Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

European Court of Auditors Reviews EFSA's Conflict Policies

The European Court of Auditors has issued a special report finding that the European Food Safety Authority (EFSA) and three other consumer health and safety agencies did not have "adequate" conflict-of-interest procedures in place as of October 2011. After auditing agency activities and comparing them with Organization for Economic Co-operation and Development Guidelines, the court evidently concluded that certain conflict-of-interest risks "are embedded in the selected Agencies' structure (e.g. the same organization is both a management representative and a supplier of services) and in the use of the research performed by the industry."

In particular, the report faulted EFSA's Management Board where four of the 15 members "have a background (including current involvement) in organizations representing consumers and other interests in the food industry." It also noted that "the impartiality of EFSA's work and decision-making might be jeopardized since three of these organizations represented on the Management Board are also represented in the stakeholder consultative platform." The court has thus called on EFSA to implement, among other things, (i) better candidate screening before appointment, (ii) "clear and objective criteria for assessment of declarations of interest," (iii) "gifts and invitations policies and procedures," and (iv) "clear, transparent and consistent breach of trust policies and procedures."

Meanwhile, EFSA has welcomed the audit's results as validation of new conflict-of-interest policies adopted in July 2012. According to an October 11 press release, the agency has explained to the court that these updated measures already comply with many of the report's recommendations. To bolster its case, EFSA has specifically pointed to its Policy on Declarations of Interest as well as its efforts to ensure that (i) "scientific opinions are the outcome of collective decision-making of EFSA's Scientific Committee or its Scientific Panels"; (ii) "minority opinions are recorded"; (iii) "all scientific outputs are published"; and (iv) "there are procedures governing the processing of mandates and requests, data collection, the selection of experts

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as well as public consultations and a comprehensive quality review program." The agency has also revamped its risk communication mandate and "begun making some of the plenaries of its Scientific Committee and Panels available for observer comment."

"But we are not complacent on this issue as we know how important it is for the perception of, and trust in, EFSA's work. We will continue to rigorously implement our new Policy on Independence and Scientific Decision-Making Processes and the related implementing rules which came into force in July," said EFSA Executive Director Catherine Geslain-Lanéelle. "These provide additional protection for EFSA's scientific experts in recognition of their commitment to support the organization in fulfilling its public health mission. Our actions will be guided by the recommendations of the European Court of Auditors' report and the views of the European Parliament." *See Europolitics,* October 12, 2012.

Texas Animal Health Commission Announces New Cattle Traceability Rules

The Texas Animal Health Commission (TAHC) has **announced** the implementation of new adult cattle traceability rules effective January 1, 2013. TAHC apparently amended its regulations after "unofficially" suspending its brucellosis test requirement for adult cattle at change of ownership. Because cattle no longer receive ear-tags at the time of testing, the updated rule stipulates that "all sexually intact cattle, parturient or post parturient, or 18 months of age and older changing ownership must still be officially identified with Commission approved permanent identification."

"The new traceability rule will help preserve the TAHC's ability to identify and trace animal movements quickly and effectively, no matter which disease is involved," stated the agency, which has anticipated that the change will primarily affect beef cattle, "as dairy cattle in Texas have had an even more stringent identification requirement in place since 2008." The Commission has also supplied a complete list of acceptable identification devices and methods on its **Website**, adding that "the most commonly used devices include [U.S. Department of Agriculture] metal tags, brucellosis calfhood vaccination tags, US origin 840 series Radio Frequency Identification tags (RFID), and breed registration tattoos or firebrands." *See TAHC Press Release,* October 4, 2012.

LITIGATION

Nationwide Class Certified in False-Advertising Suit Against POM Wonderful

A federal multidistrict litigation (MDL) court in California has certified a nationwide class of consumers who purchased a POM Wonderful pomegranate juice product between October 2005 and September 2010 and allege that the company's health-related benefit claims are false and misleading.

In re POM Wonderful LLC Mktg. & Sales Practices Litig., MDL No. 2199 (U.S. Dist. Ct., C.D. Cal., decided September 28, 2012). The suit was filed under California's False Advertising Law, Unfair Competition Law and Consumers Legal Remedies Act.

While POM argued that a nationwide class could not be certified because California law cannot be applied to consumers in other states, the company failed to specifically identify conflicts between the laws of California and other states. According to the court, the company simply cited a Ninth Circuit decision "[p]erhaps relying upon the mistaken assumption that California law cannot be applied to a nationwide class as a matter of law," and included an exhibit charting the consumer protection laws of all the states without indicating "which of these foreign laws differ from California's laws." The court found that the company thus failed "to carry its burden to demonstrate that the interests of any foreign jurisdiction outweigh California's interest in applying its own consumer protection laws to the facts of this case."

Among other matters, the court also determined that the plaintiffs were not required at the class certification stage to "present individualized evidence of reliance" finding that it could be inferred "[g]iven the wide geographical and temporal scope over which Pom disseminated its health claims and the apparent success of Pom's marketing efforts." POM also apparently sought to forestall the certification by reference to the Federal Trade Commission's action against it as well as dozens of pending individual actions, alleging that these alternatives negated the superiority of the class action device. The court rejected that contention, concluding that common questions of law or fact predominated and that the class action was superior to other available methods. The court also stated that it was "satisfied that the numerosity, commonality, typicality, and adequacy requirements of Rule 23(a) are met here."

Hard Times for Hard Rock Café Employees

A California court has reportedly denied a motion to certify a class of Hard Rock Café employees who allege that the restaurant chain wrongly classified them as exempt employees and then forced them to assume the tasks of non-exempt employees without paying them overtime or allowing them to take meal periods and rest breaks, and otherwise provided inaccurate wage statements. *In re Hard Rock Café Wage & Hour Cases*, No. JCCP 4549 (Cal. Super. Ct., Orange County, Civil Complex Ctr., decided October 3, 2012). According to the restaurant chain's counsel, the court determined that the putative class of kitchen managers lacked numerosity, the identity and number of class members could not be ascertained, and the named representative could not adequately represent the class.

The court also apparently found that individual analysis of each employee's work activities would be required to decide whether they had been properly classified as exempt. Counsel for named plaintiff Anton Barich reportedly indicated that he was considering his options "including appeal of the denial of the motion." Counsel also contended that the plaintiffs had introduced "significant evidence" that the defendants implemented a uniform labor-budget policy among all of its restaurants resulting in hourly labor shortages that required assistant managers to prepare food, wash dishes and wait tables to keep up with the workload. *See Law360*, October 5, 2012.

Citing GMOs, Putative Class Challenges Campbell Soup "100% Natural" Claims

A California resident has filed a putative class action against Campbell Soup Co. alleging that it falsely represents that some of its products are "100% Natural" when they in fact contain genetically modified organisms (GMOs) "in the form of soy, corn, soy derivatives, and or corn derivatives." *Barnes v. Campbell Soup Co.*, No. 3:12-cv-05185-EDL (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed October 5, 2012). Specifically targeted in the complaint are the company's "100% Natural Southwest-Style White Chicken Chili" and "100% Natural *HealthyRequest*® Mexican-Style Chicken Tortilla Soup." The plaintiff alleges that he "would not have purchased the Products if he had known that the Defendant's Products are not '100% Natural' because they contain GMOs."

Seeking to certify a statewide class of product purchasers, the plaintiff alleges violations of California's Unfair Competition Law, False Advertising Law and Consumers Legal Remedies Act. He requests injunctive relief; restitution; disgorgement; attorney's fees; actual, statutory and punitive damages; costs; and interest. He is represented by counsel from the Law Offices of Howard Rubinstein, P.A, which has long been active in this type of consumer-fraud litigation. Additional information about some of Howard Rubinstein's other cases appears in Issue **263** of this *Update*.

Insurance Cos. Seek Declaration of No Duty to Defend Four Loko® Lawsuits

Two commercial liability insurance companies have filed a complaint against Phusion Projects Inc., the company that makes Four Loko®, an alcoholic beverage containing stimulants such as caffeine, guarana and taurine, seeking a declaration that "they do not owe a duty to defend or indemnify" the company in personal injury and wrongful death actions filed against it in several states. *The Netherlands Ins. Co. v. Phusion Projects Inc.*, No. 1:12-cv-07968 (U.S. Dist. Ct., N.D. Ill., E. Div., filed October 4, 2012).

The underlying complaints involve a California resident who was shot to death by police after consuming the beverage and acting "in an irritated, agitated, and disoriented manner"; a New York resident who sustained injuries in an auto accident with a woman who had consumed the product and

allegedly drove her car in a reckless manner; a New Jersey resident who died from a stabbing in an attack by a woman who had allegedly "imbibed Four Loko"; a Pennsylvania resident who was run over after sitting on public transit trolley tracks in a "highly intoxicated state"; and a Florida resident who sued a Four Loko® distributor for the death of a son who was struck as an intoxicated pedestrian by several cars.

Contending that their policies contain a liquor liability exclusion, the insurance company plaintiffs note that the court previously absolved them of a duty to defend in similar litigation involving other underlying Four Loko® lawsuits. They claim that the previous determination "is preclusive of the same issues in this case" because no claim asserted in the complaints discussed above is "wholly independent of intoxication."

Deli Meat Maker Seeks Coverage from Supplier's Insurance Carrier

A company whose deli meat products were allegedly contaminated by the inclusion of the *Salmonella*-tainted red and black pepper sold to it by a supplier has sued the supplier's insurance company to recover damages resulting from the products' recall. *Daniele Int'l, Inc. v. Penn-Star Ins. Co.*, No. CA12-709 (U.S. Dist. Ct., D.R.I., filed October 9, 2012). According to the plaintiff, which was awarded a default judgment of $33.18 million in a suit against the supplier in September 2012, the defendant's insurance policies extend to the supplier's liability for the plaintiff's losses and damages. The plaintiff also contends that the insurance carrier was notified about the underlying litigation.

OTHER DEVELOPMENTS

NEJM Perspective Piece Targets "Candy at the Cash Register"

A recent perspective piece published in the *New England Journal of Medicine* has argued that "steps should be taken" to curb "spur-of-the moment, emotion-related purchases… triggered by seeing the product or a related message." Deborah Cohen & Susan Babey, et al., "Candy at the Cash Register — A Risk Factor for Obesity and Chronic Disease," *NEJM,* October 2012. The article takes issue with impulse marketing focused on "the placement and display of products in retail outlets," such as candy offered for sale at cash registers.

"Placement of foods in prominent locations increases the rate at which they're purchased; purchase leads to consumption; and consumption of foods high in sugar, fat and salt increases the risks of chronic disease," state the authors. "Because of this chain of causation, we would argue that the prominent placement of foods associated with chronic diseases should be treated as a risk factor for those diseases."

In making this claim, the authors point to eye-tracking research and other studies allegedly showing that "the attention drawn by special displays, particularly on the ends of aisles, has more to do with the display characteristics than with the goals and capacities of individual people," who tend to make impulse purchasing decisions in less than one second. "Although placement is a factor that is right in front of our noses, we should consider treating it as a hidden risk factor, like carcinogens in water, because placement influences our food choices in a way that is largely automatic and out of our conscious control and that subsequently affects our risk of diet-related chronic diseases," conclude the authors, who ultimately advocate approaches such as "limiting the types of foods that can be displayed in prominent end-of-aisle locations and restricting foods associated with chronic diseases to locations that require a deliberate search to find."

SCIENTIFIC/TECHNICAL ITEMS

Scientists Identify Gene with Role in Mood Disorders and Obesity

Researchers with McGill University have reportedly identified a genetic mutation linked to the development of mood disorders and obesity in humans. Carl Ernst, et al., "Highly Penetrant Alterations of a Critical Region Including *BDNF* in Human Psychopathology and Obesity," *Archives of General Psychiatry,* October 2012. After screening more than 35,000 people referred for genetic testing and comparing the results with data from approximately 30,000 control subjects, scientists found five participants with a rare genomic deletion of brain-derived neurotrophic factor (BDNF), "a nervous system growth factor that plays a critical role in brain development." These participants all exhibited obesity and "mild-moderate intellectual impairment" as well as a mood disorder.

"The consensus phenotype for individuals with a deletion in BDNF suggests that young children are hyperactive and have an intolerance to change. As subjects age, they likely develop more pronounced anxiety and mood disorders, exemplified by the 16-year-old and 21-year-old subjects with major depressive disorder and generalized anxiety disorder and by a 25-year-old woman with mood disturbances from a previous report," concludes the study. "Deeper investigation of the regulation of BDNF and of the molecular actions of the transcribed product will be required to better understand how hemizygosity at this locus contributes to psychopathology."

The study purportedly represents the first successful attempt to definitively link a gene mutation to mood disorders and obesity in humans. "Mood and anxiety can be seen like a house of cards. In this case, the walls of the house represent the myriad of biological interactions that maintain the structure," the lead author was quoted as saying. "Studying these moving parts can be

tricky, so teasing apart even a single event is important. Linking a deletion in BDNF conclusively to mood and anxiety really tells us that it is possible to dissect the biological pathways involved in determining how we feel and act." *See McGill University Press Release,* October 10, 2012.

Study Observes Association Between Coffee and Glaucoma

A recent study has reportedly observed an association between heavier coffee consumption and increased risk of exfoliation glaucoma or exfoliation glaucoma suspect (EG/EGS). Louis Pasquale, et al., "The Relationship between Caffeine and Coffee Consumption and Exfoliation Glaucoma or Glaucoma Suspect: A Prospective Study in Two Cohorts," *Investigative Ophthalmology & Visual Science,* September 2012. Researchers with the Channing Division of Network Medicine at Brigham and Women's Hospital in Boston, Massachusetts, used eye examination data and follow-up questionnaires from 78,977 women and 41,202 men enrolled in health studies to determine that those who reported drinking three or more cups of caffeinated coffee each day were more likely to develop EG/EGS than those who abstained. The study also found that this risk increased for women with a family history of glaucoma, but did not identify a similar association between EG/EGS and other caffeinated products, such as soda or tea, or decaffeinated coffee.

"Because this is the first study to evaluate the association between caffeinated coffee and exfoliation glaucoma in a U.S. population, confirmation of these results in other populations would be needed to lend more credence to the possibility that caffeinated coffee might be a modifiable risk factor for glaucoma," the study's lead author said in an October 3, 2012, press release. "It may also lead to research into other dietary or lifestyle factors as risk factors."

Study Allegedly Links Simple Sugar to Fatty Liver Disease

A recent study has purportedly found "for the first time a link between excess dietary sugar and the accumulation of liver fat by DNL [de novo lipogenesis]," the process by which simple sugars like fructose or glucose are converted in the liver into SFA palmitate. Ksenia Sevastianova, et al., "Effect of short-term carbohydrate overfeeding and long-term weight loss on liver fat in overweight humans," *American Journal of Clinical Nutrition,* October 2012. After placing 16 overweight subjects on a high-calorie diet for three weeks and then a low-calorie diet for six months, researchers reported that carbohydrate overfeeding induced an approximately 10-fold "greater relative change in liver fat (27%) than in body weight (2%)," with the increase in liver fat proportional to DNL.

Based on these findings, the study's authors concluded that "short-term overfeeding with simple carbohydrates markedly increases liver fat and stimulates DNL in overweight subjects." They also noted that, although the changes were

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reversible with weight loss, "these data support a role for excess simple sugar intake in the pathogenesis of NAFLD [nonalcoholic fatty liver disease]."

"[T]he results provide the impetus for the measurement of liver and plasma triglycerides and DNL after a carbohydrate challenge in a larger number of ethnically diverse subjects tested for genes associated with fatty liver," explained a concurrent editorial highlighting the study's conclusions. "In this way, the genetic heterogeneity of the lipogenic effects of dietary sugar will be defined. Dietary recommendations to restrict sugars can then have a stronger scientific rationale and target those at greatest risk and the specific mechanism or mechanisms responsible."

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