Shook, Hardy & Bacon L.L.P.

ISSUE 544 | NOVEMBER 7, 2014

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

OTA Seeks to Revise Natural Flavoring and Lignin Sulfonate Standards

The Organic Trade Association (OTA) has reportedly submitted two petitions to the National Organic Program (NOP) requesting changes to the National List of Allowed and Prohibited Substances for organic processing and handling. Citing recent innovations, OTA has asked NOP to strengthen the rules governing natural flavors in certified products to require the use of organic flavors when commercially available. The group has also moved to strike lignin sulfonate from the list "as an allowed flotation agent in post-harvest handling of organic produce."

In particular, OTA argues that "the number of organic flavors in the marketplace is now substantial," negating the need for many natural flavors that must still be made without the use of synthetic solvents, synthetic carriers, artificial preservatives, genetic engineering, or irradiation. The association also notes that innovations in organic pear handling have rendered lignin sulfonate obsolete, especially since the National List already includes an alternative floating agent preferred by most handlers. "OTA supports the rigorous process that has been established for adding or removing materials from the National List," said OTA's CEO and Executive Director Laura Batcha. "The process encourages organic stakeholders to be innovative and tenacious to find organic inputs that are most compatible with organic principles. The changes to the National List that OTA is requesting are a result of the organic industry embracing new ideas and blazing new trails." *See OTA Press Release*, November 7, 2014.

GAO Report Advocates Bolstered Federal Monitoring of Pesticide Residues in Food

The U.S. Government Accountability Office has issued a **report** related to its review of the federal government's oversight of pesticide residues in food. More specifically, the report discusses the congressional watchdog's analysis of Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA) Food Safety and Inspection Service and USDA Agricultural Marketing Service pesticide residue data, the data's reliability, and the agencies' methods for sampling foods for testing. Among other things, GAO recommends improvements in FDA's methodology and disclosure of the limitations in both agencies' monitoring and data collection efforts.

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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First Tax on Sugar-Sweetened Beverages Passed in Berkeley, California

Voters in Berkeley, California, have passed a 1-cent-per-ounce tax on sugar-sweetened beverages (SSBs) and the added-calorie sweeteners used to make them. Revised by court order to reference "sugar-sweetened beverages" as opposed to "high-calorie, sugary drinks," the **ballot measure** garnered 75-percent approval to make Berkeley the first city in the nation to adopt a soda tax.

The new tax will apparently cover (i) SSBs distributed to stores and restaurants and (ii) sweeteners distributed to restaurants and stores "where they are used to make sugar-sweetened beverages for customers." Exempted from taxation are sweeteners distributed to stores for direct sale to consumers as well as milk-based beverages, baby formula, alcoholic beverages, medical formulations, and fruit and vegetable juices that do not contain added-calorie sweeteners. Under the new rules, added-calorie sweeteners include sucrose, fructose, glucose, and high-fructose corn syrup, but not "natural, concentrated, or reconstituted fruit or vegetable juice or any combination thereof." Additional details about Measure D appear in Issues **529**, **535** and **537** of this *Update*.

"By passing Measure D, the Berkeley community is raising awareness about the link between sugary drinks and diet-related diseases, raising revenue for community programs, and reducing consumption of these harmful drinks," said Rudd Center Director Marlene Schwartz in a November 5, 2014, press release. "This is an important development that will pave the way for similar policies across the country."

Meanwhile, a similar proposal before San Francisco voters failed to achieve the two-thirds majority required for implementation. More expansive than Berkeley's measure, **Proposition E** sought to levy a 2-cent-per-ounce tax on sweeteners used in fountain-beverage mixes and SSBs containing added sugar and 25 or more calories per 12 ounces. Although it would have excluded milk or natural fruit juice without added sugar, the measure would have taxed some energy and sports drinks, sweetened teas and juices.

"Berkeley is always an outlier. It's a lot more affluent. It's a lot more eclectic," explained "No on E" campaign spokesperson Roger Salazar before the election. "San Francisco is always where the big action is. I don't think people would look at Berkeley's results and say, 'Oh, that's what the rest of the country would do.'" *See SFGate.com*, November 5, 2014.

LITIGATION

SCOTUS Declines Review of Diacetyl Liability Ruling

The U.S. Supreme Court (SCOTUS) has denied certiorari to petitioners alleging that Aaroma Holdings LLC is liable for personal injury claims stemming from the use of diacetyl by Emoral Inc., which declared bankruptcy in 2011 after Aaroma bought its assets in 2010. *Diacetyl Plaintiffs v. Aaroma Holdings LLC*, No. 14-71 (U.S., cert. denied November 3, 2014). The petitioners had argued that freeing Aaroma from liability would create a loophole for companies looking to avoid tort liability by encouraging them to sell assets before filing for bankruptcy. Additional information about the certiorari petition appears in Issue 532 of this *Update*.

D.C. Circuit Refuses to Hear COOL Regulation Challenge Again

The D.C. Circuit Court of Appeals has denied the requests of meat-producer interests to rehear arguments in a case challenging the U.S. Department of Agriculture's (USDA's) country-of-origin labeling (COOL) rules as a violation of First Amendment rights. *Am. Meat Inst. v. USDA*, No. 13-5281 (D.C. Cir., order entered October 31, 2014). Under the regulations, amended in May 2013, retailers of "muscle cuts" are required to list on product labels the countries of origin and production as to each step of production—born, raised or slaughtered. Additional details about the en banc ruling upholding the regulations appear in Issue 532 of this *Update*. USDA amended the rules to address an adverse World Trade Organization (WTO) determination that they discriminated against Canadian and Mexican livestock producers. The effort was unsuccessful, as WTO again ruled in favor of Canada and Mexico. Information about that decision appears in Issue 542 of this *Update*.

Court Decertifies Damages Class in Dole "All Natural" Fruit Suit

A federal court in California has decertified a damages class in litigation alleging that Dole Packaged Foods, LLC misleads consumers by labeling 10 of its fruit products as "All Natural Fruit" because they contain allegedly synthetic ingredients ascorbic acid and citric acid. *Brazil v. Dole Packaged Foods, LLC*, No. 12-1831 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered November 6, 2014). The court found flaws in the regression model that the plaintiff's expert (Oral Capps) used to determine the price premium attributable to the company's use of the "All Natural Fruit" label statements, finding that the model "does not sufficiently isolate the price impact" of the labeling statement.

The court disagreed with Dole that the expert performed a "price" regression rather than a "sales" regression and thus "measured the wrong thing." According to the court, while the initially proposed analysis differed from the one actually carried out, given that the expert had initially proposed a

model based on changes in labels on Dole products—which did not occur—it appropriately responded to the court's damages methodology request as long as it isolated the price impact traceable to the labeling claim. The court further rejected Dole's argument that the model confused "brand" and "label" and that it improperly used retail data.

The court agreed, however, that the regression model did not control for a number of variables affecting price, including advertising and the prices of competing products. As to the latter, the court faulted the expert for failing to actually determine whether comparable products bore the "All Natural" label and improperly made certain assumptions in this regard. According to the court, "This methodology cannot survive *Comcast*." The court was also concerned that the model failed to "account for the possibility that some products might make multiple labeling claims," such as "All Natural Fruit" and "No Sugar Added," and that it overlooked "differences in how the products are packaged." In the court's view, the desirability of a single 16-oz. can differs significantly from a "four pack," i.e., four 4-oz. cups packaged together. Thus the court found that the Rule 23(b)(3) predominance requirement was not satisfied.

Its conclusion was "only bolstered by other troubling aspects of Dr. Capps' model." He apparently offered a contradictory opinion about the efficacy of regression modeling where, as here, a label statement on a product has not changed during the class period in *Lanovaz v. Twinings North America, Inc.* As the court queried, "How is it that regression analysis was 'not possible' in *Lanovaz*, but remains eminently so here?" The court found his explanation unsatisfactory.

The court rejected Dole's request to decertify the injunctive relief class for lack of ascertainability, stating, "Here, [the plaintiff] has adequately defined the class based on an objective criterion: purchase of the identified Dole fruit products within the class period." It distinguished the case from others that involved many more products with a variety of labeling claims. The Rule 23(b)(2) class certified includes "all persons in the United States who, from January 1, 2009, until the date of notice, purchased a Dole fruit product bearing the front panel label statement 'All Natural Fruit' but which contained citric acid and ascorbic acid."

ECJ Suits Stayed Awaiting FDA Guidance

A California federal court has granted a motion for reconsideration in a case alleging that Wallaby Yogurt Co. includes "evaporated cane juice" (ECJ) on its ingredient lists rather than what plaintiffs allege is the more common name, sugar. *Morgan v. Wallaby Yogurt Co.*, No. 13-296 (U.S. Dist. Ct., N.D. Cal, order entered November 5, 2014).

Wallaby had moved for reconsideration of prior orders allowing the case to proceed. The text-only docket indicates that the motion for reconsideration has been granted and the case stayed, with a written order to follow. The stay follows a series of similar actions in other cases after the U.S. Food and Drug Administration (FDA) announced in March 2014 that it would reconsider its 2009 draft guidance discouraging use of the term.

In two similar putative class actions, courts have extended stays originally imposed in May 2014 because FDA has not yet issued further guidance. *Figy v. Lifeway Foods*, No. 13-4828 (U.S. Dist. Ct., N.D. Cal., order entered October 21, 2014); *Avila v. Green Valley Organics, L.P.*, No. 13-335 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered October 29, 2014). Additional information on stays and dismissals without prejudice in ECJ cases appear in Issues **525** and **529** of this *Update*. *See Law360*, November 5, 2014.

Class Certification Denied in "All Natural" Suit Against Reality Star's Skinnygirl Margarita

An Illinois federal court has declined to certify a class in a lawsuit alleging that Skinnygirl Margarita, a pre-mixed alcohol beverage sold by Skinnygirl Cocktails, and its founder, Bethenny Frankel of reality show *The Real Housewives of New York City* and talk show *Bethenny*, was labeled as "all natural" despite containing the non-natural preservative sodium benzoate. *Langendorf v. Skinnygirl Cocktails, LLC*, No. 11-7060 (U.S. Dist. Ct., N.D. Ill., E. Div., order entered October 30, 2014).

The plaintiff sought to represent a class of all consumers who purchased Skinnygirl Margarita spirits in Illinois after March 1, 2009, but the court identified several shortcomings with the proposed class. First, the court found that the plaintiff failed to offer a valid method to identify the purchasers. "Plaintiff says class membership can be verified by the dates of purchase, the locations of retail establishments, the frequency of purchases, the quantity of purchases, and the cost of purchase, [] but does not offer any showing that this can be done," in part because Skinnygirl Cocktails never sold the product directly to consumers. Acknowledging that this ascertainability standard could be interpreted too strictly, the court stated that it at least required "a showing by plaintiff that some method exists to identify the members. Here there has been none."

While the court found that the plaintiff met the numerosity, commonality and typicality requirements for class certification, it had concerns with the adequacy of representation. Dismissing Skinnygirl Cocktails' challenge to the plaintiff's credibility, the court assessed the company's argument that an apparent personal relationship between the plaintiff and lead counsel caused a conflict of interest. The plaintiff's father, an attorney, had in other

cases served as co-counsel with the lead attorney representing the plaintiff, which the court stated "causes genuine concern about conflicts of interest." But because the plaintiff's reply brief had largely ignored Skinnygirl Cocktails' adequacy-of-representation argument, the court found that she had not met her burden of proving that the putative class members would be adequately represented.

The court then assessed whether class members would have individual issues relevant to the determination of Skinnygirl Cocktails' liability. The plaintiff argued that why each class member purchased the product was irrelevant because "the simple fact is that Plaintiff and the Class did not get what they paid for, i.e. 'All Natural' or 'Blue Agave.'" The plaintiff failed to show that any other potential class members were actually harmed because they had purchased the product based on the "All Natural" representation, the court said. It cited *Suchanek v. Sturm Foods, Inc.*, No. 13-3843 (7th Cir., order entered August 22, 2014), to note that the plaintiffs in that case had "produced evidence tending to show the materiality of the misleading marketing." In *Suchanek*, a coffee-pod producer had allegedly sold instant coffee in pods at premium prices and implied on its label that the coffee was not instant, and the court in *Skinnygirl* said that "few (if any)" of the consumers who purchased the pods would have done so if they had known the ingredients of the product. In contrast, the court could not find any evidence to show that the potential class members who purchased the Skinnygirl Margarita product would not have bought it based on "the presence of a small quantity of sodium benzoate." Additional information about Suchanek appears in Issue **536** of this *Update*. Finally, the court dismissed as moot the plaintiff's motion to exclude Skinnygirl Cocktails' expert because it had reached its decision without relying on the expert opinion, so a full *Daubert* analysis was unnecessary.

Appellate Court Holds That Dram Shop Statutes Do Not Protect Four Loko Producer from Lawsuit

Reversing a lower-court decision, a California appeals court has ruled that state dram shop statutes—meant to protect some sellers of alcohol beverages from liability for injuries related to the beverages' consumption—do not provide immunity for City Brewing Co. in a lawsuit alleging that the company was negligent in producing Four Loko. *Fiorini v. City Brewing Co.*, No. F067046 (Cal. Ct. App., 5th D., order entered November 6, 2014).

After drinking two 23.5-ounce cans of Four Loko, the plaintiff's son was shot to death by police in October 2010. The plaintiff alleged that City Brewing, which brewed, bottled and labeled Four Loko, was liable for negligence for producing an alcohol beverage in a nonresealable can apparently containing alcohol "equivalent to five or six 12-ounce cans of beer" and "as much caffeine as two cups of coffee" because "combining alcohol, a depressant, with caffeine

and other stimulants created a product that had unreasonably dangerous propensities because it masked the intoxicating effect of the alcohol and increased the risk of violent and other high-risk behavior."

After providing a history of California's dram shop statutes, the court assessed each statute to determine if any immunities therein could apply to City Brewing. The first, Section 25602 of the Business and Professions Code, creates civil and criminal liability for anyone selling alcohol beverages directly to a "habitual or common drunkard" or an "obviously intoxicated person," and do not apply to City Brewing because the plaintiff's son bought Four Loko at a convenience store.

The court then turned to Civil Code Section 1714, which codified a common law rule that "immunized from civil liability those who furnish alcoholic beverages to a person who then injured himself or herself or a third party as a result of intoxication." The trial court had defined "furnish" to include any entity in the chain of distribution and deemed City Brewing to be a furnisher under the law, and thus immune to the allegations. The appeals court disagreed, finding that for the purposes of determining who was a furnisher of the alcohol beverage, previous cases had distinguished the entire chain of distribution from "the person who handed the beverage to the consumer." Further, the language of the statute—"injuries incurred as a result of *furnishing alcoholic beverages to an intoxicated person*" (emphasis in opinion)—suggested that the intent was to include those who actually had some control over who received the beverage, which is not possible for "manufacturers who are far removed from the ultimate consumer." Accordingly, City Brewing did not furnish the plaintiff's son with Four Loko and thus could not be immune under the statute.

City Brewing also claimed protection under Civil Code Section 1714.45, which excludes manufacturers of a common consumer product from product liability claims if the product is "inherently unsafe" and "known to be unsafe by the ordinary consumer who consumes the product" with "ordinary knowledge." The brewer argued that alcohol and caffeine are individually known to be inherently unsafe, so Four Loko qualifies as a common consumer product. The court disagreed, finding that (i) City Brewing could not find support for its deconstructionist approach for its multi-ingredient product, especially when the plaintiff accused the brewer of manufacturing an unsafe product based on the combination of ingredients; (ii) the approach was incomplete because it did not address the added guarana, taurine and wormwood; and (iii) courts will not apply immunity if adulteration or contamination of a product made it unreasonably dangerous. The court found that Four Loko was not a common consumer good, in part because the risks associated with the combination of caffeine and alcohol were not well-understood. Accordingly, the court directed the trial court to vacate its order granting City Brewing's motion for judgment on the pleadings and file a new order denying that motion.

Putative Class Action Echoes FTC Suit Against Gerber over Allergy Reduction Claims

Days after the U.S. Federal Trade Commission (FTC) filed a lawsuit to enjoin Gerber Products Co. from claiming that its Good Start® Gentle infant formula helps reduce allergies in children, a consumer filed a putative class action in Arizona federal court alleging the same facts. *Werthe v. Gerber Prods. Co.*, No. 14-8216 (U.S. Dist. Ct., D. Ariz., filed November 3, 2014). Additional information about FTC's lawsuit against Gerber appears in Issue **543** of this *Update*.

Like the FTC complaint, the consumer action alleges that Gerber advertises the partially hydrolyzed whey protein (PHWP) in its Good Start® Gentle formula as reducing the risk of atopic dermatitis in infants. As a result, Gerber charges "a significant premium" over other infant formulas, the plaintiff asserts. The complaint cites Gerber's labeling, which allegedly promises that its product is the "1st & Only Routine Formula to Reduce the Risk of Developing Allergies" and that it "Meets FDA [U.S. Food and Drug Administration] Qualified Health Claim," and contrasts it to Gerber's allegedly rejected requests to FDA to allow the company to link PHWP infant formula to a reduced risk of food allergies and atopic dermatitis in infants despite "'no credible' evidence." The plaintiff alleges a violation of the Arizona Consumer Fraud Act, breach of express warranty and unjust enrichment, and she seeks class certification, compensatory and statutory damages, an injunction, attorney's fees, and a corrective advertising campaign.

Public Interest Groups Sue FDA over Animal Drug Approvals

The Center for Food Safety and two other public interest organizations have filed a lawsuit against the U.S. Food and Drug Administration (FDA) seeking to overturn its approval of 11 animal drugs containing ractopamine hydrochloride on the ground that the agency failed to undertake the analysis purportedly required under the National Environmental Policy Act (NEPA) before approving them. ***Ctr. for Food Safety v. Hamburg*, No. 14-4932 (U.S. Dist. Ct., N.D. Cal., filed November 6, 2014)**.

The Center previously petitioned FDA to reduce the allowable levels of ractopamine, administered in animal feeds to boost growth and leanness in meat production, and to study its potential effects on human health and animal welfare. Information about the petition appears in Issue **466** of this *Update*.

The complaint sets forth the effects these drugs allegedly have on livestock, like pigs, and on the environment. The plaintiffs claim that the company that makes ractopamine has acknowledged the "risk of impacting the chemical composition of water bodies by 'potential leaching into the soil and groundwater from confinement areas," yet has "apparently never conducted a field study of ractopamine's impact on the chemical composition of waterways."

The complaint also states that the company "has acknowledged that ractopamine is moderately toxic to plants and slightly toxic to aquatic invertebrates" and that "at least ninety-eight species of threatened and endangered aquatic invertebrates and plants have critical habit[at] in areas where ractopamine is used."

The plaintiffs further allege that the substance is often used in combination with other pharmaceuticals, including tylosin, monensin and melengestrol, and note that the European Union has banned the use of these pharmaceuticals for various reasons, such as the development of resistant bacteria to drugs used in human medicine, ecological risks and endocrine-disrupting activity. According to the complaint, FDA's approvals for some of the challenged drugs rely on a single study or are based on 15-year-old documents that fail "to account for significant new circumstances and information relevant to environmental concerns raised by the use of ractopamine, particularly the current widespread use of ractopamine and other feed additives."

Alleging that "FDA unlawfully approved Topmax in violation of NEPA and the APA [Administrative Procedure Act]," and "violated NEPA by approving applications for ractopamine-based combination drugs without any NEPA review," the plaintiffs seek a declaration that the agency violated NEPA and the APA, an order vacating and remanding its decisions to approve ractopamine-based animal drugs, an injunction barring the use of ractopamine-based animal drugs until FDA complies with NEPA, and fees and expenses.

Announcing the litigation, plaintiff Center for Biological Diversity points to a study cited in the complaint, "[t]he drug's primary human health study, conducted on just six healthy men, caused heart pounding in three of the men so severe that one of them had to be withdrawn from the study." It also highlights that the European Union, China and Russia have banned the importation of U.S. pork from pigs that have been fed ractopamine. *See Center for Biological Diversity News Release*, November 6, 2014.

Trans Fat in Xtreme Wellness® Tortillas Generates Litigation

A California resident has filed a putative nationwide class action in federal court against Ole Mexican Foods, Inc., alleging that its Xtreme Wellness® whole-wheat tortillas contain partially hydrogenated vegetable oil, "banned in many parts of the world due to its artificial *trans* fat content," thus belying the health and wellness representations the company uses on product labels. *Guttmann v. Ole Mexican Foods, Inc.*, No. 14-4845 (U.S. Dist. Ct., N.D. Cal., filed October 31, 2014).

The plaintiff alleges that artificial *trans* fat causes cardiovascular disease; Type-2 diabetes; breast, prostate and colorectal cancer; Alzheimer's disease and cognitive decline; and damage to vital organs. He claims that he purchased one package each month for two years at a higher price than comparable products relying on package labeling stating "Healthy Life Style," "Better Choice for Your Health," "Whole Wheat," and "High Source of Fiber and Protein." According to the complaint, because the product contains *trans* fat, small amounts of whole wheat along with highly refined bleached flour, and less fiber than required for a "high" claim, it is deceptively promoted. The labels also allegedly state "Trans Fat Free" and include a prominent heart image in violation of federal labeling laws, the plaintiff claims.

Alleging violations of the False Advertising Law, Consumers Legal Remedies Act and the unlawful, fraudulent and unfair prongs of the California Unfair Competition Law as well as breach of express warranty, the plaintiff seeks damages in excess of $5 million, disgorgement, punitive damages, injunctive relief, a corrective advertising campaign, interest, attorney's fees, and costs.

Employees Forced to Buy Bob Evans Uniforms Sue for Unpaid Minimum Wages

Bob Evans servers who were paid under the "tip credit" provisions of the Fair Labor Standards Act (FLSA) claim in a collective action filed in a Florida federal court that they "were not compensated at least the proper minimum wage for all hours worked as a result of being required to pay for uniforms." *McDaniel v. Bob Evans Farms, LLC*, No. 14-2767 (U.S. Dist. Ct., M.D. Fla., Tampa Div., filed November 3, 2014). Named plaintiff Emily McDaniel alleges that she was paid an hourly rate of $4.77 plus tips, which increased to $4.91 plus tips, and that she and other servers "were required to pay Defendant for uniforms, including but not limited to, Bob Evans T-shirts and aprons." She claims that this resulted in an FLSA violation because servers "have not been paid the minimum wage for each hour worked during their employment." She seeks certification of a class of servers, declaratory relief and awards of unpaid minimum wages, liquidated damages or pre-judgment interest, attorney's fees, and costs.

OTHER DEVELOPMENTS

CSPI Seeks Data from FDA About Raw Milk Drug Residue Survey

The Center for Science in the Public Interest (CSPI) has submitted a request to the U.S. Food and Drug Administration (FDA) under the Freedom of Information Act for "the data collected by the Center for Veterinary Medicine under its Raw Milk Drug Residue Survey." According to CSPI, FDA conducted the survey

in 2012 "because excess and sometimes illegal drugs are more frequently found in animals from dairy farms at slaughter plants than animals coming from other sources."

CSPI's review of drug testing reports in 2011 purportedly revealed that "animals coming from dairy farms accounted for 67 percent of reported drug residue violations at slaughter" and that, in some cases, "the reported residues were for drugs that are not approved for use in cattle." While FDA informed consumer groups that it would make the raw data available when its report is released, it has yet to release the survey results. CSPI attorney David Plunkett said, "The agency doesn't get to hide information from the public by simply failing to write up a report on what it thinks the data show." *See CSPI News Release*, November 5, 2014.

SCIENTIFIC/TECHNICAL ITEMS

Byproduct of Red Meat Digestion Allegedly Linked to Heart Failure Mortality

A new study exploring the link between cardiovascular disease and a gut bacteria metabolite known as trimethylamine-N-oxide (TMAO) has reported that "higher TMAO levels predict higher future risk of death from heart failure, independent of other clinically used blood tests or risk factors." W.H. Wilson Tang, et al., "Prognostic Value of Elevated Levels of Intestinal Microbe-Generated Metabolite Trimethylamine-N-Oxide in Patients With Heart Failure: Refining the Gut Hypothesis," *Journal of the American College of Cardiology*, November 2014. Led by the Lerner Research Institute's Department of Cellular and Molecular Medicine Chair Stanley Hazen, a Cleveland Clinic team followed 720 patients with stable heart failure over a five-year follow-up period, finding that "higher plasma TMAO levels were associated with a 3.4-fold increased mortality risk." They also noted that patients with elevated levels of TMAO and B-type natriuretic peptide "had more than a 50 percent mortality rate over [five] years."

This latest study builds on work suggesting that gut bacteria produce TMAO during digestion of L-carnitine and lecithin, dietary nutrients found in red meat, egg yolks, liver, and some energy drinks. In addition, Hazen and his team previously identified "a relationship between TMAO levels and future cardiac events like heart attack, stroke, and death—even in those with no prior evidence of cardiac disease risk," a finding the American Heart Association named among 2013's top ten advances in heart disease science.

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"I am excited that these studies suggest TMAO testing may not only help identify those patients at greatest risk and for whom more aggressive monitoring is needed, but also that TMAO testing may help to tailor dietary efforts to the individual in the hopes of reducing future risks among those high-risk subjects," Hazen was quoted as saying. Additional details about previous TMAO studies appear in Issues 479 and 481 of this *Update*. *See Cleveland Clinic News Release*, October 27, 2014.

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Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.