ISSUE 476 | MARCH 22, 2013

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Physicians, Researchers, Public Health Experts Seek FDA Action on Caffeine in Energy Drinks

A group of physicians, researchers and public health experts has urged Food and Drug Administration (FDA) Commissioner Margaret Hamburg to consider the purported adverse health effects, particularly for children and adolescents, posed by energy drinks containing high levels of caffeine, apply existing generally recognized as safe standards to such beverages and require manufacturers to provide caffeine content on product labels.

In their March 19, 2013, letter, the signatories cite their own and others' research to claim that an increase in the consumption of products with added caffeine has been associated with fatalities and injuries, increased emergency room visits, cardiovascular complications, seizures, childhood obesity, and risky behaviors when combined with alcohol. They contend that while caffeine's effects on adults are known, safe levels for teenagers have not been sufficiently shown.

In a related development, several energy drink companies, including Monster Beverage, have reportedly changed their product labels to declare the caffeine content and decided to cease marketing the products as dietary supplements, evidently to avoid obligations to report adverse events to federal regulators. Monster Beverage and Rockstar Energy drinks will now apparently be marketed as beverages. Monster Energy has also reportedly become a member of the American Beverage Association.

The initiatives come in the wake of a wrongful death lawsuit against Monster Beverage and as critics increase their calls for action over safety concerns. The company recently held a press conference to challenge evidence submitted in the lawsuit and, according to a news source, has threatened to sue the publisher of a newsletter for elementary schools over statements the company says are defamatory.

According to Deborah Kennedy, the nutritionist who writes the newsletter and called for children from kindergarten through fifth grade not to consume

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the beverages, the company demanded that she retract and correct the statements or face litigation. A Monster Energy spokesperson reportedly said that the child of a company employee read the newsletter and was upset by it. He said, "No child, much less a 7-year-old, should be falsely informed that his or her father's employer is a child killer, especially since there are no facts to support the allegation." *See The New York Times*, March 19 and 21, 2013.

Petitioners Ask FDA to Regulate Use of Antibiotics in Distillers Grains

Two agricultural organizations have filed a citizen **petition** with the Food and Drug Administration (FDA) seeking to ban the use of antibiotics in ethanol production so that the leftover mash, known as "distillers grains with solubles (DGS)," which is fed to livestock, does not add to the levels of antibiotics used in the production of poultry and meat in the United States and thus contribute to the development of "superbugs," that is, bacteria resistant to multiple antibiotics. *In re Ctr. for Food Safety*, No. n/a (FDA, filed March 15, 2013). In the alternative, the petitioners request that FDA adopt regulations that deem antibiotics sold to ethanol producers for DGS production as new animal drugs, require drug sponsors to seek FDA approval for their use and ban the sale of antibiotics that have not been approved as new animal drugs.

According to the Center for Food Safety and Institute for Agriculture and Trade Policy, ethanol producers use antibiotics to manage bacterial outbreaks in their fermentation vats. The DGS left over from ethanol production is then "repurposed and sold as livestock feed to cattle, dairy, swine and poultry producers. Therefore, in addition to receiving enormous amounts of antibiotics intentionally added to their feed or drinking water, food-producing animals also receive non-therapeutic doses of antibiotics through DGS." The petition claims that FDA tested DGS in 2008 and 2010 and found antibiotics, such as penicillin, virginiamycin, erythromycin, tylosin, and tetracycline, in DGS and that "FDA currently does not regulate, monitor, or require reporting of this antibiotic use as required by Section 105 of the annual Animal Drug User Fee Amendments of 2008 (ADUFA) reports." Contending that antibiotics are unnecessary in ethanol production and have in fact been replaced by major producers, the petitioners call the practice "wholly illegal under the [Federal Food, Drug, and Cosmetic Act] and the [Administrative Procedure Act]."

Among other matters, the petitioners allege, "In the ten year period from 2000 to 2010, DGS production increased 1,264% from 2.5 to 34.1 million metric tons per year [and] is growing at such a fast clip that DGS are replacing corn and soybeans in the U.S. animal feed market." They also allege, "Without any dosage limitations or medical oversight, ethanol producers have full discretion over the quantity and frequency of antibiotic use in manufacturing fuel. FDA does not track antibiotic sales to ethanol producers as it does for use in

animals. It is thus nearly impossible to estimate with any accuracy the amount of antibiotics the ethanol industry uses." *See Center for Food Safety Press Release*, March 15, 2013.

FDA Secures Consent Decree from New Jersey Bakery over Labeling Issues

According to the Food and Drug Administration (FDA), a federal court has approved a consent decree with Clifton, New Jersey-based Butterfly Bakery, Inc. over claims that it distributed misbranded food products, such as muffins and snack cakes. *United States v. Butterfly Bakery Inc.*, No. 2:2013cv00669 (U.S. Dist. Ct., D.N.J., order entered March 5, 2013). Under the agreement, the bakery will be unable to process or distribute food until it complies with the Food, Drug, and Cosmetic Act. FDA and state testing apparently showed that foods labeled as "sugar free" contained sugar, and some products contained three times the amount of declared or labeled sugar and two times the amount of fat or saturated fat. *See FDA News Release*, March 13, 2013.

EFSA Issues Criteria for Identifying Endocrine Disruptors

The European Food Safety Authority's (EFSA's) Scientific Committee has **issued** an opinion "that clarifies the scientific criteria for identifying an endocrine disruptor." Requested by the European Commission, the opinion addresses "the testing and assessment of endocrine active substances (EASs) and endocrine disruptors (EDs)" by adopting the World Health Organization's definition for EDs, which must meet the following three criteria: "the presence of (i) an adverse effect in an intact organism or a (sub)population; (ii) an endocrine activity; and (iii) a plausible causal relationship between the two."

The opinion also identifies "a reasonably complete suite of standardized assays for testing the effects of EASs [that] is (or will soon be) available for the oestrogenic, androgenic, thyroid and steroidogenic modalities in mammals and fish" known to be sensitive to endocrine disruption. The Scientific Committee has stressed, however, that not all EASs are EDs, ultimately advocating "a risk assessment approach" that evaluates substances on a case-by-case basis and takes into account "potential adverse effects of endocrine active substances together with the likelihood of exposure."

"This was an important part of our work and it contributes to EU and international discussions in this area. We concluded that current tests generally are adequate for mammals, fish and to a lesser extent also for birds and amphibians and cover four important endocrine pathways," said EFSA Scientific Chair Tony Hardy in a March 20, 2013, press release. "However, no single test is sufficient to decide whether a substance is an endocrine disruptor and several tests need to be done and then assessed together by experts in a weight-of-evidence approach."

New York, Texas Consider *Trans* Fat Bans

New York State Assembly Member Félix Ortiz (D-Brooklyn) has introduced legislation (A6031 and A6053) that would prohibit restaurants, mobile food service establishments and retail food stores from serving items that contain artificial *trans* fat. The proposed ban would apply to any food item with more than 0.5 grams of artificial *trans* fat per serving or that uses "vegetable shortening, margarine or any kind of partially hydrogenated vegetable oil" as an ingredient. The bills would exempt food items served in the manufacturer's original packaging and prevent counties, cities and other local governments from passing more stringent *trans* fat regulations after the state's version takes effect in 2014.

Meanwhile, Texas Sen. José Rodríguez (D-El Paso) recently filed a similar measure (S.B. 1359) seeking to restrict the use of artificial *trans* fat in foods prepared, packaged, stored, or served by food service establishments. Like the New York proposal, the Texas legislation would exempt food items with less than 0.5 grams of *trans* fat per serving, but would also permit establishments to "use *trans* fat to prepare bakery items, including items made with yeast dough or cake batter." Initially applicable only to chain restaurants with 15 or more outlets in the state, the new rules would apply to all establishments as of August 31, 2015, if adopted by the state legislature.

Idaho Legislature Considers Prohibition on "Unhealthy" Food Under SNAP

The Idaho Senate has approved a joint memorial bill (S.J.M. 102) that would (i) state legislative findings, including that "taxpayers have a right to expect that their tax dollars will purchase fresh, healthy food that meets nutritional standards that will not contribute to health issues and higher medical costs," and (ii) urge the federal government "to prohibit the purchase of unhealthy food items with Supplemental Nutritional Assistance Program (SNAP) benefits." Introduced on March 19, 2013, the proposal was adopted by voice vote on March 22 and sent to the state House.

The bill lists the types of foods that the legislature deems unhealthy, including "energy drinks defined as a beverage containing at least sixty-five milligrams of caffeine per eight fluid ounces that is advertised as being specifically designed to provide metabolic stimulation or an increase to the consumer's mental or physical energy; a sweetened beverage or 'soft drink' defined as any nonalcoholic beverage to which a natural or artificial sweetener is added; packaged cookies, candy, chips and other 'junk food' with no nutritional value." The proposal also calls on the president, Congress and U.S. Department of Agriculture (USDA) to encourage healthy lifestyle choices for SNAP recipients.

USDA rejected a New York City proposal to implement a two-year pilot project that would have prohibited residents from using food stamps to purchase sugar-sweetened beverages under SNAP. Details about that proposal and USDA's action appear in issues 367 and 407 of this *Update*.

Suffolk County Restricts Energy Drink Marketing to Children

The Legislature of Suffolk County, New York, has adopted new measures (1920-2012, 1085-2013 and 1086-2013) designed to curtail the marketing of energy drinks to minors within county limits. Introduced by William Spencer (D-Centerport), the three new laws will (i) prohibit companies from providing free energy drink samples and coupons to individuals younger than age 18; (ii) ban the sale and distribution of these products to minors in county parks; and (iii) establish a "Truth About Stimulant Drinks" public education campaign "to increase awareness of side effects associated with energy drink consumption." The legislation also specifies civil penalties between $500 and $1,000 per violation of the new rules.

"Far too many people are unaware of the effects excessive caffeine consumption can have on the body," Spencer told reporters. "Excessive consumption of caffeine can aggravate pre-existing conditions and contribute to a variety of health problems. My plan levels the playing field and will create an open and fair dialogue about these products so parents and children can decide whether or not to ingest these drinks." *See Times Beacon Record,* March 19, 2013.

LITIGATION

California Court Dismisses Honey False Ad Suit with Prejudice

A federal court in California has dismissed as preempted putative class claims filed against Target Corp. and Honeytree, Inc., alleging that they retail and manufacture honey products falsely advertised as "honey" or "pure honey" despite the absence of all pollen, an allegedly "defining characteristic of honey under applicable law." *Cardona v. Target Corp.*, No. 12-1148 (U.S. Dist. Ct., C.D. Cal., decided March 20, 2013).

The court rejected the defendants' challenge to the plaintiff's standing, finding that she had sufficiently alleged an injury under *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310 (2011). But the court determined that the claims were preempted under the Nutrition Labeling and Education Act, agreeing with the defendants that the plaintiff "cannot plausibly allege that 'pollen' is a 'characterizing ingredient' of 'honey,' and that the 'common and usual name' of honey is honey, irrespective of pollen content." According to the court, "the requirement that pollen-less honey be labeled as '(without pollen)' is

not 'identical to' the 'common and usual name' requirement under 21 U.S.C. § 343(i)(1), and is therefore preempted by § 343-1(a)(3)." The court dismissed the claims with prejudice.

Environmentalists Sue EPA to Stop Use of Pesticides Allegedly Harmful to Honey Bees

Beekeepers, environmentalists and advocacy organizations have filed an action for declaratory and injunctive relief against the U.S. Environmental Protection Agency (EPA), claiming that the agency has failed to take any regulatory action on pesticide products containing the active ingredients clothianidin and thiamethoxam in violation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Endangered Species Act (ESA) and Administrative Procedure Act. *Ellis v. EPA*, No. 13-1266 (U.S. Dist. Ct., N.D. Cal., filed March 21, 2013).

According to the complaint, "In a vast and extremely risky experiment, EPA has allowed over two million pounds of clothianidin and thiamethoxam to be used annually on more than 100 million acres and on dozens of different plant corps without adhering to existing procedural frameworks and with no adequate risk assessments in place." The plaintiffs allege that this inaction has "been a major factor in excessive honey bee mortality and the decline of pollinator populations in the same time period." They contend that beekeepers and honey producers "have suffered, and will continue to suffer, devastating economic hardships unless Defendants take action, which they have refused to do despite repeated formal requests."

The plaintiffs ask the court, among other matters, to order EPA to (i) "reconsider its final action of July 17, 2012, when Defendants denied an imminent hazard pursuant to the Plaintiffs' Petition to suspend clothianidin without considering the full information filed by Plaintiffs and without consulting with [the U.S. Fish and Wildlife Service] under the ESA on whether a hazard was posed to threatened and endangered species and their critical habitats," (ii) declare that all of these chemicals' registration and changed use approvals were not published in the *Federal Register* in violation of FIFRA and vacate them, (iii) declare that all of these chemicals' conditional and unconditional use approvals violated FIFRA and vacate them, and (iv) order EPA to immediately suspend the registration of clothianidin and thiamethoxam.

POM Wonderful Seeks Review of FTC Order

POM Wonderful LLC has filed a petition seeking review in the D.C. Circuit Court of Appeals of a Federal Trade Commission (FTC) order requiring two randomized, controlled clinical trials before the company can make a claim that its pomegranate juice products treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction. *POM Wonderful LLC v. FTC*, No.

13-1060 (D.C. Cir., filed March 8, 2013). In its January ruling, FTC found that the company made false and misleading claims by advertising its products with health-benefit assertions that POM contended were backed by medical research. Additional information about the FTC rulings in the case appears in issues 441 and 467 of this *Update*.

Peanut Company Execs Enter Pleas; Government Seeks Disqualification of Defense Counsel

Since the federal government filed a 76-count indictment against the owner and managers of Peanut Corp. of America, the source of a nationwide *Salmonella* outbreak in 2009, the defendants have entered not-guilty pleas and been released on bonds ranging from $25,000 to $100,000. *United States v. Parnell*, No. 13-12 (U.S. Dist. Ct., M.D. Ga., Albany Div., filed February 15, 2013). Additional details about the charges appear in Issue 472 of this *Update*. The court has also entered orders designating the case as complex and excluding time under the Speedy Trial Act, as well as setting a scheduling conference for April 22, 2013.

OTHER DEVELOPMENTS

CSPI Report Targets Soft Drink Makers' Use of Philanthropy to Advance Interests

The Center for Science in the Public Interest (CSPI) has published a report titled "Selfish Giving: How the Soda Industry Uses Philanthropy to Sweeten its Profits." Noting that the African-American and Hispanic organizations that brought a successful court challenge against New York City Mayor Michael Bloomberg's size restrictions on sugar-sweetened beverages were the recipients of grants from the soft drink industry, the report suggests that industry sponsorships are used to leverage their reputations. While the money allows organizations serving minorities and underserved populations to achieve their goals, CSPI contends, "The [beverage] companies sometimes exploit those partnerships to support their political objectives." CSPI calls for recipient organizations to think twice about accepting money from the industry.

According to the report, advocacy organizations, government officials and health-care providers have increased their efforts to reduce sugar-sweetened beverage consumption, which CSPI indicates has dramatically increased and accuses of "increasing the risk for diabetes, heart attack, stroke, and cancer" and contributing to an obesity epidemic that drains "between $147 billion and $210 billion annually from the U.S. economy." The industry's response, says CSPI, has been aggressive, including an often overlooked element—the implementation of "corporate-responsibility and marketing programs to advance the industry's policy and profit objectives."

CSPI discusses how some cities that proposed taxes on soda and prohibitions on sugar-sweetened drinks on government property were offered millions of dollars in prize money by the American Beverage Association (ABA) to develop "personal responsibility-driven wellness campaigns." The report states that program rules for another anti-obesity contest obligated cities that accepted the grants "to host a promotional press event at which they, alongside the ABA, would publicly announce their awards." From CSPI's perspective, "The grants appear to be an attempt by the beverage industry to blunt budding local efforts to reduce soda consumption through such interventions as taxes, removing sugar drinks from government property, and education programs."

Claiming "[i]t should come as no surprise that the soft-drink industry pursues its own self-interest in constructing giving strategies," the report concludes by stating, "Years ago health advocates began to question the tobacco industry's generous contributions to popular social welfare (and other) causes, including those representing the interests of minority communities. Despite the clear need for such support, many groups recognized the potential for conflicts of interest between cigarette-company largesse and the public health and gradually reduced their dependency on funds that often came with political and policy strings attached." The report includes a list of 30 organizations that have "ties to the beverage industry," organizations that support the ABA's "Americans Against Food Taxes" initiative and model guidelines, developed by the Campaign for Tobacco Free Kids, for nonprofits to evaluate proposed relationships with other organizations. *See CSPI News Release*, March 19, 2013.

Cornucopia Institute Asks FDA to Remove Carrageenan from Food Supply

The Cornucopia Institute (CI) has issued a **report** that questions the safety of food-grade or undegraded carrageenan, "a common food additive extracted from red seaweed." Titled "Carrageenan: How a 'Natural' Food Additive is Making Us Sick," the report claims that animal studies "have repeatedly shown that food-grade carrageen causes gastrointestinal inflammation and higher rates of intestinal lesions, ulcerations, and even malignant tumors."

Distinguishing between undegraded and degraded carrageen—which the report describes as "a potent inflammatory" processed with acid instead of alkali—CI emphasizes that even the food-grade version poses a health risk to consumers who ingest the additive in a wide variety of products, including dairy and dairy alternatives, deli meats, and prepared soups and broths. In particular, the report points to a 2001 literature review published by the National Institute of Environmental Health Sciences that purportedly warned against "'the widespread use of carrageenan in the Western diet' due to evidence that 'exposure to undegraded as well as degraded carrageenan was associated with the occurrence of intestinal ulcerations and neoplasms.'"

"A convincing body of scientific literature shows negative effects caused by food-grade carrageenan," states the report, which faults the Food and Drug Administration (FDA) for ignoring recent research in favor of industry-funded studies. "Moreover, scientists are concerned that the acid environment of the stomach may 'degrade' food-grade carrageenan once it enters the digestive system, thus exposing the intestines to this potent and widely recognized carcinogen."

As a result, CI has since written a formal **letter** to FDA, asking the agency to reevaluate a 2008 citizen petition that sought to remove carrageenan from the food supply. Disputing FDA's June 11, 2012, decision to deny the petition, the letter argues that FDA did not consider all of the available scientific literature and ultimately failed to detect alleged biases in studies funded by industry interests. According to CI, the agency not only dismissed industry data on the contamination of food-grade carrageenan with degraded carrageenan, but misinterpreted an industry-backed study allegedly showing "consumption of food-grade carrageenan leads to exposure to degraded carrageenan in the intestinal tract."

"[T]here are no benefits to society or public health from adding carrageenan to foods or beverages. It is added solely to change the texture of food," concludes the letter. "Already, some food manufacturers are replacing carrageenan with other thickeners and stabilizers, or eliminating thickeners altogether and asking their consumers to shake the product before consumption. If carrageenan is prohibited, the food industry will quickly adapt."

SCIENTIFIC/TECHNICAL ITEMS

SSB Consumption Allegedly Tied to Higher Caloric Intakes Among Children

A recent study funded by the Robert Wood Johnson Foundation and National Institutes of Health has allegedly concluded that sugar-sweetened beverages (SSBs) "are primarily responsible for the higher caloric intakes" of children who consume them. Kevin Mathias, et al., "Foods and Beverages Associated with Higher Intake of Sugar-Sweetened Beverages," *American Journal of Preventative Medicine,* April 2013. Using data from 13,421 children enrolled in the What We Eat In America, NHANES 2003-2010 surveys, researchers with the University of North Carolina Department of Nutrition apparently determined "the contribution of SSBs to higher caloric intakes" by comparing the total non-SSB caloric intake of both SSB consumers and nonconsumers.

The results purportedly showed that for children ages 2 to 11, "total non-SSB intakes did not differ between nonconsumers and SSB consumers at any level of SSB consumption, indicating that SSBs were primarily responsible for the higher caloric intake among SSB consumers." The authors also reported a similar finding for adolescents ages 12 to 18, but noted that for those who

consumed more than 500 kilocalories of SSBs, "both food and SSB contributed to higher caloric intakes." In addition, increased SSB intake among this age group was associated with higher intakes of certain foods and lower intakes of non-SSB beverages like milk and fruit juice.

"Among all age groups analyzed, the energy density of food consumed increased as SSB intake increased. Given these findings, future research on the effects of dietary energy density and total caloric intake should account for these associations between total caloric intake, SSB intake, and food energy density," concludes the study. "Examinations of overall diets showed that only a small number of foods and beverages were associated with SSB intake. The largest associations were decreases in fluid milk among those aged 2-5 years and increases in intake of pizza, burgers, and fried potatoes among the highest (≥500 kcal) SSB consumers aged 12-18 years."

AHA Meeting Presentation Purportedly Links Sugary Drinks to "180,000 Deaths Worldwide"

Research presented at the American Heart Association's (AHA's) latest scientific meeting has reportedly concluded that "sugar-sweetened sodas, sports drinks and fruit juice may be associated with about 180,000 deaths around the world each year," according to March 19, 2013, press release. Featured at AHA's Epidemiology and Prevention and Nutrition, Physical Activity and Metabolism 2013 Scientific Sessions, the abstract in question apparently relied on data from the 2010 Global Burden of Diseases Study to calculate "the quantities of sugar-sweetened beverage [SSB] intake around the world by age and sex; the effects of this consumption on obesity and diabetes; and the impact of obesity and diabetes-related deaths."

The results allegedly linked SSB intake to 133,000 diabetes deaths, 44,000 deaths related to cardiovascular diseases, and 6,000 cancer deaths worldwide in 2010, raising concerns about the disproportionate impact on low- and middle-income counties. In particular, the report's authors estimated that in terms of mortality associated with SSB consumption, Latin America/Caribbean had the most diabetes deaths, East/Central Eurasia the most cardiovascular deaths, and Mexico the highest death rate of the world's 15 most populous countries, "with 318 deaths per million adults linked to sugar-sweetened beverages."

"In the U.S., our research shows that about 25,000 deaths in 2010 were linked to drinking sugar-sweetened beverages," said one of the authors with the Harvard School of Public Health. "Because we focused on deaths due to chronic diseases, our study focused on adults. Future research should assess the amount of sugary beverage consumption in children across the world and how this affects their current and future health."

Shook, Hardy & Bacon L.L.P.

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Meanwhile, the American Beverage Association (ABA) has responded to these claims with a March 19 statement highlighting the epidemiological nature of the research. "This abstract, which is not peer-reviewed nor published in a way where its methodology can be fully evaluated, is more about sensationalism than science," noted ABA. "It does not show that consuming sugar-sweetened beverages causes chronic disease such as diabetes, cardiovascular disease or cancer—the real causes of death among the studies subjects. The researchers make a huge leap when they take beverage intake calculations from around the globe and allege that those beverages are the cause of deaths which the authors themselves acknowledge are due to chronic illness."

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