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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Natural-Health Advocates Petition FDA to Require Accurate HFCS Labeling

Citizens for Health has filed a citizen's petition with the Food and Drug Administration (FDA) requesting that the agency amend its high-fructose corn syrup (HFCS) regulations. The requested changes would require food producers (i) using HFCS, to identify its concentration of fructose on product labels (e.g., HFCS with 42 percent fructose would be labeled "high fructose corn syrup 42"), and (ii) manipulating the amount of fructose in HFCS "to a different concentration than a standardized blend of 42 or 55," to also incorporate the concentration into the ingredient name (e.g., HFCS with 90 percent fructose would be labeled "high fructose corn syrup 90").

Citizens for Health also asked that FDA initiate enforcement actions against food companies using HFCS with fructose in amounts other than 42 or 55 percent because these are the concentrations FDA has apparently designated as generally recognized as safe.

According to the petition, numerous online articles and reports demonstrate that HFCS 90 "is used in soft drinks (including reduced-calorie ones), salad dressings, jams, jellies, table syrups, wines, low-calorie frozen yogurts, desserts, and 'light' foods." The petitioner, which describes itself as a natural-health advocacy non-profit, cites a 2010 study indicating that elevated fructose levels in sodas "are of particular concern because of the negative effects fructose has on the body," that is, obesity and metabolic syndrome. Citizens for Health issued an alert on August 24, 2012, seeking public support for the petition and indicating that comments would be forwarded to FDA.

Center for Food Safety Criticizes USDA BioAg Committee's Co-Existence Stance

The Center for Food Safety has issued a paper critical of the draft report prepared by the U.S. Department of Agriculture's (USDA's) Advisory Committee on Biotechnology and 21st Century Agriculture (AC21), which was scheduled to meet August 27-28, 2012, to discuss the draft. According to the advocacy organization, USDA "has increasingly strayed from its role

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as 'enhanc[er of] economic opportunities for US farmers and ranchers,' by continuing to allow genetically engineered (GE) seeds, pollen, and plants to contaminate our nation's farms without restraint." In particular, the center calls AC21's "co-existence" approach to organic, conventional and GE farming "a thinly veiled attempt to sanction allowable amounts of GE contamination in food by establishing a universal GE contamination threshold."

The paper contends that compensating conventional and organic farmers whose crops are contaminated by drifting GE pollen will not address the losses sustained when other countries ban all U.S. seed and crop imports. "Even if farmers strictly adhere to crop management protocols such as those required in the organic standards," the center contends, "GE contaminated crops cannot be sold in countries that prohibit GE food." According to the center, USDA's "policy and practice of permitting the unrestricted use of GE technologies cuts off valuable export markets and facilitates the dominance of GE above all other forms of agriculture, particularly in the face of transgenic contamination." The center calls on USDA to immediately establish a moratorium on the planting of GE crops and also notes its opposition to any compensation mechanism requiring "conventional non-GE growers to purchase insurance or pay into a fund to compensate themselves for unwanted GE contamination."

The paper cites the StarLink® corn and LibertyLink® rice contamination episodes as examples of costly incidents involving massive product recalls, import bans and federal lawsuits.

Colorado City Imposes 3 Percent Tax on Candy and Soft Drinks

The City of Lakewood, Colorado, has reportedly adopted an ordinance that will subject soft drinks and candy to a 3-percent city sales tax. The tax code change was apparently considered and approved during the city council's August 27, 2012, meeting. The ordinance is intended to align the city's taxation of food with the state by exempting sales of food for immediate consumption from sales tax, while taxing soda and candy. According to a news source, the change takes effect in 30 days. *See ABC7News, TheDenverChannel.com*, August 28, 2012.

Environmentalists Challenge GM Potato Trials in Ireland

Following the Irish Environmental Protection Agency's (EPA's) decision to allow genetically modified (GM) potato trials in County Carlow, a group of environmentalists and organic producers reportedly mounted a legal challenge under the Aarhus Convention which allows environmental legal issues to be pursued under a "non-prohibitively expensive order." According to a press report, Mr. Justice Gerard Hogan indicated that he lacked jurisdiction to make such an order, but gave the group leave to provide short notice to

the EPA of its intention to challenge the costs issue. Ratified in June 2012 and not yet evidently part of Irish law, article 9 of the convention apparently gives those challenging "critical environmental decisions" the ability to be heard in court without the threat of large legal costs if they lose. EPA's consent to the GM trials is reportedly subject to eight conditions that include reporting requirements and trial management, and the land will be monitored by scientists until 2020. *See The Irish Times*, August 29, 2012.

LITIGATION

How Far Can Government Go in Forcing Manufacturers to Tell Consumers "Don't Buy This Product"?

A divided D.C. Circuit Court of Appeals has determined that the graphic anti-smoking images which the Food and Drug Administration (FDA) selected for placement on cigarette packages for the purpose of reducing smoking rates in the United States fail the intermediate scrutiny standard for compelled commercial speech. ***R.J. Reynolds Tobacco Co. v. FDA*, No. 11-5332 (D.C. Cir., decided August 24, 2012)**. According to the court, which vacated the graphic warning requirements and remanded to the agency, "FDA failed to present any data—much less substantial evidence required under the [Administrative Procedure Act]—showing that enacting their proposed graphic warnings will accomplish the agency's stated objective of reducing smoking rates."

The court discusses the different standards applied when deciding whether government efforts to regulate speech are permissible under the First Amendment. A strict scrutiny standard, for example, gives government little leeway to compel or proscribe speech and imposes a heavy burden on government to demonstrate that the particular rule is narrowly tailored to achieve a compelling government interest. The district court applied a strict scrutiny standard when striking down the graphic warnings, concluding that a less stringent standard, a rational-basis review, was inapplicable because the warnings were not purely factual and uncontroversial disclosures. FDA argued that the latter more "lenient standard of scrutiny" should be applied to regulations serving a governmental interest: "disclosure of the health and safety risks associated with commercial products."

The court rejected the lenient approach, observing that "a disclosure requirement is only appropriate if the government shows that, absent a warning, there is a self-evident—or at least 'potentially real'—danger that an advertisement will mislead consumers." Because the law already bans any advertising representing cigarette products as light, mild, less harmful, or lower risk and because FDA did not "show that absent disclosure, consumers would likely be deceived by the Companies' packaging in the future," the court found the lenient standard inapplicable. Applying the intermediate level of review

that generally applies to commercial speech, the court still found that FDA's evidentiary support was lacking, because its consumer-perception research and studies of graphic warnings in other countries did not demonstrate that such warnings actually reduce smoking rates.

The court also found that the "inflammatory images and the provocatively named hotline [1-800-QUIT-NOW] cannot rationally be viewed as pure attempts to convey information to consumers. They are unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting."

The majority and dissenting judges differed over the appropriate standard to apply as well as over FDA's asserted interests. The majority determined that FDA's "*only* explicitly asserted interest in either the Proposed or Final Rule is an interest in reducing smoking rates." The dissenter contended that FDA's interest was "to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements." Applying the lenient standard of scrutiny, the dissenter would have found that the graphic warning label requirements were "reasonably related to" that interest and thus that the regulation was valid.

Seventh Circuit Rules Franchisee Need Not Adopt New Pricing Policy for Now

The Seventh Circuit Court of Appeals has determined that a Steak N Shake franchisee in Illinois was entitled to a preliminary injunction to stop the implementation of a new Steak N Shake policy for menu pricing and promotions. ***Stuller, Inc. v. Steak N Shake Enters., Inc.*, No. 11-2656 (7th Cir., decided August 24, 2012)**. The franchisee, in operation for more than 70 years, owns five restaurants and is the oldest Steak N Shake franchisee in the country. While Steak N Shake controls many aspects of restaurant management, some aspects are left to individual franchisees. Plaintiff Stuller, Inc. has had the ability to set menu prices throughout its history, but in June 2010, Steak N Shake demanded that all franchisees follow its menu pricing and promotions.

Stuller brought a declaratory judgment action against Steak N Shake after the franchisor threatened to terminate Stuller's franchises for refusing to implement the new policy. The district court, concluding that "the termination of the franchises that would occur if Stuller did not implement the policy was not a self-inflicted injury and that the loss of the franchises constituted irreparable harm," entered the injunction barring Steak N Shake from taking adverse action during the pendency of the litigation.

On appeal, finding sufficient evidence in the record to show that Steak N Shake's policy would harm the franchisee's business, the Seventh Circuit affirmed. In a footnote, the court found further support for the likelihood that Stuller would prevail on the merits, as the district court had, while the appeal was pending, denied Steak N Shake's motion for summary judgment on all

claims, granted Stuller's motion for summary judgment on its first claim and set a trial date to address the issue of damages.

Federal Court Narrows False Ad Claims Against Jamba Juice Co.

A federal court in California has granted in part the motion to dismiss filed by the defendant in a putative class action alleging that it falsely misrepresents its smoothie kits as "All Natural" when they actually contain "unnaturally processed, synthetic and/or non-natural ingredients," such as ascorbic acid, citric acid, xanthan gum, and steviol glycosides." *Anderson v. Jamba Juice Co.*, No. 12-1213 (U.S. Dist. Ct., N.D. Cal., order entered August 25, 2012). Additional information about the case appears in Issue 432 of this *Update*.

The court agreed with Jamba Juice that the plaintiff had failed to state a warranty claim under the Magnuson-Moss Warranty Act, because "the statement 'All Natural' is a general product description rather than a promise that a product is defect free." Still, the court dismissed the plaintiff's claim for breach of express warranty under the Act with leave to amend "to the extent some other basis may exist for this claim." The plaintiff must file his second amended complaint no later than September 14, 2012.

The court rejected the defendant's challenge to the named plaintiff's standing. According to Jamba Juice, the plaintiff could not bring claims on behalf of purchasers of smoothie kit flavors he did not buy; the plaintiff apparently purchased just two of five flavors. District courts in the Ninth Circuit have evidently "diverged on the issue of whether a plaintiff has standing to bring claims of behalf of consumers who purchased similar, but not identical products." The court noted that the critical inquiry in these cases "seems to be whether there is sufficient similarity between the products purchased and not purchased." Finding that all of the products were labeled with the "same alleged misrepresentations," the court found that the plaintiff had standing "to bring claims on behalf of purchasers of smoothie kit flavors he did not buy, and the Court has subject matter jurisdiction over such claims."

Food Safety Advocates Sue FDA for Delaying FSMA Implementation

The Center for Food Safety and Center for Environmental Health have filed a complaint for declaratory and injunctive relief against the Food and Drug Administration (FDA) alleging that the agency has unlawfully delayed adopting implementing regulations under the Food Safety Modernization Act (FSMA). ***Ctr. for Food Safety v. Hamburg*, No. 12-4529 (U.S. Dist. Ct., N.D. Cal., filed August 29, 2012)**. According to the complaint, FDA has missed seven statutory deadlines thus "failing to implement FSMA's major food safety regulations." Characterizing the failure as "an abdication of the agency's fundamental responsibilities," the plaintiffs claim that this delay "is putting millions of lives at risk from contracting foodborne illnesses." They also sued the Office of Management and Budget, claiming that it has also missed statu-

tory deadlines in failing to approve the implementing regulations that FDA has submitted for its review.

The complaint recites Centers for Disease Control and Prevention estimates that one in six Americans contract food-borne illnesses each year, 128,000 are hospitalized and 3,000 die. Among the regulations the plaintiffs claim that FDA has failed to adopt are those that (i) establish "science-based minimum standards for conducting hazard analysis, documenting hazards, implementing preventive controls and documenting the implementation of preventive controls"; (ii) address "activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership . . . and on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership"; (iii) "establish science-based minimum standards for the safe production and harvesting of fruits and vegetables"; (iv) protect against the intentional adulteration of food; and (v) impose sanitary transportation practices on shippers and carriers.

The complaint also challenges FDA's policy to "not enforce provisions that are self-executing . . . even if FDA has not promulgated final regulations." The complaint refers to "devastating outbreaks" that have occurred since Congress passed the FSMA, including *Listeria*-contaminated cantaloupes and apples, and *Salmonella*-contaminated cilantro and tomatoes. Alleging violations of the FSMA and Administrative Procedure Act, the plaintiffs seek a declaration that the agencies have violated the law by failing to promulgate regulations by statutory deadlines and an order requiring the agencies to promulgate and approve all FSMA regulations "as soon as reasonably practicable, according to a Court-ordered timeline."

High-End Oven Maker Disputes Right to Use Julia Child Images

The manufacturer that sells the Bosch®, Thermador® and Gaggenau® brands of home appliances has sued the Julia Child Foundation for Gastronomy and the Culinary Arts seeking a declaration that it has not infringed the defendant's trademarks and copyrights or the publicity rights related to the late Julia Child. *BSH Home Appliances Corp. v. The Julia Child Found. for Gastronomy & the Culinary Arts*, No. 1:2012cv11590 (U.S. Dist. Ct., D. Mass, filed August 24, 2012).

According to the complaint, Julia Child used the plaintiff's Thermador® oven for many years both on the set of *The French Chef* TV program and in her personal kitchen, which, after she died, was donated to and appears in the Smithsonian Institution. The oven maker claims that it has used images of Julia Child "and references to the well-known historical fact of her use of Thermador products in various media, including on its website and on its social media web pages." The plaintiff further notes, "These uses do not state or imply any endorsement by Ms. Child of Thermador products. Rather, Plaintiff's use of these photos and references to Julia Child's name and use of

Thermador products reflect on the long history, significance and influence of Thermador products on American society and culture, and Ms. Child's documented and well-known use of those products." The plaintiff alleges that its uses of the image and name of Julia Child "are not directly connected to the sale of any merchandise," but are used "on a timeline chronicling the company's history and in the historical 'Our Heritage' section of the Thermador website."

The defendant has allegedly warned the manufacturer that continued use of the name, image, likeness and celebrity identity of the late Julia Child, and the various trademarks and copyrights related to Julia Child, which are purportedly within the foundation's "exclusive ownership and control," constitutes infringement, trademark infringement and infringes a post-mortem right of Julia Child's right of publicity. The plaintiff seeks a declaration that (i) it has not infringed any protectable trademark, copyright or right of publicity under any state or federal law, (ii) the late Julia Child was a domiciliary of Massachusetts when she died, (iii) Massachusetts law should apply to any claim, and (iv) the plaintiff "has the right to proceed with the use of or reference to the late Julia Child's name, image, likeness, celebrity identity, and trademarks related to the late Julia Child in connection with Plaintiff's historical presentation, including but not limited to the timeline on its website and in other media."

Brazilian Court Orders Nestlé to Label GM Ingredients in Cookies

According to a news source, a Brazilian court has determined that Nestlé's strawberry-flavored Bono Cookies® contain genetically modified (GM) soybeans at levels in excess of a 1-percent limit and that the company must thus place a yellow triangle with a "T" in the middle along with the word "transgenic" on its product labels. Failure to do so will apparently result in a fine of nearly US$2,500 per product found in the market to contravene the order. The European Union and Japan also reportedly require GM foods to be labeled, and California voters will vote on a GM labeling referendum this fall. *See Food World News*, August 27, 2012.

OTHER DEVELOPMENTS

Public Health Law Conference to Address "Addiction," Preemption and FSMA Issues

The American Society of Law, Medicine & Ethics will sponsor a **conference** in Atlanta, Georgia, October 10-12, 2012, that will focus in part on food-related issues. The "Public Health law Conference 2012: Practical Approaches to Critical Challenges," event will include concurrent sessions titled (i) "If Sugar Is Addictive, What Does It Mean for the Law?," including panelist Ashley Gearhardt, who has written on this topic with the Rudd Center's Kelly Brownell in *Biological Psychiatry*; (ii) "Hot Topics in Preemption—From Fast Food to Fire

Sprinklers to Safety Nets," including panelist Mark Pertschuk, who actively promoted nonsmokers' rights from 1987-2007; and (iii) "Enhancing the Safety of What We Eat: FDA's Food Safety Modernization Act," including panelist Bruce Clark, an attorney with the Marler Clark firm which focuses its practice on food-contamination lawsuits.

Treatment for Obesity Through Brain's "Addiction" Center?

The Food and Drug Administration (FDA) has reportedly approved the use by Ohio State University (OSU) investigators of brain pacemakers as an obesity treatment. Deep-brain stimulation has apparently been approved for use in the treatment of disorders such as Parkinson's disease, tremor, dystonia, and severe obsessive-compulsive disorder, and OSU researchers and clinicians evidently made the case for use of the therapy to treat obesity in an article recently published in *Neurosurgery.* According to OSU Professor of Neurological Surgery Ali Rezai, the goal will be to stimulate the region of the brain linked to addictive behavior to improve its function, regulation and control. "Research shows that many of the complexities of obesity are traced to faulty signals in the brain. Considering the heightened health risks in obese individuals and the problems that some patients have after bariatric surgery, it is reasonable to consider deep-brain stimulation as a treatment," he said. *See Healthcanal.com*, August 27, 2012.

SCIENTIFIC/TECHNICAL ITEMS

Norwegian Study Alleges Association Between Soda Consumption and Pre-Term Births

Relying on data provided by a study of more than 60,000 Norwegian women from 1999 to 2008, Swedish and Norwegian researchers have found that a "high intake of both AS [artificially sweetened] and SS [sugar-sweetened] beverages is associated with an increased risk of preterm delivery." Linda Englund-Ögge, et al., "Association between intake of artificially sweetened and sugar-sweetened beverages and preterm delivery: a large prospective cohort study," *American Journal of Clinical Nutrition*, August 2, 2012. The women were asked about servings of carbonated soft drinks and non-carbonated beverages, both AS and SS, per day, week and month, and a serving was defined as 250 mL for all beverages. The groups were divided into AS and SS groups and further divided into intake categories.

For women consuming more than one serving per day of AS beverages, the adjusted odds ratio for preterm delivery was 1.11. Consumption of more than one serving of SS beverage per day had an adjusted odds ratio for preterm delivery of 1.25. The researchers acknowledged the study's limitations, i.e., the possibility of misreporting and underreporting, socioeconomic factors, other dietary factors, smoking status, education, and body mass index. The

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researchers declined to say that the risk of preterm delivery is caused by the effects of the beverages, but concluded that daily intake "may be associated" with an increased risk.

Study Suggests Coffee Intake Significantly Reduces Colon Cancer Risk

Researchers using data for nearly 500,000 men and women participating in the NIH-AARP Diet and Health Study have purportedly found that coffee consumption is "inversely associated with colon cancer, particularly proximal tumors." Rashmi Sinha, "Caffeinated and decaffeinated coffee and tea intakes and risks of colorectal cancer in a large prospective study," *American Journal of Clinical Nutrition*, June 13, 2012. Ninety percent of the cohort drank coffee, and 16 percent consumed more than four cups per day. "Compared with nondrinkers, heavy coffee drinkers (≥6cups/d) were more likely to be men, current smokers, and physically inactive and consumed more red meat and alcohol but less fruit and vegetables." Heavy coffee drinkers also apparently consumed predominantly caffeinated coffee.

According to the researchers, "there was an inverse association between individuals who drank 4-5 cups coffee/d compared with nondrinkers with colon cancer (HR: 0.85; 95%, CI: 0.75, 0.96), and the association was even stronger for subjects who drank ≥6 cups coffee/d (HR: 0.74; 95% CI: 0.61, 0.89)." Those who predominantly drank decaffeinated coffee allegedly had a decreased risk of both colon and rectal cancers, while no associations were found for those who drank tea. The cohort was predominantly non-Hispanic white, college educated and may have had "a healthier lifestyle than that of similarly aged adults in the US population." Other acknowledged limitations to the researchers' conclusions included smoking, red-meat consumption, self-reporting, and a lack of information about preparation methods. The authors call for additional investigations into these associations.

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