Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Meat, Poultry, Egg Interests Oppose User Fees for Food Inspections

A coalition of meat, poultry and egg industry interests recently submitted a letter to the congressional Joint Select Committee on Deficit Reduction, also known as the "Super Committee," urging it to reject a proposed U.S. Department of Agriculture (USDA) fiscal year 2012 budget that would impose "user fees" on industry for government-mandated food safety inspection programs. Claiming that the inspection programs have been funded by taxpayers for more than a century, the trade associations contend that "user fees" would affect the price of meat, effectively imposing a regressive tax on low- and middle-income families who "spend a higher portion of their income on food than do wealthier Americans." The letter does not indicate how government food safety inspections can be maintained if the Super Committee, tasked with making significant reductions in the U.S. deficit, slashes USDA's budget.

Meanwhile, Republican presidential candidate and Minnesota congresswoman Michele Bachmann (R) reportedly called for rollbacks in government food safety regulations during a visit to a Des Moines meatpacking facility. According to a news source, Bachmann cut ribeye steaks in a meat locker while claiming that government regulations are overburdening food producers. She was quoted as saying, "We want to have safety. But we also want to have common sense." Without naming which regulations should be rescinded, Bachmann apparently claimed they are too complicated and expensive. The owner of the 140-year-old family-run business at which she staged the event opined that large meat processors should be subject to more rigorous testing regimens; Kent Wiese suggested that the government just conduct tests at smaller facilities like his own just once "and be done with it." *See Huffington Post*, September 20, 2011.

FTC Considers Amendments to Children's Online Privacy

The Federal Trade Commission (FTC) has proposed amendments to rules issued under the Children's Online Privacy Protection Act (COPPA), which requires the owners and operators of Websites intended for children younger than age 13 to obtain "verifiable consent from parents before collecting,

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using, or disclosing such information from children." The amendments apparently seek to address recent changes in how children access the Internet as well as innovations in social media and other online services. According to a September 15, 2011, FTC press release, the proposal would modify the COPPA rule in five areas: (i) "definitions, including the definitions of 'personal information' and 'collection'"; (ii) "parental notice"; (iii) "parental consent mechanisms"; (iv) "confidentiality and security of children's personal information"; and (v) "the role of self-regulatory 'safe harbor' programs."

Notably, the amendments would expand the definition of "personal information" to include "geolocation information and certain types of persistent identifiers used for functions other than the Website's internal operations, such as tracking cookies used for behavioral advertising." FTC would also stipulate that parental notification take place in "a succinct 'just-in-time' notice, and not just a privacy policy," while offering new parental consent mechanisms such as electronically scanned consent forms, video-conferencing and government-issued identification, "provided that the parent's ID is deleted promptly after verification is done." At the same time, the updated rule would eliminate "the less reliable method of parental consent, known as 'e-mail plus,'" strengthen confidentiality and security requirements for any service provider or third-parties trusted with a child's personal information, and increase FTC's oversight of "safe harbor programs" that enable industry groups to implement COPPA provisions via self-regulatory guidelines.

"In this era of rapid technological change, kids are often tech savvy but judgment poor. We want to ensure that the COPPA Rule is effective in helping parents protect their children online, without unnecessarily burdening online businesses. We look forward to the continuing thoughtful input from industry, children's advocates, and other stakeholders as we work to update the Rule," said FTC Chair Jon Leibowitz. The agency will accept comments on the proposed amendments until November 28, 2011.

FDA Refutes Arsenic Apple Juice Claims

The Food and Drug Administration (FDA) recently issued a **consumer update** reassuring the public about the safety of apple juice after a TV talk show claimed that certain brands contain high levels of arsenic. Mehmet Oz, who hosts "The Dr. Oz Show," apparently sent 50 apple juices samples to EMSL Analytical, Inc., which measured total arsenic levels as high as 36 parts per billion (ppb) in one sample. After learning of the results, FDA sent two letters to the show's producers asking them not to air the segment, not only because the results seemed "erroneously high" but also because the laboratory only considered the total amount of arsenic.

"As we have previously advised you, the results from total arsenic tests CANNOT be used to determine whether a food is unsafe because of its arsenic

content," stated FDA in its September 9, 2011, letter. "We have explained to you that arsenic occurs naturally in many foods in both inorganic and organic forms and that only the inorganic forms of arsenic are toxic, depending on the amount. We have advised you that the test for total arsenic DOES NOT distinguish inorganic arsenic from organic arsenic."

As one FDA senior science advisor further explained in the consumer update, "Organic arsenic is essentially harmless, but the inorganic kind can be harmful at high and long-term levels of exposure." The agency also noted that it "has been tracking total arsenic contamination in apple and other juices for about six years, since foreign producers started gaining an increasing share of the juice market." In addition, importers must prove that their fruit juices and concentrates are safe for the domestic market.

Nevertheless, U.S. Senator Charles Schumer (D-N.Y.) has already weighed in on the matter, calling on FDA to "put in place clear standards for imported fruit and vegetable juice concentrates and step up inspection of concentrates from countries that use toxic, inorganic arsenic in their pesticides, or with high levels of environmental contaminants." Despite acknowledging the talk show's questionable methodology, Schumer issued a September 19, 2011, press release urging FDA and the Environmental Protection Agency to create a system similar to that currently used for bottled water. "Given the terrible track record of countries like China that export the vast majority of certain juices these days, you can never be too careful," opined Schumer, "and that's why I'm calling on the FDA to set standards for juices just like they do for water. Many kids drink more juice per day than water, so we need to take every available precaution and make sure standards are in place that consider the long-term exposure to inorganic arsenic."

FDA's Animal-Drug Rule Amendment Allows More Progesterone Residues in Meat

Asserting that its technical animal-drug-regulation amendment is not subject to congressional review, the Food and Drug Administration (FDA) has issued a **final rule** that increases the allowable residues of progesterone in edible tissues of cattle and sheep to reflect revised daily consumption values in a 1994 guidance document. According to the *Federal Register* notice, "Progesterone is approved for use in subcutaneous implants used for increased rate of weight gain in suckling beef calves and steers and in vaginal inserts used for management of the estrous cycle in female cattle and ewes." The rule took effect on September 19, 2011, when it was published.

LITIGATION

Former Kosher Meatpacking Plant Manager Loses Sentencing Appeal

Sholom Rubashkin, who managed a kosher meatpacking facility in Postville, Iowa, and was convicted on 86 counts related to financial fraud, lost the appeal of his conviction and the 324-month prison sentence imposed by a federal district court. ***United States v. Rubashkin*, Nos. 10-2487/3580 (8th Cir., decided September 16, 2011)**. Additional details about the case appear in **Issue 378** of this *Update*.

Among other matters, the Eighth Circuit Court of Appeals determined that evidence indicating that the trial court judge met with prosecutors before the facility was raided by immigration officials was insufficient to show bias against Rubashkin or that "the district court's decision to remain on the case prejudiced Rubashkin's verdict." The court also found no fault in the trial court severing the bank fraud charges from the immigration law violations, which the government later dismissed, and trying the bank fraud charges first. According to the appeals court, "Given the evidentiary overlap between the charges in the two trials, Rubashkin's testimony at an earlier immigration trial could have been used against him in a subsequent financial trial. Under all the circumstances the district court's scheduling order was a practical solution given the nature and number of the charges."

The court also upheld various evidentiary rulings, jury instructions and convictions, as well as the length of the prison term, which was longer than recommended by prosecutors, despite arguments by amici that it was unreasonably harsh. In this regard, the court stated, "Not only was Rubashkin's sentence of 324 months within the guideline range, it was at the low end of it. . . . Under all the circumstances the district court did not abuse its considerable discretion in imposing a 324 month sentence."

Second Circuit Returns Pesticide Findings to EPA

The Second Circuit Court of Appeals has granted, in part, the petition for review filed against the Environmental Protection Agency (EPA), challenging its risk assessments for the pesticide dichlorvos. ***NRDC v. EPA*, No. 08-3771 (2d Cir., decided September 16, 2011)**. The court agreed with the Natural Resources Defense Council, (NRDC) that EPA's failure to explain why a children's safety factor less than 10X was applied to pesticide risk assessments derived from the "Gledhill study," which involved six adults who consumed dichlorvos daily for three weeks, was arbitrary and capricious. When EPA sets tolerances for the maximum level of dichlorvos residue on food products, it is required, under the Food Quality Protection Act, to apply a tenfold children's safety factor. Vacating the portions of EPA's order assessing the risk of dichlorvos based on the Gledhill study, the court remanded the matter to the agency for further proceedings.

EPA has registered a number of dichlorvos products for sale and distribution in the United States. According to the court, it is "a synthetic pesticide used to kill many insects, including flies, mosquitos, gnats, cockroaches, and fleas. Dichlorvos belongs to a family of pesticides known as organophosphates, developed from nerve warfare agents after World War II. Like other organophosphates, dichlorvos can disrupt proper functioning of the nervous system by inhibiting an important enzyme, cholinesterase, in red blood cells and the brain." EPA, at one time, considered requiring a cancer warning on dichlorvos products, which are used on crops, animals and in pest strips to control insects in storage areas and barns.

Balance Bar "All Natural" Claims Targeted in Consumer Fraud Lawsuit

Seeking to represent a nationwide class of consumers, a California resident has filed a consumer fraud class action against the Balance Bar Co., challenging its "All Natural" claims in light of product ingredients such as ascorbic acid, cocoa (processed with alkali), glycerine, sodium citrate, and xanthan gum. *Sethavanish v. Balance Bar Co.*, No. 11-4547 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., filed September 13, 2011). She claims that she purchased different Balance Bar products since 2007 relying on the "All Natural" representations and paying more for the products "than she would have had to pay for other products that were not all natural."

In her complaint, she notes that the Food and Drug Administration does not regulate the term "natural," but contends that the agency "has established a policy defining the outer boundaries of the use of that term by clarifying that a product is not natural if it contains color, artificial flavors, or synthetic substances." The plaintiff then details in what ways the specified ingredients are artificial, artificially processed or otherwise synthetic.

Alleging economic damages only, the plaintiff brings claims for common law fraud; unlawful, unfair and fraudulent business practices under California law; false advertising; violation of the Consumers Legal Remedies Act; and restitution based on quasi-contract or unjust enrichment. She seeks restitution, compensatory and punitive damages, declaratory and injunctive relief, attorney's fees and costs, and "[a]n order requiring an accounting for, and imposition of, a constructive trust upon, all monies received by Balance Bar as a result of the unfair, misleading, fraudulent and unlawful conduct alleged herein."

Former Chili's Employee Sues over Wages

A California resident has filed a putative class action against Brinker International, Inc., alleging that when she worked for one of its Chili's Grill & Bar Restaurants she was not paid minimum wage, because the company "fraudulently and maliciously caused Plaintiff and Class members to make up the

restaurants' cash shortages." *Eldred v. Brinker Int'l, Inc.*, No. 56-2011-00403808 (Cal. Super. Ct., Ventura County, filed September 15, 2011). According to the complaint, if a customer leaves the restaurant without paying or does not leave enough money to pay the entire tab, "it is defendant's corporate policy to either inform the server that he or she has to pay for the walkout or that server will be written up and if it happens again that server may be terminated. Defendant uses the threat of termination to induce class members to pay for walkouts out of their own money."

Alleging failure to pay minimum wage, labor code violations, and unfair business practices, the plaintiff seeks to certify a statewide class of Chili's servers and also requests compensatory damages, restitution, injunctive relief, interest, costs, and attorney's fees.

Dispute over Allegedly Defective Bottles Settles

While settlement terms are apparently confidential, a high-end bottled water company has reportedly settled its claims against a company that supplied bottles which reacted to the water by causing foaming and a poor taste. *Penta Water Co. v. Zuckerman-Honickman, Inc.*, No. 09-2633 (U.S. Dist. Ct., E.D. Pa., dismissed with prejudice September 21, 2011). The water company evidently switched to the defendant's bottles in conjunction with the launch of a campaign intended to broaden its customer base beyond athletes, celebrities and health food consumers. The alleged bottle defect forced the plaintiff to halt the campaign, close its manufacturing plant and undertake "crisis management." The packaging company and the water bottler have both reportedly undergone bankruptcy proceedings. *See Law360*, September 22, 2011.

OTHER DEVELOPMENTS

CALPIRG Campaigns Against Subsidizing Sweeteners

The California Public Interest Research Group (CALPIRG) has released a September 21, 2011, **report** claiming that federal agricultural subsidies are largely allocated to commodity crops such as soybeans and corn instead of fresh produce. Titled "Apples to Twinkies: Comparing Federal Subsidies of Fresh Produce and Junk Food," the report alleges that, of the $260 billion spent on agriculture between 1995 and 2010, $16.9 billion subsidized "four common food additives—corn syrup, high fructose corn syrup, corn starch, and soy oils (which are frequently processed further into hydrogenated vegetable oils)," while only $262 million went to apple crops, "the only significant federal subsidy of fresh fruits or vegetables." According to CALPIRG, these allocations are the equivalent of giving individual taxpayers enough to buy 19 Twinkies® each year "but less than a quarter of one Red Delicious apple apiece."

"This wasteful spending not only squanders taxpayer dollars: by fueling the crisis of childhood obesity, the subsidies damage our country's health and increase the medical costs that will ultimately need to be paid to treat the effects of the obesity epidemic," opines the report, which urges U.S. agricultural policy reform. "Taxpayers are paying for the privilege of making our country sick… Subsidies to large agribusinesses are egregious enough on their own; the fact that the subsidies go to junk food adds insult to injury."

Breast Cancer Fund Targets BPA in Children's Canned Food

The Breast Cancer Fund (BCF) recently issued a **report** alleging that six canned meal products marketed to children contain bisphenol A (BPA) at levels averaging 49 parts per billion (ppb). Researchers reportedly sent 12 items total to an independent laboratory, which pureed the can contents in "BPA-free materials" and assessed BPA levels using Gas Chromatography-Mass Spectrometry. According to the results, the sampled soups averaged 77.5 ppb of BPA and the meals 21 ppb, with one canned soup purportedly registering a BPA level of 148 ppb.

"The levels of BPA we found in these canned foods marketed to children are of great concern," states BFC in its report. "While a child-sized serving (about two-thirds of an adult-sized serving, according to Kaiser Permanente's serving size estimates for children) may result in BPA exposure at a level of concern, an adult-sized serving given to a child would result in even higher BPA exposure."

The group has apparently used the findings to further its "Cans Not Cancer" campaign to remove BPA from food packaging. It has also called on legislators to support a bill introduced earlier this year by U.S. Representative Edward Markey (D-Mass.) that would ban BPA from all food and beverage containers as well as direct the Food and Drug Administration to review approved food packaging additives which "may pose a health risk, based on new scientific information."

Law School Announces Free Public Health Webinars

The **Public Health Law Center** at William Mitchell College of Law has announced the launch of a series of free Webinars that will address issues relating to tobacco control, obesity prevention, worksite wellness, active living, and public health legislation. Scheduled for October 5, 2011, the first Webinar will feature staff attorneys presenting on "Drafting Effective Public Health Policies." A number of the health center's staff attorneys focus on tobacco-control issues and projects; listed as a consulting attorney is Mark Perstchuk, who is the past president and executive director of Americans for Nonsmokers' Rights.

MEDIA COVERAGE

Frances Moore Lappé, "The Food Movement: Its Power and Possibilities," *The Nation*, October 3, 2011

The author of the 1971 bestseller *Diet for a Small Planet* has authored an essay that examines how global agriculture has changed since then. While Francis Moore Lappé notes that 1 billion people are hungry and agribusiness is concentrated in few hands—"in the United States, by 2000, just ten corporations—with boards totaling only 138 people—had come to account for half of US food and beverage sales"—a global grass-roots food movement "has been gaining energy and breadth for at least four decades." Among other matters, Moore Lappé discusses growing popular opposition to genetically modified crops and increases in connectivity through community-supported agriculture programs and farmers' markets.

Included with the essay are responses authored by Vandana Shiva, "Resisting the Corporate Theft of Seeds"; Eric Schlosser, "It's Not Just About Food"; Raj Patel, "Why Hunger Is Still With Us"; and Michael Pollan, "How Change Is Going to Come in the Food System." Shiva began a program in India to create community seed banks that counter "the corporate control of our food system and the role of governments in increasing, rather than stopping, the corporate abuse of our seeds and soils, our bodies and our health."

Schlosser, who authored *Fast Food Nation* and co-produced "Food, Inc.," lauds the increase in farmers' markets and inner-city community gardens, but suggests that more is needed to improve the lives of Americans, stating "Without a fundamental commitment to social justice, the estimated 1-2 percent of Americans who eat organic food will be indistinguishable from the 1-2 percent who control almost all of this country's wealth and power."

Pollan teaches journalism at the University of California, Berkeley, and has written frequently on food-related subjects. He contends, "the food movement can claim more success in changing popular consciousness than in shifting, in any fundamental way, the political and economic forces shaping the food system or, for that matter, in changing the 'standard American diet'—which has only gotten worse since the 1970s."

Pollan also comments, "It's worth remembering that it took decades before the campaign against the tobacco industry could point to any concrete accomplishments." Pointing to a 50-year gap between scientific findings about smoking and health and the industry's loss of influence among policymakers, Pollan notes, "By this standard, the food movement is making swift progress." According to Pollan, one of the lessons that food advocates can learn from the antismoking campaign is that when "overcoming the influence of entrenched power, it helps to have another powerful interest in your corner—an interest that stands to gain from reform." He suggests that states and the insurance

industry, which may be "on the hook for the cost of the American diet," could be those allies.

Ashby Jones, "Is Your Dinner 'All Natural'?," *The Wall Street Journal*, September 20, 2011

WSJ Reporter Ashby Jones provides an overview of the recent spate of lawsuits challenging food makers' claims that their products are "All Natural" or "100% Natural." Without an official Food and Drug Administration (FDA) definition of the term, determining whether such product claims constitute fraud can be difficult, according to lawyers such as Center for Science in the Public Interest's Stephen Gardner, who was quoted as saying, "We badly want them to provide some clarity on the issue, but they've repeatedly failed to do anything."

The article notes how FDA muddied the waters for products containing high-fructose corn syrup (HFCS) by announcing in 2008 that it is not "natural" and then later pronouncing that it actually depends on how synthetic ingredients are used to make the HFCS. Details about the FDA's HFCS actions appear in Issues 255 and 266 of this *Update*. An FDA spokesperson acknowledged that the agency has declined to address the issue head on, but noted, "With the few precious dollars the FDA has, we largely choose to focus on topics that affect public safety. The 'natural' issue doesn't. That's not to say it's not important, but we frankly have more pressing things to deal with."

Jones concludes by observing that plaintiffs' lawyers have not yet made much money litigating consumer fraud claims involving the "All Natural" product representations, "at least when compared with large-scale securities or personal-injury suits." Still, Gardner indicated that companies generally settle such claims quickly to avoid the publicity of a jury trial.

SCIENTIFIC/TECHNICAL ITEMS

NIEHS Paper Suggests FDA Focused Too Narrowly on Synthetic Food Color Effects

A new *Environmental Health Perspectives* paper discusses a Food and Drug Administration (FDA) advisory committee's recent conclusion that the evidence is too inconclusive to associate children's consumption of artificial colors in food with hyperactivity or to recommend warning labels. Titled "Synthetic Food Colors and Neurobehavioral Hazards: The View from Environmental Health Research," the paper suggests that if FDA had approached the issue from an environmental health perspective and broadened its inquiry to consider a range of adverse effects, current research findings could have supported a different outcome.

The author notes that the review confined itself "to the clinical diagnosis of hyperactivity . . . rather than asking the broader environmental question of behavioral effects in the general population; it failed to recognize the signifi-

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cance of vulnerable subpopulations; it misinterpreted the meaning of effect size as a criterion of risk." The article concludes that scientific risk reviews with "too narrow a focus on a single outcome or criterion can be misleading."

Study Alleges Link Between Glucose Levels and Desire for High-Calorie Foods

A recent **study** has suggested that non-obese individuals are better able to regulate their cravings to consume fattening foods than those who are obese. Kathleen Page, et al., "Circulating glucose levels modulate neural control of desire for high-calorie foods in humans," *Journal of Clinical Investigation*, September 19, 2011. Researchers from Yale University and the University of Southern California apparently studied brain scans of nine thin and five obese subjects as they viewed images of high-calorie foods, low-calorie foods, and non-food items during times when they had normal and low blood sugar levels.

Researchers found that non-obese participants shown pictures of high-calorie foods had increased activity in the part of their brains used for impulse control while obese people showed little activity in that part of the brain. According to the study, "higher circulating glucose levels predicted greater medial prefrontal cortex activation, and this response was absent in obese subjects. These findings demonstrate that circulating glucose modulates neural stimulatory and inhibitory control over food motivation and suggest that this glucose-linked restraining influence is lost in obesity." Study co-author Robert Sherwin of Yale University School of Medicine told a news source that although larger studies were needed to confirm the findings, the study suggests that biological reasons may be a factor in why obese people cannot control their desire for high-calorie foods. *See Reuters,* September 19, 2011.

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