract weight-loss supplement had

no more effect on weight management than a placebo. *Nathan v. Vitamin Shoppe, Inc.*, No. 17-948 (S.D. Cal., dismissal filed June 26, 2017). Additional details about the complaint appear in Issue 50 of this *Bulletin*.

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