Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

N.Y. Lawmaker Asks GAO to Review Data on Antibiotic Use in Animals

U.S. Representative Louise Slaughter (D-New York) has asked the Government Accountability Office (GAO) to review federal efforts to collect data on antibiotic use in animals. In a **letter** to Acting Comptroller General Gene Dodaro, Slaughter asked for the study because a 2005 GAO report found that the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA) were not collecting data "on the types and amounts of antibiotics used in different species of food animals or whether the antibiotics were used to promote growth, prevent disease, or treat disease."

Slaughter, who chairs the House Committee on Rules, also introduced a **bill** earlier this year to restrict the non-therapeutic use of antibiotics in animals raised for meat, citing claims that animal antibiotic use has made some antibiotics less effective in treating human health problems. Her letter requests that GAO find out what efforts USDA, FDA and CDC have made to assess the human health risks related to antibiotic use in animals. *See Congress Daily,* September 21, 2009.

FDA Hearing to Target Internet Promotion of Regulated Medical Products

The Food and Drug Administration (FDA) has **announced** a public hearing for November 12-13, 2009, to discuss issues related to ways the Internet and social media tools are used to promote FDA-regulated medical products, including prescription drugs for humans and animals. Comments from "consumers, patients, caregivers, health care professionals, patient groups, Internet vendors, advertising agencies, and the regulated industry" are requested by October 9, 2009.

FDA is "particularly interested in hearing views from the public as to how expanding Web 2.0 technologies may be used to promote medical products to both health care professionals and consumers in a truthful, non-misleading, and balanced manner." Emerging Internet technologies such as blogs, micro-blogs, podcasts, social networks and online communities, video sharing,

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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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widgets, and wikis have prompted questions from regulated companies and other interested parties regarding advertising and labeling provisions, regulations and promotion policies. *See Federal Register*, September 21, 2009.

FTC Plans Study Aimed at Food Marketing to Children, Adolescents

The Federal Trade Commission (FTC) plans to conduct a **study** of food marketing to children and adolescents for a follow-up report to its 2008 study titled "Marketing Food to Children and Adolescents: A Review of Industry Expenditures, Activities, and Self-Regulation." FTC seeks public comments by November 23, 2009, on proposed information requests to approximately 45 major food and beverage companies and quick-service restaurants about their marketing activities, expenditures and nutritional information concerning food and beverage products marketed to children and adolescents.

FTC plans to evaluate possible changes in the nutritional content and variety of youth-marketed foods, and "proposes to seek scientific and market research exploring psychological and other factors that may contribute to food advertising appeal among youth." *See Federal Register,* September 21, 2009.

New York City Planning Commission Approves Plan to Add Supermarkets to Poor Areas

The New York City Planning Commission has reportedly approved a proposal that would offer zoning and tax incentives "to encourage the development of full-service grocery stores that devote a certain amount of space to fresh produce, meats, dairy and other perishables," according to a September 24, 2009, article in *The New York Times*. The plan would apparently relax zoning restrictions in some areas to permit supermarket construction and would include tax abatements and exemptions for approved stores in parts of northern Manhattan, central Brooklyn, the South Bronx, and downtown Jamaica in Queens. In addition, the regulations would require new store owners to display entrance signs stating that their establishments sell fresh food. Based on a similar Pennsylvania program, the proposal has purportedly garnered support from food policy experts, supermarket executives and City Council members, who must also vote on the plan.

"This is about being able to walk to get your groceries in those areas that are really, really underserved and basically have no place to buy fresh produce," City Planning Commissioner Amanda Burden said.

LITIGATION

Federal Court Finds APHIS Error in Deregulating GE Sugar Beets

A federal court in California has determined that the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) erred when it deregulated a genetically engineered (GE) sugar beet without preparing an environmental impact statement. *Ctr. for Food Safety v. Vilsack*, No. 08-00484 (U.S. Dist. Ct., N.D. Cal.,

decided September 21, 2009). Thus, the court granted the motion for summary judgment filed by the Center for Food Safety and other environmental interest groups and scheduled a hearing for October 30, 2009, to decide what remedies will be appropriate.

A court in the same federal district ruled in 2007 that APHIS erred in deregulating GE alfalfa, and this court based its ruling on that decision, which resulted in an effective halt to the use of GE alfalfa. According to the court, which discussed at length how sugar beets are grown and how cross-pollination can occur with non-GE sugar beets and related Swiss chard and table beet crops, environmental effects can be significant in the context of a deregulation determination. The court was particularly concerned about the potential for GE sugar beets to eliminate farmers' choice to grow non-GE crops or consumers' choice to eat non-GE foods. The court concluded that APHIS failed to take the "hard look" that the National Environmental Policy Act requires before deregulating GE sugar beets.

The Center for Food Safety's executive director was quoted as saying, "We expect the same result here as we got in alfalfa. [The court] will halt almost any further planting and sale because it's no longer an approved crop." Industry interests sought to intervene, but were rebuffed during the litigation's first phase. The court may allow them to participate when it considers the issue of remedies. According to a spokesperson for the American Sugarbeet Growers Association, "We're going to use that opportunity to advocate the need for that technology and vigorously defend our growers' freedom to plant Roundup Ready sugar beets."

Some 10,000 farmers reportedly grow about 1.1 million acres of sugar beets in the United States, and industry surveys have estimated that 95 percent of the sugar beets planted in 2009 were genetically modified. *See The New York Times*, September 23, 2009.

Settlement Reached in Probiotic Yogurt Litigation

Without admitting liability for alleged misleading advertising involving its probiotic yogurt products, The Dannon Co. has agreed to settle claims in seven putative class actions for $35 million. *Gemelas v. The Dannon Co., Inc.*, No. 1:08-cv-00236 (U.S. Dist. Ct., N.D. Ohio, E. Div., stipulation of settlement filed September 18, 2009). If approved by the court, the settlement would also require the company to modify the advertising and labeling for its Activia® and DanActive® products to explain how they "regulate the digestive system" and to modify promotional statements about the products' effects on the digestive tract's immune system.

Under the proposed settlement, class claimants can obtain $15 by submitting a claim form, $15-$30 by submitting a claim form signed under penalty of perjury, and $30-$100 by submitting a claim form signed under penalty of perjury and register receipts or other sufficient proofs of purchase. The amount ultimately paid to claimants will depend on the number of claims made, and the settlement fund will be used to pay class counsel $10 million, expenses, administrative costs including class notice, and individual awards to named class representatives of $5,000 for those deposed and $1,000 for those not deposed. Any settlement funds not used will be distributed as product to charitable organizations that feed the hungry.

According to the lead plaintiffs' lawyer, if approved by the court, the deal will be one of the largest reached in a false-advertising case involving food products. Further details about the litigation appear in issues 245 and 274 of this Update. *See Product Liability Law 360*, September 18, 2009.

Settlement Reached over Insurance Coverage in Caffeinated Alcohol Suits

According to a news source, litigation over the alleged marketing of caffeinated alcohol products to underage consumers spawned an insurance coverage dispute that has been settled. The former Miller Brewing Co., now part of MillerCoors, LLC, was named as a defendant in a number of class actions alleging that advertisements for its Sparks® malt liquor beverage led to increased alcohol consumption by underage youths and caused injury, death, emotional distress, brain damage, an increase in risky sexual behavior, teen pregnancy, juvenile delinquency, and violent crime. The company's insurers refused to defend and indemnify it, claiming that the litigation was not covered under applicable policies. Miller filed suit in 2004, asserting breach of contract and breach of duty to defend the claims. The suit had been stayed since 2006 pending mediation and favorable outcomes in some of the underlying lawsuits. Miller reportedly removed the product from the market after state attorneys general accused it of marketing caffeinated alcoholic beverages to youths. *See Product Liability Law 360*, September 24, 2009.

False Advertising Claims Briefly Made Against Juicy Juice® Maker

A putative class action was reportedly filed in a California state court against Nestlé, alleging that the company falsely advertises its "Juicy Juice Brain Development Fruit Juice" as a product that will improve toddlers' brain function. Plaintiff Alexis Farmer, who then dismissed the complaint without prejudice several days later, reportedly claimed that she purchased the company's juice relying on labeling and advertisements stating that it contained DHA Omega-3, a "fatty acid especially important for brain development in children under two years old." Farmer was seeking damages and injunctive relief; her complaint apparently alleged false and misleading advertising, unjust enrichment, fraud, and civil code violations. *See Courthouse News*, September 23, 2009.

In a related development, Health Canada has apparently decided not to stop infant-formula manufacturers from claiming that DHA, in any amount, will support normal brain and eye development, particularly for children under two. The Canadian Food Inspection Agency asked the agency to set a minimum level if formula makers wish to make these claims, according to internal correspondence obtained through an access-to-information request. "It is unfortunate that Health Canada is removing the proposed revision to require that food actually contain a significant (source) amount of the nutrient that is the subject of the claim, otherwise you end up with situations like this one where a big deal is made about a food containing" little of the nutrient.

The Health Canada approach reportedly differs with the European Union which decided earlier in 2009 that infant-formula companies claiming that "DHA contributes to the visual development of infants" may do so only if the fatty-acid content is at least 0.3 percent DHA. *See Ottawa Citizen*, September 17, 2009.

Class Claims Filed in California Against Cereal Maker for False Advertising

A California man who alleges that he was misled by the packaging and advertising for Cap'n Crunch with Crunchberries® has brought a putative class action against the cereal maker in federal district court. *Werbel v. Pepsico, Inc.*, No. 09-4456 (U.S. Dist. Ct., N.D. Cal., filed September 22, 2009).

Alleging violations of California's unfair competition and false advertising laws, intentional misrepresentation, breach of express and implied warranties, and violations of the Consumers Legal Remedies Act, the plaintiff claims that he and a class of California consumers were misled by representations that the product contained fruit. Yet, according to the complaint, "the only fruit content is a touch of strawberry fruit concentrate—twelfth in order on the ingredient list, just after partially hydrogenated soybean oil and 'natural and artificial flavors,' and just before malic acid."

According to the complaint, the plaintiff "trusted the Quaker label because of the company's long history of producing other wholesome breakfast cereals," but learned that "many popular foods and beverages are marketed as if they are made with fruit, but actually contain little or no fruit at all." He relies on a study published by the Strategic Alliance for Healthy Food and Activity Environments which purportedly concluded that "current packaging labels and advertising are misleading consumers about the nutritional value of some of the most poplar foods and snacks." The complaint also refers to a 1967 U.S. Patent and Trademark Office letter to the defendant refusing to approve a trademark application for Crunch Berries and stating, "The word BERRIES is considered either merely descriptive or deceptively misdescriptive of the good here and should be disclaimed apart from the mark shown."

The plaintiff seeks orders enjoining the allegedly deceptive conduct, actual and punitive damages, attorney's fees, costs, and interest.

Vegetarian Group Sues KFC Under Prop. 65 for Carcinogen in Grilled Chicken

The Physicians Committee for Responsible Medicine (PCRM) has sued KFC Corp. and its parent Yum! Brands, Inc. in a California court, alleging that they have failed to comply with Proposition 65 (Prop. 65) by selling grilled chicken without warning consumers that it contains a substance, PhIP, known to the state to cause cancer. *PCRM v. KFC Corp.*, No. n/a (Cal. Super. Ct., San Francisco County, filed September 23, 2009). According to a news source, the allegations are nearly identical to litigation PCRM filed in 2008 against other fast-food restaurants.

A court dismissed that complaint, citing the preemption of Prop. 65 claims by federal law which requires chicken to be cooked to food-safe temperatures. PCRM has reportedly appealed the court's ruling, arguing that the food-safe temperature requirement is merely U.S. Department of Agriculture policy and that states traditionally govern public health and safety issues.

KFC was not apparently included in the earlier suit because its chicken at that time was fried and not grilled; PhIP, an amino compound added to the Prop. 65 list in 1994, is apparently created when meat is grilled. The company is now offering

grilled chicken, and PCRM alleges that testing has revealed the presence of PhIP in 12 samples purchased from the company's stores in California. According to the complaint, "None of the locations where Defendant's grilled chicken products were purchased for purposes of testing had posted clear and reasonable warnings that food sold on the premises contained a chemical known to the State of California to cause cancer."

PCRM is seeking permanent injunctive and declaratory relief, the imposition of civil penalties of $2,500 per day for each Prop. 65 violation, costs of suit and reasonable attorney's fees. A company spokesperson has reportedly stated that the chain "meets or exceeds all federal and state regulations for food safety, including Proposition 65." He referred to a 2006 California attorney general letter saying that warnings are not required for food products containing PhIP because cooking is needed to kill potentially dangerous pathogens than are responsible for foodborne illness, deemed to be a greater risk *See Nation's Restaurant News,* September 22, 2009.

LEGAL LITERATURE

Jennifer Butler, "Cloned Animal Products in the Human Food Chain: FDA Should Protect American Consumers," *Food & Drug Law Journal*, September 2009

Authored by a recent law school graduate, this article explores the science of animal cloning and the purported shortcomings in existing regulatory authorities to adequately protect the consuming public from potential cloned animal product risks. Noting that animal cloning technology relies, for the most part, on a process that does not create a "pure, one hundred percent genetic clone," the author recommends the creation of a Food and Drug Administration "Office of Transgenic and Cloned Products" to regulate cloning processes and "take a holistic approach to risk assessment." She also calls for cloned animal product labeling to "ensure human food consumption safety" and "allow American consumers to choose not to eat cloned animal products, thereby respecting their moral, religious and ethical values."

OTHER DEVELOPMENTS

BMA Report Examines Impact of Alcohol Advertising on Young People

The British Medical Association (BMA) has issued a September 2009 **report** titled *Under the Influence: The Damaging Effect of Alcohol Marketing on Young People,* which aims "to identify effective ways of protecting young people from the influence of alcohol promotion and marketing." Led by Institute for Social Marketing Director Gerald Hastings, the report purportedly "confirms that alcohol marketing is independently linked to the onset of drinking in young people and the amount they drink," according to an accompanying article published in the September 12, 2009, edition of the *British Medical Journal.* The report also apparently criticizes regulators for allowing the UK alcohol industry, which allegedly spends approximately £800 million per year on advertising, to fund the public education program known as Drinkaware Trust. The BMA Science Board has urged UK policy makers to counter

these "ineffective educational initiatives and partial solutions" by adopting several measures, including a comprehensive ban on all alcohol marketing and "any products that either appeal to young people more than adults, or are particularly associated with problematic drinking."

Meanwhile, *BMJ* editor Fiona Godlee published a September 12 editorial on the report, predicting that "(as with tobacco) the UK and Europe will get a ban eventually" as "more people, at younger and younger ages, succumb to alcohol related liver disease." In addition, she calls on Thomas Frieden, director of the U.S. Centers for Disease Control and Prevention, to consider similar regulations. "[Frieden] built a reputation on bold action on smoking and unhealthy eating, always in the face of fierce industry opposition," concludes Godlee.

MEDIA COVERAGE

Slate Writers Challenge Effectiveness of Proposed "Fat Tax"

"It may take more than an analogy with tobacco to convince voters," argues Daniel Engber in the first of two recent *Slate* articles questioning the effectiveness of a proposed federal tax on sugar-sweetened beverages and other "hyperpalatable" food products. Titled "Let Them Drink Water: What a Fat Tax Really Means for America," the article asserts that state-levied soda taxes have thus far "turned out to be way too small to make anyone lose weight." It states that any successful effort to deter consumption would require redefining soda as drug, not a beverage.

"It's hard to draw a line, though, between foods that are drugs and foods that are merely delicious," opines Engber, who notes that under this regime, "Doughnuts are a drug; brioche is treat." He concludes that fat taxes, which "[discriminate] among the varieties of gustatory experience," would create an "apartheid of pleasure" that disproportionally affects those consumers most sensitive to food prices.

Meanwhile, William Saletan examines the greater policy implications of fat taxes in a related article titled "Then They Came for the Fresca: The Growing Ambitions of the Food Police." Saletan charges "lifestyle regulators" with "stretching the evidence about obesity and addiction" to support a federal soda tax, which he describes as a slippery slope leading to other paternalistic policies. He points to a recent *New England Journal of Medicine* (NEJM) article that suggests taxing some non-caloric beverages because, according to Arkansas Surgeon General Joseph Thompson and his co-authors, "there are concerns that diet beverages may increase caloric consumption by justifying consumption of other caloric foods or by promoting a preference for sweet tastes." Although the *NEJM* piece reportedly concedes a lack of consistent data in this area, it proposes further research to determine whether such a tax might be justified in the future.

"If studies show that [diet beverages] indirectly increase caloric consumption 'by promoting a preference for sweet states,' the food police are explicitly prepared to tax them," warns Saletan. "And the crusade won't end with soda. Anything sweet is a target." *See Slate.com,* September 21 and 22, 2009.

Marion Nestle Discusses Sugar Policy with *SFGate* Readers

"Sugar is the most absurdly protected agricultural commodity in America," according to health nutrition author and New York University Professor Marion Nestle, who answered reader questions about sugar policy during a September 20, 2009, online forum hosted by the *San Francisco Chronicle's* Web site, *SFGate.com*. In explaining the so-called "sugar crisis," Nestle stated that "Quotas allow U.S. producers to grow only specified amounts of sugar cane and sugar beets each year, for which the USDA [U.S. Department of Agriculture] guarantees a higher-than-market price." She noted that these quotas and import tariffs have "ensured that Americans pay two or three times as much for sugar," resulting in the "unnecessary transfer of $3 billion a year from 350 million Americans to a few thousand sugar growers and processors."

With these industry interests allegedly invested in "sugar protectionism," Nestle reported that these policies might finally change partly "because the gap between domestic and world market sugar – and for high fructose corn syrup – has narrowed recently." Ultimately, however, she downplayed a potential sugar shortfall, suggesting that "if sugar is responsible for any true crisis, it is because of its role as ingredient in processed foods."

"[W]e would be healthier eating less sugar, anyway," Nestle told readers. "So here's my solution to the sugar non-crisis: Eat less sugar!"

SCIENTIFIC/TECHNICAL ITEMS

Diet High in Fructose Allegedly Linked to High Blood Pressure in Men

A recent study presented at the American Heart Association's High Blood Pressure Research Conference has reportedly claimed that a diet high in fructose raises blood pressure in men, but that the gout drug allopurinol may counteract this effect. "This is the first study to show that fructose can raise blood pressure in humans," lead author Richard Johnson of the University of Colorado, Aurora, was quoted as saying.

The study followed 74 adult men, whose average age was 51, for two weeks as they consumed 200 additional grams of fructose per day. In addition, one-half of the participant pool acted as a control and one-half received allopurinol. The results apparently showed that the control group experienced significant average increases in systolic and diastolic blood pressure, while the men taking allopurinol saw little or no increase in systolic pressure.

Johnson told a news source that it was "remarkable" how quickly people with diets high in fructose developed increased blood pressure and other risk factors associated with heart disease and type 2 diabetes. Allopurinol apparently seemed to halt the blood pressure increase by lowering uric acid, which affects blood pressure.

The Corn Refiners Association (CRA) has reportedly refuted the study, saying it erroneously suggests that pure fructose and high-fructose corn syrup are equivalent ingredients consumed by Americans. "It is important not to treat studies

involving massive levels of pure fructose as if they reflect what Americans eat," the association's president said in a September 24, 2009, press release. "A laboratory diet consisting of extreme amounts of pure fructose is not how sweeteners are consumed by real people, most of whom understand the value of moderation in what they eat. As many dietitians agree, all sugars should be consumed in moderation as part of a balanced lifestyle. Sugar, high-fructose corn syrup, and several fruit juices are all roughly equal in both fructose and glucose content and are nutritionally the same. High-fructose corn syrup is simply a kind of corn sugar." *See Reuters Health*, September 23, 2009.

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Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.