Shook, Hardy & Bacon L.L.P.

ISSUE 466 | JANUARY 11, 2013

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATIONS, REGULATIONS AND STANDARDS

FTC Amends COPPA to Fortify Kids' Privacy

The Federal Trade Commission (FTC) recently **adopted** final amendments to the Children's Online Privacy Protection Rule (COPPA) that aim to "strengthen kids' privacy protections and give parents greater control over the personal information that Websites and online services may collect from children under 13." Based on the findings of a review initiated in 2010, these amendments (i) "modify the list of 'personal information' that cannot be collected without parental notice and consent, clarifying that this category includes geolocation information, photographs, and videos"; (ii) "offer companies a streamlined, voluntary and transparent approval process for new ways of getting parental consent"; (iii) "close a loophole that allowed kid-directed apps and websites to permit third parties to collect personal information from children through plug-ins without parental notice and consent"; (iv) "extend coverage in some of those cases so that the third parties doing the additional collection also have to comply with COPPA"; (v) "extend the COPPA Rule to cover persistent identifiers that can recognize users over time and across different websites or online services, such as IP addresses and mobile device IDs"; (vi) "strengthen data security protections by requiring that covered website operators and online service providers take reasonable steps to release children's personal information only to companies that are capable of keeping it secure and confidential"; and (vii) "require that covered website operators adopt reasonable procedures for data retention and deletion."

The amended COPPA rules will also require self-regulatory "safe harbor programs" to audit members and report the results of these audits annually. In addition, FTC has expanded the definitions for "operators," "websites or online service directed to children," "personal information," and "collection" of personal information, partly to cover third-party plug-ins and advertising networks with "actual knowledge that they are collecting personal information through a child-directed website or online service."

"The Commission takes seriously its mandate to protect children's online privacy in this ever-changing technological landscape," said FTC Chair Jon

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

Leibowitz in a December 19, 2012, press release. "I am confident that the amendments to the COPPA Rule strike the right balance between protecting innovation that will provide rich and engaging content for children, and ensuring that parents are informed and involved in their children's online activities."

FDA Proposes Food Safety Standards

The Food and Drug Administration (FDA) has proposed two new food safety rules addressing foodborne illness prevention and produce safety under the Food Safety Modernization Act. According to FDA, the **first rule** would require both foreign and domestic food manufacturers "to develop a formal plan for preventing their food products from causing foodborne illness" and to establish plans "for correcting any problems that arise." The **second rule** proposes "enforceable safety standards for the production and harvesting of produce on farms," including "science- and risk-based standards for the safe production and harvesting of fruits and vegetables."

Before drafting the rules, FDA apparently conducted "extensive outreach" involving the produce industry, consumers, other government agencies, and the international community. It will accept comments on both rules until May 16, 2013, and plans to issue further proposals addressing the safety and oversight of imported foods. "We know one-size-fits-all rules won't work," said FDA Deputy Commissioner Michael Taylor. "We've worked to develop proposed regulations that can be both effective and practical across today's diverse food system." *See FDA Press Release,* January 4, 2012.

FDA Seeks Comments on Setting Food Allergen Thresholds

The Food and Drug Administration (FDA) is seeking comments and other information, including data, to help determine whether the agency can establish regulatory thresholds for major food allergens such as milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.

In a recent **notice**, FDA states that although "[We have] used several risk management strategies to reduce the risk from unlabeled major food allergens, such as targeted inspections or discussions with industry organizations, we have not established regulatory thresholds or action levels for major food allergens. The establishment of regulatory thresholds or action levels for major food allergens would help us determine whether, or what type of, enforcement action is appropriate when specific problems are identified and also help us establish a clear standard… Regulatory thresholds also would help industry to conduct allergen hazard analyses and develop standards for evaluating the effectiveness of allergen preventive controls."

In particular, FDA invites comments on the following matters: (i) How should we define "an allergic response that poses a risk to human health?"; (ii) Which major food allergens are of greatest public health concern and what is the size of the at-risk population?; (iii) How should clinical dose distribution data be used when establishing regulatory thresholds for the major food allergens?; (iv) What approaches exist for using biological markers or other factors related to the severity of allergic responses in a threshold risk assessment?; (v) What data and information exist on dietary exposure patterns for individuals on allergen avoidance diets?; (vi) What data or other information exist on current levels of exposure associated with the consumption of undeclared major food allergens in packaged foods?; (vii) What other information or data should we consider in establishing regulatory thresholds for major food allergens?. Comments may be submitted by February 12, 2013. *See Federal Register,* December 14, 2012.

Groups Criticize Delay in Release of GE Salmon Documents

The Food and Drug Administration (FDA) has recently drawn criticism over the delayed release of documents evaluating the environmental impact of genetically engineered (GE) salmon. Created by Massachusetts-based AquaBounty Technologies, the GE salmon in question evidently contain genes from Chinook salmon as well as ocean pout that allow the company to bring the fish to market in half the normal time. After a publicly contentious review process, FDA **released** the May 4, 2012, **draft assessment** and a **preliminary finding** of no significant impact in late December, raising questions among groups such as the Genetic Literacy Project (GLP) about whether the agency froze the application to avoid political turmoil during the election season.

"The delay, sources within the government say, came after meeting with the White House, which was debating the political implications of approving the [GE] salmon, a move likely to infuriate a portion of its base," GLP Executive Director Jon Entine wrote in a December 19, 2012, article published by *Slate.com*. In 2010, FDA found that AquAdvantage salmon were safe for human consumption and the environment, needing only to decide whether the fish pose any threat to wild salmon under the Endangered Species Act. According to GLP, the agency should have published its finding of "no effect" in the *Federal Register* as soon as it reached this conclusion, the final step in an approval process that began in 1995.

"This shouldn't be happening," agreed Center for Science in the Public Interest Director of Biotechnology Gregory Jaffe despite the consumer group's qualms about GE foods. "AquaBounty deserves regulatory due process. We need science-based decisions made in a timely fashion. The public deserves this, and there are questions whether that is what's going on in this case."

Meanwhile, GLP has pointed to several factors blamed for the delay, among them the White House's alleged interest in the effects of the application's approval and reports circulated by environmental groups about a salmon virus found in AquaBounty's testing facilities. "The FDA, apparently caught in the political crossfire, appears to be in violation of its own scientific integrity guidelines, adopted last February," claimed Entine. "Scientists and staffers involved in the process say they have been instructed not to discuss the application. Key provisions of the guidelines require the agency to shield its staff from 'political influence' and to allow the 'FDA staff to communicate their personal scientific or policy views to the public, even when those views differ from official Agency opinions.'"

Meanwhile, the agency has reportedly attributed the delay to bureaucratic oversight. "Yes there was a delay," a spokesperson told the press. "As you are aware, we've been working on this for a while, and it was oversight in our [quality control] process. We are working to address it now." The agency has requested comments on the draft environmental assessment and its preliminary finding of no significant impact by February 25, 2013. But with final approval for GE salmon now looming, consumer groups have already stepped up efforts to block the product or at least require special labeling. "[I]t's [] outrageous that FDA would take AquaBounty's word over that of dozens of legislators and scientists, including the National Oceanic and Atmospheric Administration (NOAA) and the U.S. Fish and Wildlife Service, not to mention hundreds of thousands of concerned consumers," opines a Food & Water Watch campaign asking its followers to submit comments. "We have until February 25 to submit comments to the FDA asking them to stop their mad dash to put GE salmon in our grocery stores and to reject this franken-fish!" *See Los Angeles Times,* December 26, 2012.

EFSA Launches Public Consult on Aspartame Assessment

The European Food Safety Authority (EFSA) has **launched** a public consultation on its "first full risk assessment" of the artificial sweetener aspartame. According to a January 8, 2013, news release, EFSA's Scientific Panel on Food Additive and Nutrient Sources Added to Food (ANS Panel) has issued a draft scientific opinion on the safety of aspartame that entailed "an in-depth review of peer-reviewed scientific and other literature on aspartame and its breakdown products, including new human studies." Based on this information, the ANS Panel has concluded that aspartame and its breakdown products "pose no toxicity concern for consumers at current levels of exposure. The current Acceptable Daily Intake (ADI) is considered to be safe for the general population and consumer exposure to aspartame is below this ADI."

"The ANS Panel's draft opinion has benefitted from the latest scientific thinking and methodological approaches," concludes EFSA, which has requested comments on the draft opinion by February 15, 2013. "This

comprehensive review was made possible following two public calls for data which made available a large body of scientific information, comprising both published and previously unpublished data and studies… This information has been critically evaluated and interpreted by EFSA's experts to underpin the key discussion points addressed in the draft opinion."

Health Canada Reclassifies Energy Drinks, Caps Caffeine Content

New Canadian regulations that took effect January 1, 2013, have reclassified energy drinks as food instead of natural health products and capped their caffeine content at 180 mg per serving. First proposed in 2011, the **regulations** aim to address concerns that consumers imbibing such beverages could exceed the maximum caffeine intake levels recommended by Health Canada. "Therefore, Health Canada conducted a scientific assessment of the potential hazards and exposure associated with the common ingredients found in these caffeinated beverages (including caffeine, vitamins, minerals, taurine etc.)," stated the agency, which ultimately reported that children and adolescents were "most at risk of exceeding Health Canada's Recommended Maximum Daily Intakes (RMDI) for caffeine because of the volumes potentially consumed and the lower RMDI established for these populations, in comparison to adults."

In particular, the new regulations establish "an initial maximum limit for total caffeine of 400 mg per liter with a maximum amount of caffeine not to exceed 180 mg per container presented as a single-serve container." Under these rules, Health Canada will treat any container that cannot be re-sealed or any re-sealable container less than 591 mL as a single-serve container. In addition to bearing labels that identify the amount of caffeine from all sources, these products must also bear a statement that the beverage is a "high source of caffeine" and "not recommended for children, pregnant/breastfeeding women, individuals sensitive to caffeine," as well as warning against mixing the beverage with alcohol.

According to the *Toronto Star,* the changes have required companies to reformulate 28 of 96 reclassified beverages to meet the new limits. "For the next five years, companies have only temporary authorization to sell energy drinks, during which they'll be required to report annual data on sales, consumption and incidents," concludes the December 31, 2012, article. "As of January, only the reformulated versions can be made, although stores don't have to pull drinks already in stock. For products that already met the requirements, labels don't have to be updated until December 2013."

Nestlé's Community Trademark for KitKat® Shape Upheld

According to a news source, the United Kingdom's Community Trade Mark Office has determined that the shape of a KitKat® bar, which Nestlé registered

as a community trademark in 2006, is valid, thus barring any other confectioners from selling products with a similar shape in the European Union. Nestlé competitor Cadbury makes a similar product and sought to invalidate the mark shortly after it was registered, claiming that the trait was too general to be protected. Cadbury is reportedly considering whether to appeal the ruling. *See Huffington Post*, January 3, 2013.

OEHHA Calls for Comments on Listing Styrene Under Prop. 65

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has issued a **notice** of intent to list styrene as a chemical known to the state to cause cancer under Proposition 65 (Prop. 65), citing the National Toxicology Program's (NTP's) finding that styrene is "reasonably anticipated to be a human carcinogen." Comments are requested by February 4, 2013.

According to the notice, the proposed listing "meets the standard set out in the recent Court of Appeal decision in the *Styrene Information and Research Council v. Office of Environmental Health Hazard Assessment (3rd District,* Nov. 15, 2012) case because the NTP conclusion is based on *sufficient* evidence of carcinogenicity in experimental animals." Often used in food packaging materials, styrene occurs naturally at low levels in certain shrubs and trees. California consumers must be provided with warnings about those chemicals included on the Prop. 65 list. *See OEHHA Notice of Intent*, January 4, 2013.

New Mexico, Washington Support GMO Labeling Legislation

New Mexico has joined Washington and California in considering GM (genetically modified) labeling on food products. Sponsored by state Senator Peter Wirth (D), the **proposal** (S.B. 18) seeks to amend the New Mexico Food Act and Commercial Feed Law to require the labeling of any food or commercial animal feed containing more than 1 percent of GM material. It would also require the label to be "conspicuous and easily understandable to consumers."

The bill is the latest in a series of state-based initiatives aiming to force companies to label foods containing GM ingredients and follows California's Proposition 37—which was narrowly defeated in November 2012—and Washington's **I-522**, a citizen-backed initiative which recently secured enough signatures to go be submitted to the secretary of state.

Maine Supports BPA Ban in Infant Formula Packaging

The Maine Department of Environmental Protection (DEP) has reportedly indicated its support of a state ban on the chemical bisphenol A (BPA) for infant formula packaging, but stopped short of suggesting that the chemical be prohibited from baby and toddler food containers, which environmental activists have been requesting.

Maine already bans the chemical from baby bottles, sippy cups and reusable food and beverage containers, but, according to news sources, DEP officials claim that the scientific evidence is limited on whether the most common baby food containers—glass jars with metal lids that contain BPA—cause children to be exposed to the chemical. Agency officials are also apparently concerned about whether rules implementing the chemical ban would be sufficiently clear for consumers and companies to follow. News sources state that DEP is expected to make a recommendation on extending the BPA ban by the end of January 2013, and that an expanded ban would take effect in September at the earliest. *See Bangordailynews.com,* January 3, 2013; *Morning Sentinel*, January 9, 2013.

LITIGATION

Eighth Circuit Affirms Judgment in Supply Chain Dispute over Recalled Westland Beef

The Eighth Circuit Court of Appeals has affirmed a $1.6-million award of damages and attorney's fees in a contract dispute between General Mills and the company that sold it beef obtained from the Westland Meat Co. and recalled in 2008 after "[v]ideo footage from the Humane Society allegedly showed Westland employees improperly handling cattle designated for slaughter." ***General Mills Operations, LLC v. Five Star Custom Foods, Ltd., Nos. 12-1731 and 12-1826 (8th Cir., decided January 7, 2013)***. General Mills destroyed the Progresso soups in which the recalled beef had been used. The Eighth Circuit affirmed the district court's grant of summary judgment to General Mills on its breach-of-contract claim and dismissed as moot the company's cross-appeal of the lower court's grant of summary judgment to Five Star on the breach-of-warranty claims.

At issue was whether Five Star had materially breached its contract with General Mills. The contract required the meatballs to be of food grade and for the beef to be procured under "[s]tunning, slaughter, and processing practices [that] meet or exceed the requirements established by the USDA and the World Animal Health Organization for safe trade in animal products." General Mills relied on the recall press release issued by the U.S. Department of Agriculture's (USDA's) Public Affairs Office to establish that the Food Safety and Inspection Service (FSIS) had determined the beef was "unfit for human consumption." While the court agreed that the document was hearsay, it also determined that it fell within the public-records exception because it "sets out findings from an investigation pursuant to authority granted by law, and is therefore admissible."

Similarly, the court found that a USDA technical briefing transcript providing a summary of the investigation which revealed Westland practices "not compliant with FSIS regulations" fell under the public-records exception. This

evidence, and the admission of Five Star's corporate designee at deposition that the beef was recalled because "it didn't meet the USDA's regulations," according to the court, sufficiently established that the contract was breached. The court rejected Five Star's claim that General Mills was required to prove that the specific product received was adulterated, or procured in a noncompliant manner.

Additional details about the Westland video and recall appear in Issues 247, 248 and 249.

Federal Court Dismisses "All Natural" False Claims Suit Against Arizona Beverage Maker

After deciding that the plaintiff lacked standing to bring a consumer-fraud class action under the Class Action Fairness Act, a federal court in New Jersey has granted his motion to dismiss without prejudice, while denying the defendants' cross-motion for partial summary judgment because it lacked subject matter jurisdiction. *Robinson v. Hornell Brewing Co.*, No. 11-2183 (U.S. Dist. Ct., D.N.J., decided December 13, 2012).

The plaintiff had sought declaratory and injunctive relief on behalf of a class of purchasers of Arizona beverages that contain high-fructose corn syrup and were labeled as "all natural." He sought to certify the class under Rule 23(b)(2). According to the court, the evidence showed that the plaintiff had no intention of purchasing these products in the future and therefore could not show a reasonable likelihood of future injury from the defendants' conduct. Thus, the court denied his motion to certify the class for lack of standing to seek injunctive relief. Thereafter, the plaintiff sought dismissal without prejudice arguing that the court lacked subject matter jurisdiction over the action after denying class certification.

Agreeing with the plaintiff, the court noted that in those cases in which courts in other circuits had ruled that denial of certification did not affect a court's jurisdiction, the certification denial was based on a failure to meet Rule 23's requirements and not, as here, a failure of Article III standing and a defect in subject matter jurisdiction. Characterizing the matter as "the exceptional case," the court opined that it "never had jurisdiction from the start. This case failed to present an Article III case or controversy because the sole plaintiff lacked standing to seek injunctive relief. This defect in jurisdiction existed at the time of filing this class action complaint."

Orange Juice Labeling Claims Dismissed with Prejudice

A federal court in Alabama has dismissed breach of contract and warranty claims filed against a company that makes Florida Natural® orange juice and markets it as "fresh," "100%" or "pure," finding that the plaintiff lacked standing

to bring the claims on behalf of a putative class of purchasers. *Veal v. Citrus World, Inc.*, No. 12-801 (U.S. Dist. Ct., N.D. Ala., S. Div., decided January 8, 2013).

The court refused to allow the plaintiff to amend his complaint for a fourth time on the grounds that no amendment can cure its deficiencies and bad faith. According to the court, "This is plaintiff's counsel's fourth attempt (not counting the arguments before the MDL [multidistrict litigation] panel) to pursue a class action against defendant based on the same inherently flawed theory of liability. Upon not being included as class counsel in the MDL, plaintiff's counsel returned here and went shopping for plaintiffs in an attempt to manufacture a claim which could survive a motion to dismiss."

The court determined that the plaintiff lacked standing because he alleged no actual or concrete injury. In this regard, the court noted, "Here, the plaintiff alleges that his injury was the actual purchase of orange juice. However, he does not explain how buying packaged orange juice, when he wanted packaged orange juice, injured him." The court also observed, "despite plaintiff's protestations that he did not receive the product he believed he was purchasing, he makes no allegation that he has stopped purchasing what he considers to be an inferior product in favor of purchasing what he actually sought, which is apparently unpasteurized fresh squeezed orange juice." The court also found that injunctive relief would not redress the plaintiff's purported injury, because "[h]e does not allege how he will suffer a future injury, or even to what extent he has suffered a past injury by purchasing packaged orange juice from a store which was, in fact, not fresh squeezed orange juice."

The court concluded, "the fact that the plaintiff may have believed defendant hired individuals to hand squeeze fresh oranges one by one into juice cartons, then boxed up and delivered the same all over the country does not translate into a concrete injury to plaintiff upon his learning that beliefs about commercially grown and produced orange juice were incorrect."

Court Approves FDA Consent Decree over Tainted Peanut Butter Outbreak

A federal court in New Mexico has approved a consent decree of permanent injunction between the Food and Drug Administration (FDA) and Sunland, Inc., which owns a facility where peanut butter products purportedly tainted with *Salmonella* were produced. ***United States v. Sunland, Inc.*, No. 12-1312 (U.S. Dist. Ct., D.N.M., filed December 21, 2012)**. The outbreak affected "at least 35 people from 19 states," eight of whom "were hospitalized as a result of their infection." While the company neither admits nor denies FDA's allegations, it agreed to take a number of actions to correct food-handling practices "that likely resulted in cross-contamination between raw peanuts and peanuts that had been roasted or brined."

The company must "develop and implement sanitation control programs; provide FDA the opportunity to inspect the facilities to assure Sunland's compliance with the consent decree, the Food, Drug, and Cosmetic Act, and applicable regulations; and receive written authorization from FDA to resume operations. Sunland must also implement testing, monitoring and remediation protocols." The company will be unable to sell processed foods until it complies with the agreement. *See U.S. Department of Justice Press Release*, December 21, 2012.

Insurance Dispute in Oatmeal Recall Resolved in Favor of Insured

A federal court in Minnesota has granted the motion for summary judgment filed by a company whose insurance carrier claimed it was not required to cover the company's settlement of claims arising from a recall of instant oatmeal purportedly contaminated with instant milk produced at a facility where the Food and Drug Administration "detected insanitary conditions and salmonella." *The Netherlands Ins. Co. v. Main St. Ingredients, LLC*, No. 11-533 (U.S. Dist. Ct., D. Minn., decided January 8, 2013).

The company had supplied the instant milk to Malt-o-Meal which used it to make instant oatmeal. After the instant milk and downstream products such as the oatmeal were recalled, Malt-o-Meal sued both the supplier and the company that had produced the instant milk. While none of the supplier's instant milk was found to contain *Salmonella,* the case ultimately settled for $1.4 million.

The insurance company sued the supplier, Main Street Ingredients, for a declaration that it had no duty to defend or indemnify Main Street. Applying Minnesota law, the court found that the unambiguous insurance contract covered the recall which it found to be an "occurrence" that was not a "known loss" and constituted "property damage." The court also determined that none of the policy exclusions—"your property," "impaired property" or "recall"—applied because (i) the supplier sought indemnity not for damage to its milk, but for damage to the Malt-o-Meal oatmeal caused by the inclusion of the milk; (ii) the oatmeal could not be restored and thus was impaired "since the ingredients were inextricably blended together"; and (iii) the recall involved a third party and not the insured.

Court Refuses to Certify Class in Skinnygirl Margarita® "All Natural" Suit

Ruling that the named plaintiff's claims are not typical of those of the putative class in a false-labeling suit brought against the companies that made and marketed Skinnygirl Margaritas®, a federal court in New York has denied his motion for class certification. *Rapcinsky v. Skinnygirl Cocktails, L.L.C.*, No. 11-6546 (U.S. Dist. Ct., S.D.N.Y., decided January 9, 2013). The named plaintiff, a Massachusetts resident, allegedly purchased the product in that state as a gift

for his wife who had indicated that she had been served the beverage during a party with friends and liked it. He brought the suit under New York statutes that apply to products purchased in New York and involve deceptive acts or practices involving in-state residents. He also claimed common-law breach of warranty.

According to the court, the laws invoked do not protect the plaintiff's purchases. While his alleged injury may be the same as class members, the plaintiff, "having not purchased his products in New York State, is an atypical representative of the New York class he purports to represent." As for the warranty claim, the law in both states requires some showing of reliance. The plaintiff "bought the product to thank his wife for all she does in the home, after hearing her remark that she liked it while at the party of a health-conscious friend. And while incentives are not monolithic, Defendants will assert as a defense to [his] claim that there was no causation . . . as (1) he stated he would have bought the product regardless of price and (2) his belief with respect to its naturalness was irrelevant to his purchasing decision, given the statements about the impetus for the purchase. Such defenses are unique to [his] claims and underscore the atypicality of [his] alleged reliance."

Court Refuses to Lift Ban on Shark Fins in California

A federal court in California has determined that Asian-American interest organizations have not sustained their burden of showing that they are entitled to preliminarily enjoin the shark fin ban that took effect January 1, 2012, in the state. *Chinatown Neighborhood Ass'n v. Brown*, No. 12-3759 (U.S. Dist. Ct., N.D. Cal., decided January 2, 2013). Additional details about the case appear in Issue **447** of this *Update*.

The court found that the plaintiffs were unlikely to prevail on their claims of discrimination against the Chinese-American community that uses shark fins in traditional dishes served at many banquets and special events. Finding that the state had a rational basis to impose limits on shark finning and that the state regulations did not overlap federal restrictions, the court denied the plaintiffs' motion for a preliminary injunction.

Putative Class Challenges "100% Natural" Labeling on GM Foods

A California resident has filed a putative class action against General Mills, Inc. alleging that two of its frozen vegetable "steamers" products are falsely advertised as "100% Natural" because they contain genetically modified (GM) ingredients. *Cox v. General Mills, Inc.*, No. 12-6377 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed December 17, 2012). According to the complaint, the products contain GM corn, soy, corn derivatives, and/or soy derivatives.

Seeking to certify a statewide class of those who have purchased Green Giant Valley Fresh Steamers®, the plaintiff alleges violations of California's False Advertising and Unfair Competition laws and the California Consumers Legal Remedies Act. She requests injunctive relief; restitution; disgorgement; actual, statutory and punitive damages; attorney's fees; costs; and interest.

OTHER DEVELOPMENTS

NAD to Investigate 5-Hour Energy® Claims Highlighted in *NYT* Report

The Council of Better Business Bureaus' National Advertising Division (NAD) has reportedly decided to review "no crash later" claims made by Living Essentials LLC about its caffeinated energy supplement 5-Hour Energy® after *The New York Times* published a January 2, 2013, article questioning the scientific evidence behind such assertions. According to media sources, NAD ruled in 2007 that Living Essentials could not support its unequivocal "no crash" claims, even though its product evidently causes less of an energy level reduction than beverages made by its competitors. As a result, Living Essentials modified its labeling to include an asterisk on its "no crash later" declaration, but NAD has apparently advised the company to drop the claim altogether or submit to a compliance review. *See Law360,* January 3, 2013.

The claim now facing NAD scrutiny also caught the attention of *Times* writer Barry Meier, who noted that energy drink manufacturers demand premium prices by promoting their products "not as caffeine-fueled concoctions but as specially engineered blends that provide something more." In particular, Meier argues that scientific studies have not borne out the alleged physical and mental benefits of various proprietary formulas or individual additives such as glucuronolactone and taurine. With regard to 5-Hour Energy®, Meier notes that Living Essentials founded its "no crash later" claims on a study based in "the office of a proctologist in a small Maine town" and has yet to produce evidence undergoing peer review.

"Ms. Lutz, the Living Essentials spokeswoman, said the bold 'No Crash Later' statement on product was followed by a special mark. That mark, which also appears on the back of the label, explains in fine print that 'no crash means no sugar crash,'" opines Meier. "That is hardly surprising, because 5-Hour Energy® does not contain sugar."

Activists Seek Lower Ractopamine Limits in Meat

The Center for Food Safety (CFS) and the Animal Legal Defense Fund (ALDF) are petitioning the U.S. Food and Drug Administration (FDA) for an immediate reduction in the allowable levels of ractopamine—a controversial drug used to boost growth and leanness in meat production—and to study the drug's potential effects on human health and animal welfare.

The petition was reportedly filed days after Russia announced that it would require meat it imports to be tested and certified free of ractopamine—a move that jeopardizes the more than $500-million worth of U.S. beef and pork exported to that country annually.

According to CFS staff attorney Elisabeth Homes, "The continued use and abuse of ractopamine in our food supply needs to be put in check. FDA must do its job of assessing risks, questioning health impacts, and providing better solutions for our food system. American families and, potentially, the nation's economy are at risk."

CFS and ALDF say that ractopamine is fed to an estimated 60 to 80 percent of U.S. pigs and has resulted in more reports of sickened or dead pigs than any other livestock drug on the market. "Ractopamine effects may include toxicity and other exposure risks, such as behavioral changes and cardiovascular, musculoskeletal, reproductive, and endocrine problems."

FDA spokeswoman Shelly Burgess said the agency had extensively evaluated ractopamine before approval and "continues to monitor the safety and effectiveness of animal drugs like ractopamine" after they receive FDA approval.

About 160 countries reportedly ban or restrict the use of ractopamine, including the European Union, China, Taiwan, and Russia. *See Animal Legal Defense Fund News Release,* December 20, 2012.

MEDIA COVERAGE

Bittman Condemns Beyoncé's Marketing Deal with Pepsi

According to *New York Times* food commentator Mark Bittman, Beyoncé Knowles has joined a list of celebrities who have entered endorsement deals for products "that may one day be ranked with cigarettes as a killer." The singer has apparently agreed to "have the Pepsi logo painted on her lips and have a limited-edition Pepsi can bearing her likeness." She will also be seen during the "Pepsi Super Bowl halftime show, where she'll be introduced by 50 of her luckiest and best-gyrating fans who have been selected through a contest."

In his article titled "Why Do Stars Think It's O.K. To Sell Soda?," Bittman notes that Knowles supported first lady Michelle Obama's "Let's Move" campaign by stating that she was "excited to be part of this effort that addresses a public health crisis," but has now "become part of an effort that promotes a public health crisis."

He observes that product placement and super-star endorsements are both commonplace and ubiquitous and that some might consider the practice harmless. "Some will say that soda is food and that there's no smoking gun as there is with tobacco," he states. "But food provides nourishment, and

soda doesn't. In fact it packs calories that provide no satiety and directly cause weight gain." Bittman calls for "anti-tobacco-style legislation and public opinion" to counter multi-million dollar soda advertising campaigns and suggests that Knowles "take some of her creative time and produce a public service announcement that would positively affect the attitudes of millions of children and teens on the subjects of health, self-image, nutrition and exercise." *See Opinionator*, January 5, 2013.

In a related development, the Center for Science in the Public Interest's executive director wrote to Knowles in December 2012 to express disappointment with her "$50-million endorsement deal with PepsiCo." According to Michael Jacobson, "You occupy a unique position in the cultural life of this country and are an inspiring role model for millions of young people. Your image is one of success, health, talent, fitness, and glamour. But by lending your name and image to PepsiCo, you are associating your positive attributes with a product that is quite literally sickening Americans." He concluded by asking the star to "consider donating your proceeds to a hospital, diabetes organization, or other reputable charity involved in the prevention or treatment of soda-related diseases."

Psychiatry Professor Calls for Anti-Tobacco Initiatives to Address Obesity Epidemic

In a University of Oxford Press (UOP) blog post titled "From cigarettes to obesity, public health at risk," University of Florida Psychiatry Professor Mark Gold advances his food addiction hypothesis and suggests, "If overeating is due to food acquiring drug-like or tobacco-like brain reinforcement properties, then the current globesity and overating-related health crisis might have lessons to learn from tobacco." Gold recently co-edited a book of essays, *Food and Addiction*, and claims that taxes on soft drinks, like taxes on cigarettes, could reduce consumption.

According to Gold, animal tests show "that sucrose and fructose corn syrup are self-administered as if they were drugs and that an opiate-like abstinence syndrome could be produced by detoxification or antagonist administration." He claims that new treatments based on the addiction hypothesis should address food preferences "and not just appetite." He concludes, "New approaches, evidence-based approaches, like those that have been used successfully to develop novel public health and treatment approaches for tobacco, alcohol, and other addictions are needed." *See UOPBlog*, January 3, 2013.

SCIENTIFIC/TECHNICAL ITEMS

Study Alleges BPA Linked to Increased Risk of Kidney Disease

A recent study has reportedly concluded that bisphenol A (BPA) exposure is associated with low-grade albuminuria in U.S. children, suggesting they may be at a greater risk for kidney and heart disease as adults. Leonardo Trasande, et al., "Bisphenol A exposure is associated with low-grade urinary albumin excretion in children of the United States," *Kidney International,* January 2013.

Using data from 710 children enrolled in the 2009-10 National Health and Nutrition Examination Survey, researchers reported that those "with the highest as compared to the lowest quartile of urinary BPA [uBPA] had a significant 0.91 mg/g higher albumin-to-creatinine ratio, adjusted for urinary BPA concentration." These results were evidently consistent with previous studies associating BPA exposure with low-grade albuminuria in Chinese adults.

"Long-term observational studies will be needed to ascertain whether uBPA-associated changes in low-grade albuminuria potentiate the features of the metabolic syndrome—hypertension, hyperlipidemia, or insulin resistance—and augment the risk of developing glomerular disease," conclude the study's authors. "Future studies of the relationship between uBPA and markers of vascular function such as pulse-wave velocity and carotid intima media thickness in children would lend support to our suggestion that BPA promotes generalized endothelial dysfunction."

JAMA Commentaries Focus on Energy Drinks

The *Journal of the American Medical Association (JAMA)* recently highlighted energy drinks in its December 19, 2012, online issue, where two commentaries discussed caffeine-related adverse events and the risks of mixing energy drinks with alcohol. Authored by Memorial Sloan-Kettering Cancer Center infectious disease specialist Kent Sepkowitz, the first viewpoint article notes that "the swift change in public perception of energy drinks from harmless mild stimulant to lethal, unregulated drug is unprecedented." Summarizing recent cases of unintentional caffeine overdoses and caffeine poisoning, the article claims that "a person would need to ingest at least 12 of the highly caffeinate energy drinks within a few hours" to reach a lethal dose of caffeine. Sepkowitz argues, however, that this estimate does not take into account variables such as medications that may slow the metabolism of caffeine or preexisting cardiac or liver conditions "that could increase susceptibility to caffeine-related adverse events."

"The appropriate role of the FDA and other regulatory in the oversight of energy drinks is yet to be defined," concludes Sepkowitz. "A logical first step might be to require placing the caffeine content of energy drinks on their

label… Publicity about energy drink-related deaths should inform the public of the potential dangers of these products."

Meanwhile, a second viewpoint article co-authored by Jonathan Howland (Department of Emergency Medicine, Boston University) and Damaris Rohsenow (Center for Alcohol and Addiction Studies, Brown University) outlines the risks of alcohol mixed with energy drinks (AMED). Howland and Rohsenow hypothesize that (i) the caffeine component of AMED offsets the sedating effects of alcohol and reduces the sensation of intoxication, (ii) a reduced sensation of intoxication impairs judgment relative to risky behaviors, and (iii) a reduced sensation of intoxication induces more alcohol consumption.

Although they admit that the data are inconsistent on these points, the authors nevertheless believe that the public needs "more definitive information and education about the safety threshold for caffeine consumption and, in particular, the effects of caffeine on adolescent behavior and development." As they thus conclude, "Policy makers should hold energy drink manufacturers accountable for claims regarding the health and psychological benefits of their products… For the present, however, consensus about these questions, and identification of gaps in knowledge, could be achieved by targeting research on this topic and by convening experts to assess existing evidence."

Researchers Suggest Fructose Tricks Brain into Eating More

A recent study using magnetic resonance imaging (MRI) has allegedly suggested that compared with glucose consumption, fructose consumption resulted "in a distinct pattern" of cerebral blood flow (CBF) in brain regions linked to appetite and reward pathways, and "a smaller increase in systemic glucose, insulin, and glucagon-like polypeptide 1 levels." Kathleen Page, et al., "Effects of Fructose vs Glucose on Regional Cerebral Blood Flow in Brain Regions Involved With Appetite and Reward Pathways," *JAMA,* January 2013. Researchers relied on 20 adult volunteers who underwent to MRI sessions "together with ingestion of either a fructose of a glucose drink in a blinded, random-order crossover design."

The MRIs evidently showed that within 15 minutes, "glucose significantly reduced hypothalamic CBF, whereas fructose did not." As the authors explained, "[I]ngestion of glucose but not fructose reduced cerebral blood flow and thus activity in specific regions that regulate appetite and reward processing. In keeping with these data, ingestion of glucose but not fructose produced increased ratings of satiety and fullness."

"Not only did fructose fail to diminish hypothalamic activity, but it instead induced a small, transient increase in hypothalamic activity, a response similar to insulin-induced decrements in levels of circulating glucose," they concluded. "These findings suggest that ingestion of glucose, but not

Shook, Hardy & Bacon L.L.P.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 466 | JANUARY 11, 2013

fructose, initiates a coordinated response between the homeostatic-striatal network that regulates feeding behavior."

Blue Lollipops Allegedly Present Health Risks

A recent **study** targets the alleged health effects of two food and beverage dyes—Brilliant Blue (E133) and Patent Blue (E131)—after systemic absorption. Marianna Lucová, et al., "Absorption of triphenylmethane dyes Brilliant Blue and Patent Blue through intact skin, shaven skin and lingual mucosa from daily life products," *Food and Chemical Toxicology,* February 2013.

A particular focus of the study was to "assess the potential for lingua mucosa absorption of the dyes from human saliva as a consequence of licking lollipops." The findings were "troubling," the study noted, "particularly with regard to the repeated licking of lollipops by children."

The study concludes that because both dyes can potentially enter the bloodstream through the dorsum of the tongue and cause adverse health effects, such as attention deficit hyperactivity disorder, allergies and asthma, neither dye should be used in the manufacturing of lollipops and hard candies. Brilliant Blue is used as food additive in the United States, but the use of Patent Blue is not allowed in many countries, including the United States, Australia, Canada, Japan, and New Zealand.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400