Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Schumer Urges FTC to Investigate Alcoholic-Energy Drinks

U.S. Senator Chuck Schumer (D-N.Y.) has asked the Federal Trade Commission (FTC) to investigate the marketing of certain caffeinated malt beverages that "seem to be explicitly designed to attract underage drinkers" and to determine whether new enforcement actions are warranted. In a July 12, 2010, press release, Schumer singled out popular drinks "that appear hip with flashy colors and funky designs" but contain 12 percent alcohol, which is more than twice the amount in a bottle of beer or glass of wine.

"However, the labeling and packaging of these beverages renders them nearly indistinguishable from ordinary energy drinks," Schumer said. "Some stores even stock them directly next to other energy drinks causing further confusion for legal and illegal consumers."

Schumer called the marketing "extremely troubling" in a letter to FTC Chair Jon Leibowitz. "Frankly, it looks to me as if manufacturers are trying to mislead adults and business owners who sell these products, while at the same time actively courting underage drinkers," he wrote. *See Press Release of Senator Charles Schumer*, July 12, 2010.

Congressman Asks FDA to Investigate Toxins in Gulf of Mexico Seafood

U.S. Representative Edward Markey (D-Mass.) has called on the Food and Drug Administration (FDA) to respond to reports that the April 20, 2010, oil spill has contaminated the marine food chain in the Gulf of Mexico with toxins such as arsenic. In a July 13 letter to FDA Commissioner Margaret Hamburg, Markey expressed concern "that the mixture of oil, dispersants, arsenic and other toxic compounds are having effects on seafood that may not be detectable for months."

Markey, chair of the House Select Committee on Energy Independence and Global Warming, said researchers have uncovered droplets of oil found inside crab larvae harvested from gulf waters near Pensacola, Florida; Galveston, Texas; and Grand Isle, Louisiana. "In some areas, 100 percent of the larvae recovered contain droplets of oil hydrocarbons, a major concern given that crab is a favorite food for both humans and multiple fish species that live in the marshes," Markey wrote. "What this means is that despite fishery closures in areas that are known to be contaminated by oil, contamination could still be spreading into the human food chain as predators eat oil-tainted species, then travel to areas that are not themselves closed to fishing."

Markey has asked FDA to provide information that includes (i) how the agency will monitor human health risks and the long-term effects of oil, other hydrocarbons and other toxic compounds on aquatic life; (ii) how the agency plans to conduct long-term monitoring of arsenic to ensure that it will not bioaccumulate in the food chain for months or years after the oil is visibly removed; and (iii) how much arsenic in seafood can be consumed by humans per federal standards.

FTC Settles First Probiotics Advertising Case, Nestlé to Stop Touting Health Benefits

The Federal Trade Commission (FTC) has **announced** a settlement with Nestlé HealthCare Nutrition, Inc., which the agency contends has deceptively marketed a children's drink, BOOST Kid Essentials®, as a product clinically shown to reduce illness in children by strengthening the immune system and helping them recover more quickly from diarrhea. The beverage, intended for children ages 1 to 13, contains probiotics embedded in a straw that was "prominently featured in ads for the product."

According to the FTC, the company has agreed to stop making health-related claims about cold or flu viruses "unless the claim is approved by the Food and Drug Administration." The company has also agreed to cease making claims about diarrhea and reduced absences from day care or school "unless the representation is non-misleading and, at the time of making such representation, the [company] possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true."

Nestlé may not, under the agreement, make any other health representations without "reliable scientific evidence," defined as "tests, analyses, research, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results." The agreement will bind the company for the next 20 years. The company did not admit to any wrongdoing and is not required to pay a fine under the settlement. *See FTC Press Release*, July 14, 2010; *The Wall Street Journal*, July 15, 2010.

FDA Seeks Comments on Federal Law Requiring Calorie Postings on Menus, Vending Machines

The Food and Drug Administration (FDA) is **seeking** public comments on a new federal law that requires certain chain restaurants and retail food operations to post the calorie content of individual items on menus, menu boards and drive-through menu boards. Enacted March 23, 2010, **section 4205** of the Affordable Care Act applies to food establishments with 20 or more locations, such as restaurants, coffee shops, delis, movie theaters, bakeries, and ice cream shops. Per-serving information related to the amount of calories, cholesterol, fiber, sodium, sugars, total and complex carbohydrates, total and saturated fat, and total protein must be available in writing on request. The law also compels vending machine operators with 20 or more machines to list calorie information "in close proximity to" each article of food or the selection button.

The law instructs FDA to issue proposed regulations to carry out these provisions by March 23, 2011. The agency has requested comments from the food industry, state and local governments, consumers, and other interested parties by September 7, 2010. *See Federal Register*, July 7, 2010.

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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FDA Announces Information Collection on Food Labeling Regulations

The Food and Drug Administration (FDA) has **submitted** to the Office of Management and Budget a proposed information collection related to food labeling regulations. According to FDA, these regulations govern the submission of food labeling petitions and require food producers to: (i) disclose specific information about themselves or their products on labeling; (ii) retain records establishing the basis for the information contained on labeling; and (iii) provide these records to regulatory officials.

The information collection notice provides estimated annual reporting and recording keeping burdens for these regulations. FDA has noted that it is no longer combining these burden hour estimates with those in information collections titled, "Food Labeling: Nutritional Labeling of Dietary Supplements on a 'Per Day' Basis" and "Food Labeling: Trans Fatty Acids in Nutrition Labeling," although "[s]uch consolidation may occur in the future." The agency will accept comments until August 16, 2010. *See Federal Register,* July 15, 2010.

European Commission Issues New Recommendation for GM Crops

The European Commission has proposed **legislation** that would allow member states to set their own policies for regulating genetically modified (GM) crops. If approved by the European Parliament and individual governments, the proposal would permit countries to approve, restrict or prohibit the cultivation of GM crops, even those deemed safe by the scientific mechanisms currently in place. Under this new framework, member states could bar GM crops for reasons "other than the identification of a risk for the environment, human or animal health." *See EC Citizen's Summary,* July 13, 2010.

The proposed legislation apparently seeks to end a 12-year gridlock among member states with different stances toward GM crops. In light of this dilemma, the commission has also drafted new **recommendations** for avoiding the unintended presence of GM products in those marketed as GM-free. This non-binding guidance (i) "allows for measures aiming to limit GMO content in conventional food and feed to levels below the labeling threshold of 0.9 [percent]"; (ii) "clarifies that Member States can establish 'GMO-free' area [sic]"; and (iii) "provides better guidance to Member States to develop co-existence approaches." In addition, according to a July 13, 2010, press release, the European Co-existence Bureau will continue developing "best practices for co-existence as well as technical guidelines on related issues."

Meanwhile, Friends of the Earth (FOE) has publicly dubbed the proposal "deeply flawed, legally and politically." The environmental group has reportedly argued that the legislation offers member states additional ethical objections only, "which are legally intangible, subjective and easily overturned in court," in exchange for relaxed vigilance during the application and scientific review process. "Any country wanting to ban GM crops under these proposals will open themselves up to legal challenges from biotech corporations who want to force GM crops into Europe," one FOE spokesperson was quoted as saying. *See The Parliament,* July 14, 2010.

FSA Targeted as Next Victim of Coalition Government's Austerity Measures

The UK Food Standards Agency (FSA) is reportedly the next target of the new Conservative-Liberal Democrat coalition government and Secretary of State for Health Andrew Lansley, who has released a **white paper** pledging to cut the

National Health Service (NHS) and abolish quasi-governmental organizations "that do not need to exist." Although a **structural plan** published alongside the paper recommends reforms to the food safety watchdog, media reports have cited unidentified sources as suggesting that Lansley plans to eliminate FSA and relocate its duties to the Department of Health (DH) and the Department for Food, Rural Affairs and the Environment (Defra). DH, however, has countered these claims, maintaining that under the proposed reorganization, FSA would relinquish its oversight of nutrition policy but continue to serve "a robust regulatory function." *See The Guardian,* July 12, 2010; *DH Press Statement,* July 15, 2010.

The rumor has drawn swift criticism from consumer and health groups such as the National Obesity Forum, which lambasted the Conservative Party for "being the political wing of business." In addition, former European Food Safety Authority Chair Patrick Wall told *FoodProductionDaily.com* that complete abolition of FSA "would be a retrograde step." He noted that the non-ministerial agency was created in 1999 to alleviate conflicts of interest arising from Defra's mandate to both promote agriculture and police it. "The FSA has one of the best scientific advisory structures in the world and to dismantle this and go back to a politically set agenda may be a huge mistake and both the agrifood sector and consumers could be losers," he was quoted as saying. *See FoodProductionDaily.com,* July 13, 2010.

Meanwhile, Lansley has already **announced** termination of the $120 million Change4Life anti-obesity marketing campaign. He has purportedly asked the commercial sector to pick up the tab for these health education efforts in exchange for a non-regulatory approach. "No government campaign or program can force people to make healthy choices," Lansley reportedly said in a July 7 speech at the UK Faculty of Public Health Conference. "We want to free business from the burden of regulation, but we don't want, in doing that, to sacrifice public health outcomes." *See The Guardian,* July 7, 2010; *Advertising Age,* July 8, 2010.

Change to Cadmium Prop. 65 Maximum Allowable Dose Level Proposed

California EPA's Office of Environmental Health Hazard Assessment has issued a **notice** indicating that it has proposed adding the qualifier "oral" to the maximum allowable dose level (MADL) for cadmium. Apparently, this qualifier was inadvertently omitted when the MADL of 4.1 micrograms per day was adopted under Proposition 65 (Prop. 65) in 2002. Comments must be submitted no later than August 23, 2010. Cadmium has apparently been used as a plasticizer, and some studies have indicated that it can be transferred to food by its use in fertilizer.

LITIGATION

Ninth Circuit Disciplines Lawyers Who Tried to Enforce Nicaraguan Pesticide Exposure Judgment in U.S. Courts

The Ninth Circuit Court of Appeals has imposed a suspension, a formal reprimand and fines on several attorneys who attempted to enforce in U.S. courts a $489 million default judgment entered by a Nicaraguan court against a business entity that did not exist for allegedly exposing hundreds of banana plantation workers to pesticides. ***In re: Thomas V. Girardi, Esq.*, Nos. 08-80090, 03-57038 (9th Cir., decided July 13, 2010)**. The litigation in Nicaragua had been filed against "Dole Food

Corporation" and "Shell Oil Company," but should instead have named "Dole Food Company" and "Shell Chemical Company."

According to the court, "In a high-stakes gamble to enforce a foreign Judgment of nearly a half billion dollars, Respondents initiated and directed years of litigation against Defendants. Respondents efforts went beyond the use of 'questionable tactics'—they crossed the line to include the persistent use of known falsehoods." Those falsehoods included that (i) "Dole Food Company was named as a judgment debtor by a Nicaraguan court"; (ii) "the Nicaraguan court corrected any mistakes it might have made regarding Dole Food Company in its judgment by the Writ of Execution"; and (iii) "Respondents had submitted the corrected Writ of Execution to the state court and the federal district court."

The court reportedly suspended Walter Lack from practicing before the Ninth Circuit for six months and reprimanded Thomas Girardi. Fees and costs of nearly $400,000 were also imposed against the lawyers and their law firms. *See New York Lawyer*, July 14, 2010.

In a related development, a federal court has reportedly reversed a $2.3 million verdict against Dole Food Co. in a case alleging that the use of pesticides on its Nicaraguan plantations caused the sterilization of six plantation workers. The court had heard testimony that the verdict was a product of fraud and apparently concluded that the company and court were the victims of a massive fraud that included testimony offered by the plaintiffs from workers who had never worked on the plantations and others who fathered children after their alleged exposure made them sterile. *See The Kansas City Star,* July 7 and 15, 2010.

Expert Testimony Excluded as Unreliable; Consumer's Popcorn Lung Claims Dismissed

A federal court in Washington has dismissed the lawsuit filed by a man who alleged that inhaling the diacetyl in fumes from four to six bags of microwave popcorn daily caused his lung disease. *Newkirk v. ConAgra Foods, Inc.*, No. 08-273 (U.S. Dist. Ct., E.D. Wash., decided July 2, 2010). Additional information about this litigation appears in issue 274 of this Update.

Represented by the Independence, Missouri, attorney who has brought claims on behalf of popcorn factory workers and other consumers, Larry Newkirk sought to introduce the general causation opinion of physician David Egilman and the specific causation opinions of Dr. Charles Pue, Dr. Allan Parmet and William Ewing. The court analyzed Egilman's proposed testimony and found it unreliable on a number of grounds, including that he sought to extrapolate residential diacetyl exposures from industrial exposures, which have been extensively studied and associated with bronchilitis obliterans, a debilitating lung disease also referred to as "popcorn lung." According to the court, the witness had no basis for making this extrapolation.

Because the proffered specific causation witnesses relied on Egilman's opinion, the court ruled that their testimony was also unreliable and must be excluded. Lacking any evidence of causation, the plaintiffs' claims for negligence, design defect, failure to warn, and loss of consortium were dismissed with prejudice, and the court ordered the file closed.

Third Crunch Berries® Class Action Dismissed

A federal court in California has dismissed a putative class action alleging that consumers were misled into believing that Cap'n Crunch's Crunch Berries® cereal contained real berries or fruit. *Werberl v. PepsiCo, Inc.*, No. 09-04456 (U.S. Dist. Ct., N.D. Cal., Oakland Div., decided July 1, 2010). Noting that one law firm had filed unsuccessful suits in two other California federal district courts on behalf of two other class representatives, the court observed that the claims before it were "virtually identical." Additional information about the dismissal of one of the other cases appears in issue **306** of this Update.

According to the court, "no reasonable consumer would believe that Cap'n Crunch derives any nutritional value from berries" and any reliance on the use of the term "crunch berries" to imply "that real berries or fruit are contained in the cereal would neither be reasonable nor justifiable." The court also found that leave to amend was unwarranted and denied plaintiff's request for leave to amend "on the grounds of bad faith." In this regard, the court stated, "This is Plaintiff's counsel's third attempt to pursue a class action against PepsiCo based on the same inherently flawed theory of liability. Instead of pursuing further relief in the Central and Eastern District actions, Plaintiff's counsel simply abandoned those cases, undoubtedly aspiring to obtain a favorable result in another District. The Court will not countenance such forum shopping."

Court Asks FDA to Decide Whether HFCS Is "Natural"

A federal court in New Jersey has reportedly stayed for six months consumer fraud litigation against the company that makes Arizona Iced Tea® beverages and has asked the Food and Drug Administration (FDA) to determine whether high-fructose corn syrup (HFCS) qualifies as a "natural" ingredient. *Coyle v. Hornell Brewing Co.*, No. 08-2797 (U.S. Dist. Ct., D.N.J., stay order entered June 15, 2010). Claiming that these beverages are deceptively marketed as "100% Natural" despite containing HFCS, the plaintiff alleges violation of the New Jersey Consumer Fraud Act, unjust enrichment and common-law restitution, and breach of express and implied warranties.

The court issued the stay rather than dismiss the putative class action outright as requested by the defendants on the basis of the doctrine of primary jurisdiction. According to a news source, the court acknowledged that "categorizing HFCS as either natural or artificial for the purpose of food and beverage labeling does not fall within the conventional experiences of judges." He also reportedly said, "Although Plaintiff contends that she is not asking the Court to define the term 'natural,' the entire claim—that Defendants improperly labeled their beverages as '100% NATURAL' despite containing HFCS—rests on an initial determination of whether HFCS is a 'natural' substance. This question lies within the FDA's particular field of expertise regarding food chemistry and the labeling of food and beverage products." *See New Jersey Law Journal*, June 17, 2010; *Mealey's Food Liability*, July 2, 2010.

NRDC Continues Challenge to BPA in Contact/Packaging Materials

As part of its ongoing campaign to persuade government authorities to prohibit the use of bisphenol A (BPA), the Natural Resources Defense Council (NRDC) recently filed a lawsuit in the D.C. Circuit Court of Appeals seeking to force the Food and Drug Administration (FDA) to take action on a petition the organization filed

in October 2008 requesting that the agency prohibit the chemical's use in food packaging. ***In re: NRDC, Inc.*, No. 10-1142 (D.C. Cir., filed June 29, 2010)**.

One year ago, NRDC also submitted a petition to California EPA's Office of Environmental Health Hazard Assessment, requesting that BPA be added to list of chemicals "known to the state to cause reproductive toxicity" under the Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Prop. 65).

In its lawsuit, NRDC notes that more than 600 days have passed since its FDA petition was filed, and the NRDC reiterates its contentions that (i) FDA has the authority to regulate food additives such as BPA; (ii) BPA in food packaging and food contact materials leaches into food products and can be found in the urine samples of 93 percent of Americans tested; and (iii) BPA exposure "at current levels presents a clear risk to human health."

The bulk of NRDC's brief focuses on the organization's standing to seek a writ of mandamus and how the matter meets relevant legal standards that support the grant of such writs. Among other matters, NRDC argues that FDA has no competing priorities justifying the delay in addressing its petition, citing FDA's **express concerns** about BPA's potential effects "on the brain, behavior, and prostate gland of fetuses, infants and children."

Attached to the brief are affidavits, including one from a physician discussing the purported "health effects of endocrine-disrupting chemicals, including bisphenol A (BPA)." It outlines scientific research on this topic and refers to the governmental authorities that have taken action to prohibit the chemical's use in products, such as baby bottles and sippy cups, to which infants and toddlers would be exposed.

The American Chemistry Council responded to news about the lawsuit by issuing a statement, saying that the industry trade group "believes that the scientific process and the public interest are both best served by allowing the FDA to complete its ongoing review of the science surrounding the safety profile of BPA." The council also stated, "In an update in January, the U.S. Department of Health and Human Services and the FDA made it clear that BPA 'is not proven to harm children or adults…' This is consistent with a draft assessment issued by FDA in 2008, and the scientific conclusions of many other government regulatory agencies around the world."

In a related development, the Australian government has reportedly reached an agreement with major retailers to phase out the sale of BPA-containing baby bottles, beginning July 1, 2010. While Parliamentary Secretary for Health Mark Butler noted that "Food Standards Australia New Zealand (FSANZ) has evaluated the safety of BPA and plasticizers in baby bottles and concluded that levels of intake of BPA or plasticizers are very low and to not pose a risk to babies' health," he commented that the voluntary agreement was designed to allay public concerns about the chemical. *See ACC Press Release*, June 29, 2010; *FoodProductionDaily.com*, June 30, 2010.

Louisiana Rice Farmer Awarded $.5 Million Against GM Rice Maker

According to news sources, a St. Louis jury has awarded more than $500,000 to a Louisiana farmer who alleged that when the U.S. rice supply was contaminated in 2006 with a genetically modified (GM) crop that was somehow released from testing facilities, he lost $1.5 million due to lost sales abroad. *In re: Genetically*

Modified Rice Litig., MDL No. 1811 (U.S. Dist. Ct., E.D. Mo.). The lawsuit is the third to reach trial of more than 500 consolidated before a multidistrict litigation court in eastern Missouri; it marks the third loss in federal court for the defendant, which is facing more than $52 million in jury awards. Two state trials also resulted in plaintiff verdicts. While the defendant has not apparently disputed the contamination, it has denied that it was negligent and contends that rice sales recovered shortly after the initial plunge. *See Bloomberg Businessweek* and *Post Dispatch*, July 14, 2010.

MEDIA COVERAGE

Food Blogger Claims Agribusiness Takes Page from Tobacco Playbook

La Vida Locavore blogger Jill Richardson claims in a July 6 AlterNet article that a recent Webinar touting a "perspective on pesticide residues" was benignly marketed to federal and state health officials by a "self-described non-profit organization," the Alliance for Food and Farming. While the Alliance's Website does not identify its supporters, Richardson asserts that the organization is an industry "front group" representing California-based farm and pesticide interests, one of which apparently argued in the film *Food, Inc.* that "foods containing clones should not be labeled."

"[F]ront groups are a common vehicle industry uses to delude, confuse, and sometimes overtly defraud the public," Richardson says. She cites author Anna Lappé's book *Diet for a Hot Planet* highlighting a 1969 tobacco industry internal memo that discusses "establishing a controversy," and Lappé opines that "The food industry long ago saw the benefits of fomenting confusion; confusion defuses public outcry about our toxic food system. Long after the discovery of the neurotoxic, carcinogenic, endocrine-disrupting effects of farm chemicals, we're still debating the merits of organic agriculture."

Richardson points to other purported industry front groups, naming the American Council on Science and Health and the Center for Consumer Freedom, and refers to Websites maintained by companies that promote industrial agriculture and processed foods. She characterizes the American Farmers for the Advancement and Conservation of Technology, which defends the use of recombinant bovine growth hormone and calls itself "grassroots," as "about as grassroots as a smokers' rights group organized by a tobacco company." Richardson also discusses how industry spends millions to "influence government, the media, health professionals, and consumers." She recommends that consumers consult certain Internet resources to decide which sources of information are credible, clearly implying that the industry point of view cannot be trusted. *See AlterNet*, July 6, 2010.

Elana Schor, "Hydrocarbons in Cereal Stoke New Debate Over Food Safety," *The New York Times,* July 13, 2010

This article examines the fallout from Kellogg Co.'s recall of 28 million cereal boxes that, according to a public statement, contained "elevated levels of hydrocarbons, including methyl naphthalene, normally found in the paraffin wax and film in the liners." The company voluntarily pulled the products after receiving complaints about an "off-flavor and smell," which caused nausea and other gastrointestinal ailments in some consumers.

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Schor highlights the failure of Congress to pass reform measures that would allow the Food and Drug Administration (FDA) to issue mandatory recalls. "[T]he legislation sits in limbo in the upper chambers as industry groups chafe at Sen. Dianne Feinstein's (D-Calif.) bid to ban another chemical with an unclear safety history, bisphenol A, from food containers," she writes.

Citing a recent Environmental Working Group (EWG) report that underscores the potential toxicity of methyl naphthalene, Schor raises questions about the overall safety of food packaging. EWG has "urged Kellogg to release its third-party testing of the recalled cereal boxes and recommended stricter food safety laws." In addition, states Schor, EWG has noted that "U.S. EPA and the Agency for Toxic Substances and Disease Registry (ATSDR), a division of the Centers for Disease Control and Prevention, have both cited a lack of data in declining to rule on the human carcinogenicity of methylnaphthalene."

Meanwhile, the Center for Science in the Public Interest (CSPI) has also called on FDA to "take a closer look at the packaging of consumer products and this chemical that's been identified as a problem." As EWG Vice President for Research Jane Houlihan added, "There are potentially many thousands of chemicals that could leach out of these materials into our food. In this case, methylnaphthalene and other hydrocarbons are what Kellogg's is saying publicly about what ended up in their cereal. They need to be more forthcoming about exactly what they found." *See FoodProductionDaily.com*, July 13, 2010. ■

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