Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Officials Question Safety of Melatonin-Laced Baked Goods

U.S. Senator Dick Durbin (D-Ill.) has **asked** the Food and Drug Administration (FDA) "to clarify its authority to regulate foods that contain additives, such as baked goods that contain high doses of melatonin," after media reports drew attention to so-called "relaxation brownies" touted for allegedly alleviating stress and easing sleep deprivation.

In a May 18, 2011, letter to FDA Commissioner Margaret Hamburg, Durbin argues that melatonin-laced sweets "with names such as Lazy Cakes, Kush Cakes and Lulla Pies" could raise health concerns for consumers who "may not recognize they are consuming a neurohormone, that they should consult a doctor before eating it, and that it may not be appropriate for children, people with auto-immune diseases, or women who are pregnant or breast-feeding." He notes that these products contain "roughly 8 milligrams of melatonin—almost double the upper limit of a typical dose" set by the Natural Medicines Comprehensive Database, which advises consumers to avoid driving or using machinery for four to five hours after taking melatonin, and warns that melatonin "may interact with contraceptive drugs, diabetes medications, and depressants."

Durbin questions whether FDA should continue to classify "relaxation brownies" as dietary supplements that do not require pre-market approval, noting that some of these baked goods "appear to be promoting themselves as therapeutic alternatives to medications," and, as such, "may be marketed in ways that are inconsistent with federal law." As his letter concludes, "The FDA has not approved melatonin as an additive in foods. If the FDA makes a determination that these products are foods containing a dietary ingredient additive, the manufacturers would be responsible for determining that melatonin is generally regarded as safe or failing this, the FDA would have to approve or reject melatonin as a food additive."

Meanwhile, the Arkansas Department of Health (ADH) has already recalled Lazy Cakes, and two Massachusetts towns—New Bedford and Fall River—are reportedly seeking to ban similar products. ADH has advised consumers to

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discard the product and prohibited its sale in the state, claiming that melatonin "has not been approved for general food use" and that its side effects are not fully known. "ADH believes this product poses a potential health risk to consumers, especially young children," states a May 19, 2011, press release. "The ADH has received complaints about this product being sold in food stores (mainly convenience stores) without prominent labeling and easily accessible to children." *See The New York Times,* May 14, 2011; *Reuters,* May 18, 2011; *Law360,* May 19, 2011.

FDA Oversight of Imported Seafood Lacking, Says GAO

The Government Accountability Office (GAO) has issued a **report** criticizing the Food and Drug Administration's (FDA's) oversight of imported seafood safety. Noting that about one-half of imported seafood comes from fish farms that may use antibiotics to prevent bacterial infections, the report claims that "residues of some drugs can cause cancer and antibiotic resistance."

Titled "FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources," the report urges FDA to enhance its import sampling program. "FDA's oversight program to ensure the safety of imported seafood from residues of unapproved drugs is limited, especially as compared with the European Union," the report states, adding that FDA inspectors "generally do not visit the farms to evaluate drug use or the capabilities, competence, and quality control of laboratories that analyze the seafood."

The report also recommends that FDA (i) "study the feasibility of adopting practices used by other entities to better ensure the safety of imported seafood," and (ii) "develop a strategic approach" to enhance collaboration with the National Marine Fisheries Service.

Imported Food Safety Target of IOM Meeting

The Institute of Medicine's (IOM's) Food and Nutrition Board has **announced** a June 7, 2011, meeting that will focus on the safety of imported foods "with the purposed of engaging science, technology, and policy personnel representing the global food supply chain, government agencies, and academia."

Titled "Food Forum Meeting on Supply Chain and Policy/Regulatory Approaches to Import Safety," the meeting will include a morning panel featuring actors representing the supply chain "from producer to retailer/food service provider" and an afternoon panel of government officials representing "governance processes from the state to global level."

By focusing on the Food and Drug Administration's new authority granted under the Food Safety Modernization Act (FSMA), including "importer accountability, third party certification, certification for high risk foods,

voluntary qualified importer program, and authority to deny entry," the meeting aims to "provide perspectives and ideas useful for the development and implementation of the multifaceted import tools available in FSMA," according to IOM.

California Bill Would Ask Docs to Study Effects of Food on Health

The California Senate's Business, Professions and Economic Development Committee has reportedly passed a bill (**S. 380**) that would permit the Medical Board of California to "set content standards for any educational activity concerning a chronic disease that includes appropriate information on the impact, prevention, and cure of the chronic disease by the application of changes in nutrition and lifestyle behavior." The legislation would amend Section 2190 of the Business and Professions Code that deals with mandatory continuing medical education and authorize the board "to also set content standards for an educational activity concerning chronic disease, as specified." *See John McDougall Press Release,* May 16, 2011.

Backed by the American College of Lifestyle Medicine and the Physicians Committee for Responsible Medicine, the bill was evidently authored by John McDougall, a physician known for emphasizing the role of diet in preventing chronic disease. McDougall currently appears in the film **"Forks over Knives,"** which apparently "examines the profound claim that most, if not all, of the so-called 'diseases of affluence' that afflict us can be controlled, or even reversed, by rejecting our present menu of animal-based and processed foods."

LITIGATION

False Advertising Case Against Cereal Maker Dismissed with Leave to Amend

A federal court in California has reportedly dismissed without prejudice putative class claims filed against General Mills Inc. alleging that the company falsely conveyed to consumers that its Total Blueberry Pomegranate® cereal product contained real fruit. *Dvora v. Gen. Mills Inc.*, No. 11-1074 (U.S. Dist. Ct., C.D. Cal., dismissed May 16, 2011). According to a news source, the court determined that the plaintiff's state-law claims were preempted by federal product-labeling laws that allow a manufacturer to use a fruit's name and image to describe a flavor even if the product contains no fruit. The claims were apparently based on allegations that the product was falsely labeled "naturally and artificially flavored" and the packaging was misleading.

The court disagreed, saying, "If you look at the ingredients table, blueberry and pomegranate aren't there. So I don't understand how a reasonable consumer is somehow tricked into thinking it contains blueberry and pomegranate." The court also said in its tentative ruling, "The cereal package

includes a picture of the cereal containing 'clusters.' Although—with all respect to plaintiff—it is difficult to imagine anyone mistaking said clusters for actual blueberries or pomegranate seeds." While the plaintiff sought to convince the court that the claims were about false advertising and unfair competition, the court maintained that this was a "flavors case," and that the company complied with federal flavoring regulations. The plaintiff will have until June 7, 2011, to amend his complaint. *See Law360*, May 16, 2011.

Court Gives Preliminary Approval to Settlement of Discrimination Case Against USDA

A federal court in the District of Columbia has issued an order granting preliminary approval of a settlement agreement involving a class of African-American farmers who "submitted late-filing requests under Section 5(g) of the *Pigford v. Glickman* Consent Decree on or after October 13, 1999, and on or before June 18, 2008," but had not yet obtained a determination on the merits of their discrimination complaints. *In re: Black Farmers Discrimination Litig.*, No. 08-0511 (U.S. Dist. Ct., D.D.C., filed May 13, 2011). The order certifies the class and sets a "cost cap" of $35 million with payment of up to $3.5 million for class counsel fees and costs. Class members are enjoined from bringing any other claims arising out of section 14012 of the Food, Conservation, and Energy Act of 2008. These lawsuits alleged that the U.S. Department of Agriculture systematically discriminated against African-American farmers on the basis of race. The court has scheduled at September 1, 2011, hearing for final settlement approval.

Infringement Alleged for "Give 'Em the Bird" Bourbon Mark

Rare Breed Distilling has filed a trademark infringement action in a Kentucky federal court alleging that Jim Beam Brands' use of "Give 'Em the Bird" in connection with its Old Crow bourbon whiskey "is likely to confuse and deceive consumers and purchasers of bourbon whiskey products." *Rare Breed Distilling LLC v. Jim Beam Brands Co.*, No. 11-292 (U.S. Dist. Ct., W.D. Ky., filed May 13, 2011). Rare Breed has apparently used "Give Them the Bird," which evolved into "Give 'Em the Bird," since 2006, in connection with its Wild Turkey® bourbon whiskey products. The plaintiff alleges that Jim Beam adopted identical marks for use and filed a still pending application to register the mark in March 2010. According to the complaint, Jim Beam has refused to acknowledge Rare Breed's prior rights to the mark and continues to use it.

Alleging federal trademark infringement and unfair competition, and common law unfair competition, the plaintiff seeks an order enjoining Jim Beam from using Rare Breed's mark "and any other marks that are confusingly similar to Plaintiff's marks in connection with Old Crow bourbon whiskey or any other beverage alcohol product." The plaintiff also seeks an order requiring Jim Beam

to destroy infringing material, to provide an accounting of all sales related to its use of the mark and to abandon its application to register the mark. Rare Breeds seeks actual, treble, exemplary, and punitive damages.

Earlier this year, a federal court in New York dismissed a complaint filed by a tequila maker which sought a court order declaring that its use of a crow image, "the Cuervo Bird Design," did not infringe Jim Beam's federal trademark rights. *Tequila Cuervo La Rojena, S.A. de C.V. v. Jim Beam Brands Co.*, No. 10-203 (U.S. Dist. Ct., S.D.N.Y., decided February 8, 2011). According to the court, Jim Beam offered to stipulate that it would not sue Cuervo for infringement, and this made the declaratory judgment action moot. Jim Beam apparently owns four trademarks depicting crows and entered a contract with Cuervo in 1997 under which Cuervo agreed to limit its use of the Cuervo Bird Design. In 2008, Jim Beam accused Cuervo of violating those limits and sued it for breach of contract in state court. That action, which seeks royalties, remains pending.

Family Farmer Says FDA's Tomato Recall Was Reckless, Seeks Damages

A South Carolina-based family farming operation has filed a complaint seeking damages that it alleges were sustained in 2008 when the Food and Drug Administration (FDA) issued a nationwide recall of round tomatoes due to a purported *Salmonella* outbreak. *Seaside Farm, Inc. v. United States*, No. 11-1199 (U.S. Dist. Ct., D.S.C., Beaufort Div., filed May 18, 2011). The plaintiff claims that independent audits before the recall was announced verified that its produce and practices were safe.

Still, according to the complaint, "At the time of the recall, the FDA had not positively identified a single tomato as a current source of the salmonella outbreak in the United States" and "The FDA never identified any contaminated tomatoes and ultimately conceded that tomatoes were not the source of the salmonella contamination." Claiming that the recall "decimated the market price for fresh tomatoes," the plaintiff seeks unspecified general and special compensatory damages and interest under the Federal Tort Claims Act. The farming operation alleges negligence, violations of the Takings Clause and the South Carolina Uniform Trade Practices Act, and defamation.

Waffle House Worker Claims Owner Falsely Reported That Minimum Wage Was Paid

A former employee of an Olathe, Kansas, waffle venue has brought a collective action against his employer alleging that it reported inaccurate tip earnings so that it would appear that his total earnings were compliant with the federal minimum wage. *Spears v. Mid-America Waffle House, Inc.*, No. 11-2273 (U.S. Dist. Ct., D. Kan., filed May 2010). Jared Spears, who was paid an hourly wage of $2.13 plus tips, contends that when he complained about the issue, he was given fewer hours to work and his wage "was further reduced by a mandatory

meal credit that was deducted from his compensation whether he ate a meal or not." He claims damages in excess of $75,000 and seeks injunctive and declaratory relief.

Alcohol Energy Drink Maker Sued in Teen's Death

According to a news source, the family of a teenager has sued Phusion Projects, which makes the alcohol energy drink Four Loko®, alleging that their son's disorientation after drinking two of the beverages led to his fatal accident. *Rupp v. Phusion Projects*, No. n/a (Cook County Cir. Ct., Illinois, filed May 19, 2011). He allegedly consumed the beverage during a concert in 2010, and his parents picked him up after concert staff contacted them claiming the boy "appeared extremely intoxicated." The family alleges that their son acted "paranoid and disoriented" on the ride home and took off running when they arrived home. He apparently died when he was struck by a car after running onto a busy highway.

The family reportedly alleges in the wrongful death lawsuit that the company "was careless and negligent in formulating a caffeinated, alcoholic beverage that desensitizes users to the symptoms of intoxication, and increases the potential for alcohol-related harm." The complaint contends that one 23-ounce can of Four Loko® contains about as much alcohol as a six-pack of beer and that the company targets youths by making the product with fruit flavors. The teen's mother was quoted as saying, "I hope other parents will talk to their children about this drink. We don't want any other family to go through the sheer terror of losing a child."

Phusion has reportedly indicated that it plans to fight the lawsuit and denied marketing its products to underage drinkers. The company removed the product's caffeine in December 2010, after the Food and Drug Administration warned that the added caffeine was an "unsafe food additive." *See Chicago Sun Times*, May 19, 2011.

OTHER DEVELOPMENTS

Physicians, Scientists Call for More Pesticide Testing on Kids' Favorite Fruits, Veggies

A group of physicians and scientists has written a **letter** to federal agencies calling for more pesticide testing on children's favorite fruits and vegetables. Noting that the U.S. Department of Agriculture (USDA) typically releases latest data on pesticide residues on fruits and vegetables each January but has yet to do so this year, the May 6, 2011, letter urges officials from the USDA, EPA and FDA to "speed the release" of such data.

Signed by leaders of medical schools such as Columbia University, Harvard, Mount Sinai, and Stanford, the letter warns that growing evidence shows pesticide consumption can cause lasting harm to children's brain development. "Children are uniquely sensitive to harmful effects from pesticides," the letter states. "Yet they eat substantial quantities of certain fresh fruits and vegetables—apples, berries, peaches, for example—proven to contain multiple pesticide residues. We urge you to expand testing programs and share ample information with the public about pesticides in all produce, especially those that show up in children's diets."

The letter also specifically calls for the federal government to (i) "bolster FDA's Total Diet Study and USDA's Pesticide Data Program to make them even more informative and transparent", (ii) "test annually all fresh produce commonly eaten by children, especially those likely to carry significant pesticide residues"; (iii) "conduct more extensive CDC and EPA dietary studies to assess varying risks to children who eat seasonal and local produce"; (iv) "expand monitoring of pesticide residues for imported foods"; (v) "tighten regulations governing pesticide residues on food crops to ensure 'reasonable certainty of no harm' for children and other people most sensitive to pesticide effects"; and (vi) "enhance efforts to promote organic fruits and vegetables as options for consumers concerned about pesticide exposure, especially for children."

McDonald's Declines to Retire Iconic Clown

McDonald's Corp. investors have reportedly rejected a shareholder proposal that asked the company to prepare a report assessing the role of fast food in "childhood obesity, diet-related diseases and other impacts on children's health." Led by the Sisters of St. Francis of Philadelphia, which apparently owns $2,000 in company stock, the proposal coordinated with an open letter campaign launched by Corporate Accountability International (CAI) that asked McDonald's CEO Jim Skinner to retire "marketing promotions for food high in salt, fat, sugar, and calories to children, whatever form they take—from Ronald McDonald to toy giveaways." The letter apparently ran in several media outlets, including the *Chicago Sun-Times, New York Metro* and *San Francisco Examiner*, and garnered signatures from more than 550 health professionals and organizations.

At the May 19, 2011, shareholder meeting, however, the company recommended a "no" vote on the proposal, and Skinner evidently defended the iconic clown as an "ambassador for good" and the face of the Ronald McDonald House. "He does not advertise unhealthy food to children," Skinner was quoted as saying. "McDonald's does not advertise unhealthy food choices to children. It is up to them to choose and their parents to choose. And it's their responsibility to do so. Ronald McDonald is going nowhere." *See Advertising Age,* May 17, 2011; *The Wall Street Journal,* May 18, 2011; *Reuters* and *Syracuse.com,* May 19, 2011; *QSR Web.com,* May 20, 2011.

Growth Chemical Blamed for Bursting Watermelons in China

Watermelons have reportedly been bursting on farms in eastern China during recent wet weather, a phenomenon that state media attribute to the growth chemical forchlorfenuron. Jumping into a burgeoning watermelon market, approximately 20 first-time users of the chemical reportedly lost up to 115 acres after applying it too late in the season on an inappropriate variety of melon. Dubbed the "exploding melon" because of its tendency to split, most of the ruined fruit was apparently fed to fish and pigs. Legal in the United States on kiwi and grapes and allowed in China in general, forchlorfenuron is safe when used properly, according to a horticulture professor quoted by a news source. *See Associated Press,* May 17, 2011.

MEDIA COVERAGE

Natasha Singer, "Foods with Benefits, or So They Say," *NYT*, May 14, 2011

"Push a cart through … any supermarket anywhere in America, and you just might start believing in miracles—or at least in food miracles," according to Natasha Singer writing in *The New York Times* about the latest trends in functional foods. "In aisle after aisle, wonders beckon. Foods and drinks to help your heart, lower your cholesterol, trim your tummy, coddle your colon. Toss them into your cart and you might feel better. Heck, you might even live longer." Singer asks whether these products are actually healthy "or are some of them just hyped."

Noting that the functional food market increased by nearly $10 billion since 2005 to $37.3 billion in 2009, Singer reports that federal regulators and others are concerned about the accuracy of health marketing claims. The article quotes New York University Professor Marion Nestle, who contends, "Functional foods, they are not about health. They are about marketing." As an example of possibly misleading claims, the author points to an oatmeal-based cereal that proclaims in large print that it "helps reduce cholesterol," while the small print indicates that three servings, at nearly 650 calories, would have to be consumed to obtain the amount of soluble fiber recommended daily to benefit health.

According to the article, consumers cannot evaluate such products and have to rely on experts and regulators to ensure that health-benefit claims are valid. While industry trade groups contend that most of the claims are within the letter of the law, the author reports that the Federal Trade Commission (FTC) has begun pursuing food companies that have allegedly crossed that line and secured agreements restricting the health-related claims they make. FTC Bureau of Consumer Protection Director David Vladeck is reportedly concerned that people will buy these products and, lacking health insurance, will forego flu shots or medical tests thinking the foods they eat will bolster

their immunity or reduce the risk of disease. Vladeck said, "If people are going to spend their money for health benefits, they ought to get them." Food and Drug Administration regulators have expressed frustration with limited resources in an environment where marketers simply change their claims after one is deemed misleading.

The author concludes by observing that whether functional foods actually provide health benefits, they can evidently provide a placebo effect, because "many people want to believe."

Is Ethical Line Crossed When Children "Like" Products?

An *Advertising Age* article discusses recent litigation filed by parents against Facebook® alleging that the social network has used names and/or likenesses of their children in product endorsements without obtaining parental consent. While no child younger than age 13 is supposed to be able to set up a Facebook® account, *Consumer Reports* estimates that some 7.5 million of these children have such accounts, with an additional 14.4 million users between ages 13 and 17. When they click a "like" button for a product, such as a food or beverage, no mechanism is apparently available to limit how the children's images and preferences are then used for advertising purposes on the Internet. According to the article, a large part of the social network's advertising strategy is to turn users' "likes" into advertisements showing the users' names and images. Legal experts are reportedly unsure whether this strategy is legal, even when adults' names and images are used without consent. *See Advertising Age*, May 19, 2011.

SCIENTIFIC/TECHNICAL ITEMS

New Study Compares Salt-Reduction Strategies, Urges Product Reformulations

A recent study examining national salt-reduction strategies around the world has concluded that such programs are "likely to be one of the simplest and most cost-effective ways of improving public health." Jacqueline Webster, et al., "Salt Reduction Initiatives Around the World," *Journal of Hypertension*, June 2011. The study used existing reviews, literature and relevant Websites to identify 32 national salt-reduction initiatives, finding that "the majority of the activity was in Europe." Twenty-six of the 32 strategies "were led by government, five by nongovernment, and one by industry," and some were "multifaceted including food reformulation, consumer awareness initiatives and labeling actions." Of the countries identified as having a salt-reduction strategy, (i) 27 "had maximum population salt intake targets, ranging from 5 to 8 g/person per day," (ii) 28 "had some baseline data on salt consumption and 18 had data on sodium levels in foods," (iii) 28 "were working with the food industry to reduce salt in foods," (iv) "10 had front-of-pack labeling schemes,"

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(v) "28 had consumer awareness or behavior change programs," and (vi) five "had demonstrated an impact, either on population salt consumption, salt levels in foods or consumer awareness."

The authors noted, however, that "no country has achieved, or is likely to achieve, a significant fall in population salt consumption if the salt reduction program is restricted to consumer education, and uptake is left to consumer choice." The study therefore concludes that "national salt reduction efforts must be delivered centrally though changes to the environment that make it easy for the population as a whole to consume less salt," with a focus "on the food industry and reformulation of products towards lower salt with the goal being to reduce the salt content of every salt product progressively in small incremental steps." ■

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