

DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

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FIRM NEWS

Muehlberger and Lingwall Highlight the Role of Refunds in Avoiding Class Actions

Shook, Hardy & Bacon Partner **Jim Muehlberger** and Associate **Jeff Lingwall** assert in an April 29, 2015, *Law360 analysis* that offering refunds to dissatisfied consumers can benefit companies by lessening the impact of a class action or averting one altogether.

"If *many* refunds are claimed, a court may find that named plaintiffs are not adequately protecting class interests and that a class action is not the superior method for resolving the dispute. If *few* refunds are claimed, this is evidence that plaintiffs' counsel is creating litigation when none existed, again strengthening superiority arguments. If the *named plaintiffs* receive refunds, this can defeat their standing to bring a lawsuit and end the class action before a motion for class certification," they argue. "In each circumstance, a refund policy provides valuable preemptive insurance that can help stop a class action in its tracks."

Muehlberger and Lingwall provide examples for each proposition, citing cases in which courts looked to refund policies to determine whether a class action was the appropriate method of resolving the dispute and ultimately denied class certification. "Whether a company's refund policy is widely used by consumers, largely ignored by consumers or only affects the named plaintiffs in a lawsuit, it can provide a valuable tool for combating class actions," they conclude.

McDonough Joins CVM Panel Discussion at FDLI's 2015 Annual Conference

Shook, Hardy & Bacon Pharmaceutical and Medical Device Practice Chair **Madeleine McDonough** recently joined a panel of animal health industry executives and Bernadette Dunham, director of the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM), during a session at the Food and Drug Law Institute's 2015 Annual Conference in Washington, D.C. Their discussion focused on CVM's

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Shook offers expert, efficient and innovative representation to clients targeted by plaintiffs' lawyers and regulators. We know that the successful resolution of health, wellness and personal care product-related matters requires a comprehensive strategy developed in partnership with our clients.

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current initiatives and priorities, including antimicrobial resistance, genetically engineered animals and food safety, among other topics. Shook was a co-sponsor of the annual gathering of diverse stakeholders involved in food and drug law.

SPOTLIGHT

Proposed Changes to California's Prop. 65 Could Expand Warning Label Requirements

After two years of debate, the California Environmental Protection Agency's (Cal/EPA's) Office of Environmental Health Hazard Assessment may soon modify Proposition 65, the state law regulating chemicals alleged to cause cancer, birth defects or reproductive harm. After holding a public hearing in March 2015 and closing the public comment period in April, the office is likely to soon finalize its proposed changes to regulations that govern "clear and reasonable" warnings for Prop. 65 chemicals. These changes could have a major impact on dietary supplement and cosmetic manufacturers and retailers.

Prop. 65—officially the Safe Drinking Water and Toxic Enforcement Act of 1986—requires the state to annually publish a list of chemicals that can have a toxic effect on humans. There are currently more than 900 chemicals on the list. The statute also makes businesses responsible for warning consumers if their products contain any of the listed chemicals. If a manufacturer or retailer fails to provide a "clear and reasonable warning" on a label or in a store, the business may face an enforcement action brought by the state attorney general or private citizen suits, which seek statutory penalties and attorney's fees. Critics of the changes warn that the proposed revisions could encourage more "bounty hunter" plaintiff suits.

Cal/EPA has proposed modifying the general warning that is now required so that if a product contains one of the so-called "Dirty Dozen" chemicals, the warning must specifically mention that chemical. These 12 chemicals include acrylamide, arsenic, benzene, cadmium, carbon monoxide, chlorinated Tris, formaldehyde, hexavalent chromium, lead, mercury, methylene chloride, and phthalates. The new regulation would also mandate that warning labels direct consumers to a stand-alone website maintained by the environmental agency.

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Online sellers of products must “prominently” display a hyperlink warning to a purchaser before the sale is completed. The changes also attempt to minimize the burden on retailers by making manufacturers primarily responsible for warning consumers about potential chemical exposures. Retailers, however, must still provide a Prop. 65 warning if the product is being sold under a brand or trademark licensed by the retailer, if the retailer “knowingly and intentionally” introduces a listed chemical into the product, if the retailer covers or alters the warning label provided by the manufacturer, if the retailer has actual knowledge of potential exposure, or if the manufacturer or importer of the product cannot be compelled to comply with Prop. 65 because they are foreign entities. Finally, the revised regulations expressly include dietary supplements under the statutory definition of a food product and give specific examples of the content required for warnings on supplements and food.

The state is expected to act soon to adopt these regulatory changes before its January 2016 deadline. Businesses would have two years to comply with the new warning requirements.

LITIGATION

Centrum® Suit over Allegedly Deceptive Labels Dismissed

A putative class action in the U.S. District Court for the Eastern District of New York has been dismissed after the judge determined that the plaintiffs failed to demonstrate how Centrum® multivitamin labeling was false or deceptive. *Kardovich v. Pfizer Inc.*, No. 13-7378 (E.D.N.Y., order entered March 31, 2015). Filed against Pfizer, Centrum’s manufacturer, the lawsuit cited labeling claims that specific vitamins within the multivitamin provide “energy support” and “vitality” and counter the effects of environmental and physical stress. The court, however, found that the medical studies cited by the plaintiffs failed to show how the science contradicts Centrum’s claims and therefore failed to support the plaintiffs’ theory that the label’s claims were false, deceptive or misleading. “Such a stark disconnect between the scientific studies and the claims made about Centrum’s benefits is fatal to plaintiffs’ complaint,” the court concluded.

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**Federal Court Denies Neutrogena’s Motion to Dismiss
Sunscreen Lawsuit**

The U.S. District Court for the Southern District of Florida recently denied Neutrogena’s motion to dismiss, finding that federal law does not preempt the plaintiff’s claims that Neutrogena deceptively marketed two sunscreen products, Ultra Sheer Body Mist SPF 30 and Beach Defense Broad Spectrum SPF Lotion 70. *Dapeer v. Neutrogena Corp.*, No. 14-22113 (S.D. Fla., order entered March 25, 2015). Neutrogena argued that plaintiff’s claims were preempted because they seek to impose labeling requirements that differ from those established by the U.S. Food and Drug Administration (FDA). The plaintiff argued that he was not seeking to change the way Neutrogena displays SPF value, but that the marketing of higher SPF ratings by charging a premium and claiming greater protection is misleading and deceptive.

**False Advertising Suit over Vitamin C Supplement Not Preempted
by Federal Law**

A New York federal court has denied Ester-C’s motion for partial summary judgment in a false advertising putative class action, finding that the plaintiffs’ challenge to the phrase “immune support” on the Ester-C supplement label is not preempted by federal law. *Hughes v. The Ester C Co.*, No. 12-0041 (E.D.N.Y., order entered March 27, 2015). The plaintiffs alleged that Ester-C falsely advertised its namesake supplements as supporting the immune system, decreasing the likelihood or recovery time of illness and providing a superior source of vitamin C.

In its motion for partial summary judgment, Ester-C argued that the challenge to the “immune support” phrase on the label was preempted by federal law because the U.S. Food and Drug Administration and the Food, Drug, and Cosmetic Act directly address what statements manufacturers may and may not make on nutritional supplement labeling. The court disagreed, finding that the “immune support” claim is part of a broader challenge to the representations that Ester-C made on its label.

“Were ‘Immune Support’ the sole claim being challenged by Plaintiffs on Ester-C’s packaging, Defendants might be correct. . . . However, Defendants’ motion artificially narrows the nature of Plaintiffs’ claims, which do not hinge exclusively on Ester-C’s ‘Immune Support’ statements. Rather, Plaintiffs assert that Ester-C’s ‘immune support’ statements, in combination with the disease prevention/treatment statements that appear in the packaging and marketing of Ester-C products, constitute misleading representations as to Ester-C’s health benefits.”

Accordingly, the court dismissed Ester-C’s motion, allowing the “immune support” challenge to be considered as part of the plaintiffs’ misrepresentation claims.

Vitamin Shoppe, Inc. Requests Dismissal of Proposed Class Action

Vitamin Shoppe, Inc. has requested dismissal of a purported class action filed in the Southern District of California claiming that the company falsely advertised a dietary supplement, arguing that the product referenced in the complaint does not exist. *Scheurman v. Vitamin Shoppe Indus. Inc.*, No. 15-0025 (S.D. Cal., motion filed March 13, 2015). The plaintiff alleges that the supplement, Reserve™ Trans Resveratrol, does not disclose that it contains Japanese knotweed. The company changed the formulation and labeling of the product in June 2013. The previous version contained Japanese knotweed, which was reflected on the label. The company argued that because the plaintiff neither described the bottle she purchased nor provided an image of it in her complaint, it could not determine whether she purchased an old or new formulation of the supplement. The company further argued that if the plaintiff purchased the old formulation, then the supplement could not have caused any injury because the label clearly discloses that Japanese knotweed was present. The company also argued that if the plaintiff purchased the new formulation, she could still claim no injury because the new formulation does not contain Japanese knotweed.

Purported Class Action Against Estee Lauder Products to Go Forward

Claims of breach of contract, false advertising and deceptive practices over Estee Lauder’s Advanced Night Repair products are going forward in the U.S. District Court for the Eastern District of New York. *Tomasino*

v. The Estee Lauder Cos. Inc., No. 13-4692 (E.D.N.Y., order entered March 26, 2015). The plaintiff, who seeks to bring a class action, alleges that the cosmetics do not live up to their claims that they “repair past visible DNA damage” so that skin looks younger. The court found that the complaint stated a claim that was plausible on its face and rejected defendant’s arguments that the plaintiff’s scientific studies do not support her assertions.

“Natural” Sunscreen Label Suit Proceeds Under Connecticut Consumer Protection Statute

The U.S. District Court for the District of Connecticut has denied Johnson & Johnson’s motion to dismiss a putative class action over Aveeno® sunscreen products labeled as “natural protection” with “100 percent naturally sourced sunscreen ingredients.” *Langan v. Johnson & Johnson Consumer Cos. Inc.*, No. 13-1470 (D. Conn., order entered March 31, 2015). The plaintiff argued that the label deceived buyers into thinking the entire product was natural, not just the active ingredients. The court noted that the U.S. Food and Drug Administration has not defined “natural” in the context of cosmetics products and that it was “perfectly reasonable” for a typical consumer to assume that the label meant the entire product was natural. It also disagreed that the claim under the Connecticut Unfair Trade Practices Act was federally preempted.

LEGISLATION, REGULATIONS AND STANDARDS

Proposed Personal Care Products Safety Act Could Significantly Expand FDA Authority over Cosmetics

U.S. Sens. Dianne Feinstein (D-Calif.) and Susan Collins (R-Maine) introduced the Personal Care Products Safety Act (**S. 1014**) on April 20, 2015. The bill addresses a range of issues, including registration of facilities and products, mandatory recall authority, adverse and serious adverse event reporting, good manufacturing practices, and user fees. The legislation appears to have been drawn from Food, Drug, and Cosmetic Act (FDCA) provisions applicable to non-prescription drugs. The proposed requirements for adverse reporting would exceed those applicable to non-prescription drugs by requiring companies to report “serious” adverse events within 15 business days and all non-serious

adverse events in an annual report. The U.S. Food and Drug Administration's (FDA's) mandatory recall authority would be limited to instances in which the use or exposure to a cosmetic were likely to cause serious adverse health consequences or death, and the company refused to voluntarily recall the product. Additionally, FDA would be tasked with investigating at least five different cosmetic ingredients for safety each year. Implementation of these amendments to FDCA has been estimated to cost \$20.6 million annually and would be covered by registration fees.

FDA Warns Supplement Manufacturers over Unapproved Stimulant

The U.S. Food and Drug Administration (FDA) has sent warning letters to five companies for product misbranding because the dietary supplements they sell containing *Acacia rigidula* also contain an unapproved stimulant, beta-methylphenylethylamine, or BMPEA. The *Acacia rigidula* plant does not naturally contain the stimulant, which has been classified as a doping agent by the World Anti-Doping Agency. Studies have shown it to raise blood pressure and heart rate and act like an amphetamine. The letters were sent to Hi-Tech Pharmaceuticals, Tribavus Enterprises, Train Naked Labs, Better Body Sports, and Human Evolution Supplements regarding products that include Fastin™-XR, Lipodrene®, Sudden Impact, Core® Burner, and Phoenix Extreme.

New York AG Reaches Agreement with Supplement Maker

GNC has reached an agreement with New York Attorney General Eric Schneiderman to develop a number of procedures to ensure that its supplements contain the ingredients advertised. Earlier in 2015, Schneiderman sent cease-and-desist letters to GNC and four other retailers after testing their herbal supplements and finding that the products did not contain the advertised supplement or were contaminated with potential allergens. Under the agreement, GNC will perform DNA barcoding on "active" plant ingredients in its products to authenticate the herbal ingredients, test for potential allergens, and post signs advising customers of "the processed, chemical nature of extracts."

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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.

Shook is widely recognized as a premier litigation firm in the United States and abroad. The firm's clients include large multinational companies in the tobacco, pharmaceutical, medical device, automotive, chemical, food and beverage, cosmetics, oil and gas, telecommunications, agricultural, and retail industries.

GLOBAL TRENDS

WADA Science Director Discusses Supplements at Science of Botanicals Conference

Olivier Rabin, science director of the World Anti-Doping Agency (WADA), advocated more stringent regulation of dietary supplement manufacturers during a presentation at the 13th Annual Oxford International Conference on the Science of Botanicals in mid-April 2015. WADA is an international non-governmental agency dedicated to fighting doping and works with Interpol and the World Customs Organization on investigations.

Rabin reportedly noted that dietary supplements are a major concern because they are heavily used by athletes seeking an edge and heavily cited as a reason that some athletes fail doping tests. Rabin acknowledged that there has been improvement in the dietary supplement market over the years and that the proportion of dietary supplements containing prohibited substances has dropped from about 15 to 22 percent to less than 1 percent. Rabin believes that there is a need for pre-market approval and strong legal and financial sanctions for unscrupulous manufacturers. *See NutraIngredients-USA*, April 17, 2015.

EU Limits Common Parabens in Cosmetics, Bans Use in Diaper Creams

European Union regulations limiting concentrations of butylparaben and propylparaben in cosmetics products have taken effect for all new stock as of April 16, 2015. The new requirements set a maximum concentration of 0.14 percent for the two preservatives "when used individually or together," in addition to banning their use in creams designed for the diaper area of infants.

The restrictions apparently follow Denmark's 2011 decision to ban propyl and butylparaben in all products directed to children younger than age 3. "Preservatives in cosmetics serve a valuable function ensuring that the products we use on a daily basis are free from pathogens," said European Commissioner for Consumer Policy Neven Mimica. "We need however to ensure that the preservatives guarantee the maximum degree of protection. With these measures consumers can be reassured that their cosmetics are safe." *See European Commission Press Release*, September 26, 2014.