

FOOD & BEVERAGE LITIGATION UPDATE



CONTENTS

Legislation, Regulations and Standards

USDA Criticized for Proposed Changes to Poultry and Hog Inspection	1
EPA Withdraws Proposed Rules on BPA and Phthalates	3
USDA Announces Public Meeting of NOSB	3
FDA Reports Arsenic Levels in Rice Pose No Short-Term Risk	3
FDA Extends Comment Deadline for Proposed Arsenic Action Level in Apple Juice	4
Mexico Proposes Tax on Sugar-Sweetened Beverages	4

Litigation

Ninth Circuit Upholds Ruling in Challenge to California's Foie Gras Ban ..	5
Federal Court Refuses to Enjoin Amended COOL Rules	6
Court Reduces Damages Award in Consumer Diacetyl Exposure Lawsuit ..	7
Economic Loss Class Action Filed Against Chobani for Mold in Yogurt	8
Class Complaint Against Hain Celestial Amended	8
Court Grants Final Approval to Class Settlement in Frosted Mini-Wheats Suit	9
California Claims Pet Products at Whole Foods Violate Pesticide Limits ..	9
Turkish Authority Fines Frito-Lay \$8.6 Million for Anticompetitive Activity ..	10

Legal Literature

PHAI Attorneys Discuss "Cheeseburger" Bills and Obesity-Related Lawsuits ..	10
---	----

Other Developments

McDonough & Awong Contribute to FDLI Primer on Veterinary Drug Product Regulation	11
Former CDC Director of Nutrition Urges Parents to Tackle Food Marketing to Children	11

Scientific/Technical Items

Study Examines Role of Gut Bacteria in Obesity	12
Meta-Analysis Allegedly Links SSBs to Weight Gain in Children and Adults ..	13

LEGISLATION, REGULATIONS AND STANDARDS

USDA Criticized for Proposed Changes to Poultry and Hog Inspection

The Government Accountability Office (GAO) recently issued a [report](#) finding that the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) did not adequately evaluate the impact of proposed poultry and hog inspection changes that would replace some USDA inspectors on slaughter lines with plant personnel tasked with ensuring quality and safety standards. According to the report, USDA implemented several pilot projects at poultry and hog processing plants over the past decade but ultimately failed to gather enough data to assess the effectiveness of these new systems. Nevertheless, the agency has since proposed an optional inspection scheme for both poultry and hog operations "based on its experience with the pilot projects at young chicken and young turkey plants."

Asked to review these pilot projects by Sen. Kirsten Gillibrand (D-N.Y.), GAO determined that the proposed changes would give production plants more flexibility and responsibility while allowing inspectors to focus their efforts on food safety activities. It also found, however, that (i) "training of plant personnel assuming sorting responsibilities on the slaughter line is not required or standardized"; (ii) "faster line speeds allowed under the pilot projects raise concerns about food safety and worker safety"; and (iii) USDA failed to provide accurate cost-benefit information to stakeholders and did not disclose "certain limitations in sources of information it relied on to develop the cost-benefit analysis supporting the proposed rule on modernizing poultry slaughter inspections." In the case of the pilot projects implemented at hog farms, GAO expressed additional concern that small sample sizes "would not provide reasonable assurance that any conclusions can apply more broadly to the universe of 608 hog plants in the United States in 2012."

Based on these findings, GAO has called on USDA to (i) "collect and analyze information to determine if the young hog pilot project is meeting its purpose" and (ii) "clearly disclose to the public limitations in the information it relied on for the proposed rule to modernize poultry slaughter inspections." Although USDA has concurred with these recommendations, consumer

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

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.

For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com



or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com



If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

groups such as the Center for Science in the Public Interest (CSPI) have already urged USDA to scrap the new inspection systems altogether in light of GAO's conclusions.

"The government does not have enough evidence that the existing hog and poultry pilot programs—on which the new poultry program is based—have succeeded in resulting in safer meat," said CSPI Senior Food Safety Staff Attorney Sarah Klein in a September 9, 2013, statement. "While you can't see *Salmonella*, it's clear that these carcasses are whizzing by too fast for inspectors to keep the product free from even visible contamination."

Meanwhile, *The Washington Post* has reported that these pilot programs have "repeatedly failed to stop the production of contaminated meat" at plants in Australia, Canada and the United States. Citing internal documents and interviews, the *Post* claims that the new inspection system—which purportedly increases the speed of processing lines "by as much as 20 percent" and replaces half of the USDA safety inspectors at each plant with private inspectors—has "experienced a rash of problems," resulting in at least one recall of 8.8 million pounds of Canadian beef products allegedly tainted with *E. coli*.

"In interviews, six USDA inspectors working in the pilot plants raised health concerns," writes government accountability reporter Kimberly Kindy in the September 8, 2013, article. "Several said company and government workers are yelled at, threatened and shunned if they try to slow down or stop the accelerated processing lines or complain too aggressively about adequate safety checks. They also warned that the reduction in the ranks of government inspectors in the plants has compromised the safety of the meat."

In a related development, FSIS has [reissued](#) a notice clarifying the "responsibilities and authorities relating to assessing and reducing slaughter or evisceration line speed" for inspectors-in-charge (IICs), public health veterinarians (PHVs), and off-line and on-line inspection program personnel (IPP) working at processing plants. According to FSIS, PHVs and IICs "are to ensure that IPP can perform a post-mortem inspection of poultry and livestock carcasses at all times" and "to slow maximum allowed line speeds when slaughter process control is not maintained because of inconsistencies in size, weight, class of animal or bird, health, pathology, contamination, sanitary dressing or presentation." In particular, the notice emphasizes that on-line IPP must alert PHV, ICC or off-line IPP "if they detect trends of increasing contamination, pathology, disease, or improper presentation" and can stop the line when necessary "to prevent the production of adulterated or unwholesome product." See *FSIS Notice*, September 10, 2013.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

EPA Withdraws Proposed Rules on BPA and Phthalates

According to news sources, the U.S. Environmental Protection Agency (EPA) recently withdrew two draft rules, including one that would have designated bisphenol A (BPA) and certain phthalates as “chemicals of concern,” submitted for approval in 2010 and 2011 to the Office of Management and Budget’s Office of Information and Regulatory Affairs (OIRA) where they remained beyond their prescribed 90-day period of review. The other rule would have clarified that health and safety studies on pre-market chemicals submitted to EPA would not have been deemed confidential business information and would have been made publicly available. The proposed rules were opposed by the chemical industry, which has praised EPA’s decision to abandon the rulemaking.

According to an Environmental Defense Fund scientist, OIRA’s failure to act “has effectively denied the public its voice in the rulemaking process.” Richard Denison also said, “By blocking EPA from even proposing the rules and taking public comment—which would have been the proper venue for airing questions and concerns from all stakeholders—OIRA has taken on the unauthorized role of serving as judge and jury. And because none of its reasons for blocking the proposed rules has or will be made public, that outside role flies in the face of basic principles of transparency and democracy.” *See Huffington Post, American Chemistry Council News Release and EDF Health, September 6, 2013.*

USDA Announces Public Meeting of NOSB

The U.S. Department of Agriculture’s (USDA’s) Agricultural Marketing Service has announced an October 22-24, 2013, public [meeting](#) of the National Organic Standards Board (NOSB) in Louisville, Kentucky. The meeting will address “several petitions pertaining to changes to the National List of Allowed and Prohibited Substances, including several substances for use in aquaculture, streptomycin for use to control fire blight in pears and apples, and glycerin,” in addition to featuring updates from the NOSB subcommittees on Compliance, Accreditation, and Certification; Crops; Handling; Livestock; Materials; Policy Development; and Genetically Modified Organisms (GMO). In particular, the GMO Ad-Hoc Subcommittee will discuss how to ensure and enforce the genetic purity of seed used in organic crop production. NOSB will accept written public comments on the meeting agenda and registrations for oral public comments by October 1, 2013. *See Federal Register and NOSB Press Release, September 5, 2013.*

FDA Reports Arsenic Levels in Rice Pose No Short-Term Risk

The U.S. Food and Drug Administration (FDA) has reported that after testing 1,300 samples of rice and rice products for the presence of arsenic, the agency

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

has determined that although the levels varied significantly depending on the product tested, the [amount of detectable arsenic](#) is “too low” to cause any “immediate or short-term adverse health effects.” The new findings represent the latest of the agency’s ongoing efforts to manage possible arsenic-related risks associated with the consumption of rice in the United States.

FDA has apparently been monitoring arsenic levels in rice for more than 20 years and has seen no evidence of change in levels of total arsenic in rice. The agency’s next step will be to use new tools that provide greater specificity about different types of arsenic present in foods to analyze the effect of long-term exposure to low levels of arsenic in rice. It plans to conduct a risk assessment to consider how much arsenic is consumed from rice products and whether variations in health effects exist for certain segments of the population. *See FDA News Release*, September 6, 2013.

FDA Extends Comment Deadline for Proposed Arsenic Action Level in Apple Juice

The U.S. Food and Drug Administration (FDA) has extended until November 12, 2013, the [period](#) for submission of comments, scientific data and other information related to its draft guidance titled “Arsenic in Apple Juice: Action Level.” Originally published in the July 15 *Federal Register*, the [guidance](#) proposes an action level of 10 parts per billion for inorganic arsenic in apple juice, which FDA considers “protective of human health and achievable with the use of good manufacturing practices.” The U.S. Environmental Protection Agency has set the same level for arsenic in drinking water. FDA extended the deadline in response to a request “to allow interested persons additional time to submit comments.” More details about the proposed rule appear in [Issue 490](#) of this *Update*. *See Federal Register*, September 13, 2013.

Mexico Proposes Tax on Sugar-Sweetened Beverages

Lawmakers in Mexico have reportedly proposed a tax on all sugar-sweetened beverages in an effort to curb the nation’s obesity and Type 2 diabetes epidemics. According to a news source, the proposed legislation, intended for flavored beverages, concentrates, powders, syrups, and essences or flavor extracts, would apply a tax of one peso (US eight cents) for each liter of sugar-sweetened beverage. Soft drinks sold at movie theaters would evidently be exempt.

Consumer advocacy groups support a tax on sugary beverages, but argue that it should be higher to have a greater impact on public health. “It’s good that there would be a tax. We have to acknowledge that. But to have a significant impact on consumption of sugary drinks, assessments show that it should be a 20 percent tax,” said Alejandro Calvillo, head of the consumer watchdog group Consumer Power A.C. Calvillo, who has linked the consump-

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

tion of sugary drinks in Mexico to the lack of drinking water in public places, said that the Mexican government should provide details of how it would spend the 2 billion pesos (US\$152 million) likely to be raised by the soda tax and suggested that some of the money be used to put drinking fountains in schools and public places. See *The Wall Street Journal* and *Rudd Radar*, September 9, 2013; *HurriyetDailyNews.com*, September 11, 2013.

LITIGATION

Ninth Circuit Upholds Ruling in Challenge to California's Foie Gras Ban

The Ninth Circuit Court of Appeals has affirmed a lower court ruling denying the request for a preliminary injunction to halt the application of a California statute that forbids the sale of products resulting from force feeding a bird to enlarge its liver and prohibits force feeding birds to enlarge their livers beyond normal size. [*Association des Éleveurs de Canards et d'Oies du Québec v. Harris, No. 12-56822 \(9th Cir., decided August 30, 2013\)*](#). While the court dismissed the governor and state as defendants on the basis of immunity, it agreed with the district court that the state attorney general was not immune from suit under the Eleventh Amendment. Additional information about the lawsuit appears in issues [446](#) and [454](#) of this *Update*.

Because the court found that the plaintiffs, out-of-state foie gras producers and a California restaurant that sold the product before the law took effect, were not likely to succeed on the merits, it did not address the remaining preliminary injunction elements. Among other matters, the court determined that the statute did not prohibit the sale of anything other than duck livers produced by force feeding in California, rejecting the plaintiffs' argument that it would also prohibit them from selling down or breast meat from its force-fed ducks. The court also rejected the plaintiffs' contention that the law is unconstitutionally vague, because the terms "demonstrate that the statute covers Plaintiffs' conduct in this case." The court further found that the law did not violate the plaintiffs' rights under the Commerce Clause.

Two of the court's determinations were based on the preliminary nature of the proceedings: (i) "Plaintiffs would have us assume, without evidentiary support, that § 25982 amounts to a flat ban on foie gras. Plaintiffs' declarations do not demonstrate that foie gras may be produced only by force feeding. . . . At this stage in the proceedings, Plaintiffs have not shown that the effect of § 25982 is a complete import and sales ban on foie gras"; and (ii) "At this stage in the proceedings, Plaintiffs have not demonstrated that a nationally uniform foie gras production method is required to produce foie gras. If no uniform production method is required, Plaintiffs may force feed birds to produce foie gras for non-California markets. California's standards are therefore not imposed as the sole production method Plaintiffs must follow."

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

Federal Court Refuses to Enjoin Amended COOL Rules

A federal court in the District of Columbia has denied the American Meat Institute's motion for a preliminary injunction in a challenge to the amended country-of-origin labeling (COOL) rules adopted by the U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service in response to a World Trade Organization (WTO) determination that the original rules violated the WTO Agreement on Technical Barriers to Trade by according less favorable treatment to foreign livestock. [*Am. Meat Inst. v. USDA, No. 13-1033 \(U.S. Dist. Ct., D.D.C., decided September 11, 2013\)*](#).

The court was not persuaded that the plaintiffs, meat processing interests, were likely to succeed on the merits of their First Amendment and statutory challenges to the amended rule. Additional information about the challenge appears in Issue [495](#) of this *Update*.

Assessing the First Amendment claims under a lenient reasonableness standard because the rule involved commercial speech that mandated purely factual and uncontroversial disclosures, the court determined that the rule, requiring disclosure of specific product-step information, was reasonably related to the government's interest in preventing consumer confusion about the origins of muscle-cut meat. The court also rejected the plaintiffs' claim that the agency exceeded its statutory authority in enacting regulations that mandate the disclosure of "born, raised, and slaughtered" information. According to the court, "the text and structure of the COOL statute present obstacles that appear to be too great for Plaintiffs to overcome." The court also disagreed that USDA exceeded its mandate by adopting a rule that will allegedly end commingling, that is, processing animals from different countries of origin together during a single production day. As the court noted, not only does "commingling" not appear anywhere in the COOL statute, but the concept of commingling is not "unambiguously present in the statutory text." The court dismissed other commingling arguments because they were "based on the same type of loose textual analysis."

The court concluded that the plaintiffs' statutory arguments, which "cherry-pick the trees and miss the forest," are "unlikely to succeed on the merits in the overall scheme of things." In this regard, the court noted that it was clear Congress intended to provide consumers with more information about the origins of their meat, not less. Because the plaintiffs based their textual arguments on the opposite assumption, their "reading of the statute is flatly inconsistent with nearly every statement that members of Congress made about COOL when the law was enacted and amended," the court said.

As to the plaintiffs' Administrative Procedure Act challenge, the court rejected claims that the amended rule would require inaccurate or misleading labels, stating "it is of no moment that Plaintiffs can dream up scenarios in which, under the Final Rule, 'labels will in many cases be inaccurate' or will 'some-

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

times omit relevant production step information.” The court also found that the agency did its best to comply with the WTO ruling and any shortcomings that may lead to further proceedings before that body do not prove that it acted arbitrarily and capriciously. The court further found fault with the plaintiffs’ argument that the rule’s effective date was arbitrary and capricious, finding that it was mandated by the WTO ruling and the agency thus had a sufficiently reasoned basis for establishing it, given the potential for retaliatory sanctions as a result of any delay in compliance with WTO’s deadline.

Addressing the other preliminary injunction factors, the court determined that the plaintiffs had not shown they were likely to experience irreparable harm, finding the statements of dire economic consequences filed by the declarants speculative in that they were based on what the meat producers expected to happen in the marketplace, what their customers were likely to demand and what could happen to their businesses if required to follow the rule. While the court found that the rule would impose significant compliance costs that may not be outweighed by sanctions that could result from the U.S. government’s failure to comply with its international trade obligations, this was insufficient alone to merit preliminary injunctive relief.

Court Reduces Damages Award in Consumer Diacetyl Exposure Lawsuit

A federal court in Colorado has reduced the damages awarded to a man who allegedly contracted bronchiolitis obliterans, a debilitating respiratory condition, after consuming microwave popcorn containing the butter flavoring compound diacetyl. *Watson v. Dillon Cos., Inc.*, No. 08-91 (U.S. Dist. Ct., D. Colo., judgment entered September 5, 2013). The jury awarded the plaintiff and his wife more than \$7 million, including punitive damages, apportioned among a number of defendants, and the court reduced the total award by more than half to \$3.04 million with interest. Additional information about the lawsuit appears in issues [244](#), [454](#) and [480](#) of this *Update*.

The court agreed with defendant Gilster-Mary Lee, a private label food manufacturer, that a statutory cap applied to the \$800,000 non-economic damages award against it because the plaintiff discovered or should have discovered his lung injury and its cause before a statutory cut-off in January 2008. The court further refused to double the statutory cap, finding that the case did not present exceptional circumstances. According to the court, the plaintiff was not completely disabled, he works part-time, takes walks outdoors with his wife, and can move upstairs and downstairs in his home. The court also noted that once he stopped eating popcorn, the plaintiff’s condition stabilized.

Because the court determined that the defendant ceased using diacetyl in its product before the case was filed, punitive damages could not exceed the amount of actual damages. Thus the court reduced a \$5-million punitive award to \$1.26 million. The court also refused the plaintiffs’ request to treble

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

the damages for the defendants' alleged bad faith; according to the court, the plaintiffs may not recover both punitive and treble damages.

As to attorney's fees, the court rejected the plaintiffs' request for nearly \$1.4 million, agreeing with the defendants that the billing statement contained vague entries and included "many instances of duplicative or redundant charges." The court also questioned the need for multiple attorneys and paralegals traveling from the Independence, Missouri, law firm to Colorado for certain pre-trial hearings. Reducing the number of hours by half and declining to adjust the lodestar figure upward, the court awarded the attorneys \$826,500.

Economic Loss Class Action Filed Against Chobani for Mold in Yogurt

While dozens of consumers have purportedly experienced nausea and cramps after eating Chobani Greek Yogurt products allegedly contaminated with mold, a California resident without apparent physical injury has filed a putative class action against the company to recover damages for purchasing a defective product. *Green v. Chobani, Inc.*, No. 13-2106 (U.S. Dist. Ct., S.D. Cal., filed September 9, 2013). Plaintiff Harold Green alleges that he purchased 16 cups of yogurt subject to a company recall and that he and his family members consumed some of them before the September 5, 2013, recall date. After receiving notice of the recall, the plaintiff claims that he returned six cups to the store.

Seeking to represent a nationwide class and statewide subclass of purchasers, the plaintiff alleges negligence and breach of the implied warranty of merchantability for food. He requests restitution, disgorgement, interest, compensatory damages, attorney's fees, and costs. See *NBCNews.com*, September 10, 2013.

Class Complaint Against Hain Celestial Amended

A second amended complaint has been filed in a putative nationwide class action alleging that The Hain Celestial Group's food and beverage product labels render their products misbranded and further mislead consumers because they use the terms "No Trans Fat," "Evaporated Cane Juice" or "All Natural" in violation of state law. *Smedt v. The Hain Celestial Group, Inc.*, No. 12-3029 (U.S. Dist. Ct., filed August 30, 2013). Details about the court ruling dismissing the claims with leave to amend appear in Issue [495](#) of this *Update*. The plaintiff has omitted any claims that the company's Website misled consumers and has otherwise attempted to address the court's concerns about ambiguous fraud allegations in her initial pleadings.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

Court Grants Final Approval to Class Settlement in Frosted Mini-Wheats Suit

A federal court in California has granted a motion for final settlement approval in a nationwide class action alleging that Kellogg Co. falsely advertised its Frosted Mini-Wheats cereal products as a food that could help improve children's attentiveness by 20 percent. *Dennis v. Kellogg Co.*, No. 09-1786 (U.S. Dist. Ct., S.D. Cal., order entered September 10, 2013). Details about prior rulings in the case appear in Issue [483](#) of this *Update*.

The court had previously given reluctant approval to the preliminary settlement, concerned that the class relief appeared to have diminished after remand from the Ninth Circuit, with attorney's fees appearing to remain constant—the original settlement had a cash value of about \$10.5 million with \$2 million for attorney's fees and claims administration; the revised settlement has a cash value of \$4 million with \$1.5-2 million reserved for attorney's fees and claims administration. According to the court, the plaintiffs demonstrated that “the seemingly unchanged total amount reflects the increased cost of expanded claims notice administration rather than static fees. In fact, the requested attorneys' fees are 50% less than provided under the initial settlement.” Thus the court found that no aspect of the settlement suggested collusion.

The court further rejected the concerns of objectors who lacked standing, raised baseless objections or were irrelevant. One objector sought attorney's fees for the objectors' prior success on appeal, but the court noted that neither this objector nor “his counsel, Theodore Frank of the Center for Class Action Fairness, participated in the appeal.” The class members who had participated in the appeal, said the court, “are no longer participating in the case.”

California Claims Pet Products at Whole Foods Violate Pesticide Limits

California's pesticide regulator has reportedly filed a petition against Whole Foods alleging that several of its pet products, including cat litter and dog and cat flea spray, contain pesticides that have not been registered with the state. *Cal. Dep't of Pesticide Registration v. Whole Foods Mkt. Cal., Inc.*, No. 2013-00150499 (Cal. Super. Ct., Sacramento Cnty., filed September 9, 2013). State law evidently requires pre-approval of pesticide products so they can be tested and approved for safe use. The company is reportedly cooperating with the state and has indicated that it “looks forward to addressing the matter before a judge.” If Whole Foods has violated state law, California may impose fines. According to an agency spokesperson, failure to register pesticide products has been an ongoing issue with the Austin-based retail grocery chain and the agency intends to investigate it for a range of purportedly unregistered products. See *Huffington Post*, September 12, 2013; *Associated Press* and *ABJ Morning Call* (Austin), September 13, 2013.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

Turkish Authority Fines Frito-Lay \$8.6 Million for Anticompetitive Activity

According to a news source, the Turkish Competition Authority has concluded a 15-month investigation and imposed a fine of 17.9 million Turkish Liras (US\$8.6 million) on Frito-Lay, finding that it engaged in practices to ensure that it was the only salty snack brand available for sale in retail shops. While the initial decision and fine have apparently been issued to the company, a more detailed “reasoned decision” will be forthcoming. The company, which contends that it “has strong policies in place to achieve compliance with the laws and regulations everywhere we do business,” will reportedly have the right to file an appeal. See *BakeryandSnacks.com*, September 6, 2013.

LEGAL LITERATURE

PHAI Attorneys Discuss “Cheeseburger” Bills and Obesity-Related Lawsuits

Public Health Advocacy Institute (PHAI) Staff Attorney Cara Wilking and President Richard Daynard, a self-described “strategic litigation expert with a focus on combating the epidemics caused by tobacco and obesity,” have co-authored an article titled “Beyond Cheeseburgers: The Impact of Common-sense Consumption Acts on Future Obesity-Related Lawsuits.” 68 *Food & Drug Law Journal* 229 (2013).

Beginning with the premise that “[a]ffirmative litigation is an important tool in the public health toolkit to recover healthcare costs stemming from harmful commercial practices and to prevent future health harms,” they provide a detailed analysis of the “Common Sense Consumption” acts (CCAs) enacted in 25 states to shield the food industry from civil liability for obesity-related harms allegedly caused by the long-term consumption of food. According to the authors, the National Restaurant Association took a leadership role in getting the measures before state legislatures.

Noting that CCAs “have yet to be meaningfully tested in the courts and that is where their ultimate scope will be determined,” the authors observe that a number of them limit obesity-related claims brought by state attorneys general, who, they contend, “play an important role in maintaining the integrity of food labels.” They also suggest that CCA legislation is not necessary to curb frivolous obesity-related litigation, because such litigation is extremely expensive, has been brought only twice by one attorney and has been unsuccessful. Contending that state laws apportioning civil damages and proscribing frivolous lawsuits are adequate to curtail frivolous obesity cases, they conclude that the point of CCA proponents “was not to prevent *frivolous* litigation, from which industry already had plentiful protection, but rather to limit legally and factually sound litigation, which might eventually have harmed industry’s bottom line and forced it to change its practices.”

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

The article suggests that plaintiffs can still craft claims that sidestep CCAs “by limiting the alleged harms to simple restitution for the cost of the food products purchased as a result of the alleged illegal conduct and any available statutory damages. While cases structured this way would be much too expensive to bring on an individual basis, class actions are possible and could be promising to protect citizens in CCA states from unlawful food industry conduct.” Research for the article was supported by a National Cancer Institute grant.

In a related development, a CCA proposal ([SB 12](#)) that was introduced during a special Oklahoma legislative session on August 30, 2013, was signed into law by the governor on September 9. It is intended to “prevent frivolous suits against manufacturers, packers, distributors, carriers, holders, sellers, marketers or advertisers of food products . . . for any claim arising out of weight gain, obesity, or a health condition associated with weight gain or obesity.” It applies to all pending claims and those filed after its enactment “regardless of when the claim arose.”

OTHER DEVELOPMENTS

McDonough & Awong Contribute to FDLI Primer on Veterinary Drug Product Regulation

SHB Pharmaceutical & Medical Device Practice Chair [Madeleine McDonough](#) and Associate [Lael Awong](#) have [co-authored](#) a chapter in a Food and Drug Law Institute (FDLI) primer titled *FDA's Regulation of Veterinary Drug Products*. Researched, referenced and edited by experienced professionals, FDLI primers are designed to be practical and user-friendly. McDonough and Awong contributed to the “Human Food Safety” chapter, which addresses Food and Drug Administration (FDA) regulations aimed at ensuring that food is safe for human consumption regardless of the use of an animal drug in a food-producing animal. They explain how veterinary drug sponsors can meet FDA requirements for the analysis of drug residues in food-producing animals in the preparation of new animal drug applications. The primer is available for purchase on FDLI’s [Website](#).

Former CDC Director of Nutrition Urges Parents to Tackle Food Marketing to Children

William Dietz, the former director of the Division of Nutrition, Physical Activity and Obesity at the Centers for Disease Control and Prevention (CDC), has authored a September 2013 commentary in the journal *Health Affairs*, urging the “mobilization of parents as a political force to improve standards for food marketed to children.” William Dietz, “New Strategies to Improve Food Marketing to Children,” *Health Affairs*, September 2013. Recounting the past efforts of the Federal Trade Commission and other government agencies to curb food marketing to children, Dietz argues that these initiatives “have had a modest but positive impact” on the media landscape but have ultimately foundered in the face of industry opposition.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

“Because groups that support the needs of children will never have the same resources in the political arena as those of the industries that market to children, it is time to consider alternative strategies,” Dietz writes. In particular, he suggests that reframing screen time as “advertisement time” and focusing on the privacy issues raised by digital media could galvanize parents “to act on behalf of children’s health.” He also recommends “the use of social media for counteradvertising” as well as “the development of new technologies to decrease exposure to food advertisements.”

“My premise is that advocates have not framed this issue in a way that has engaged parents,” concludes Dietz. “Increased efforts by pediatricians, advocates, and consumer groups to inform parents about the pervasive and intrusive nature of food marketing and the impact of such advertising on their children’s health may help mobilize parents as an effective political force and increase demand for technological and other strategies that will help parents limit the food marketing to which their children are exposed.”

SCIENTIFIC/TECHNICAL ITEMS

Study Examines Role of Gut Bacteria in Obesity

A recent study examining the role of gut bacteria in obesity has reported that germ-free mice transplanted with human fecal microbiota either gained weight or stayed lean depending on the body profile of the human donor. Vanessa Ridaura, et al., “Gut Microbiota from Twins Discordant for Obesity Modulate Metabolism in Mice,” *Science*, September 2013. Using mice with no gut microbiota of their own, researchers with the Washington University School of Medicine apparently conducted two separate experiments, the first of which involved transplanting fecal microbiota from one lean twin and one obese twin into mice that were then kept in separate cages and fed a diet low in fat and high in plant polysaccharides. After 15 days, the mice that received bacteria from the lean twin reportedly stayed lean while the mice that received bacteria from the obese twin gained weight and fat in addition to developing signs of insulin resistance.

In the second experiment, the study’s authors co-housed the mice with “lean microbes” with those that received “obese microbes.” When the mice were both fed a healthy diet, the lean twin’s microbes were purportedly able to colonize the guts of mice with the obese twin’s microbes, thus preventing these animals from gaining weight. The researchers noted, however, that a diet high in saturated fats and low in fruits and vegetables effectively prevented the lean microbes from colonizing the obese-microbe mice, which continued to gain weight and fat as before.

According to a September 5, 2013, press release, the authors purportedly associated these observations “with an invasion of a group of bacteria called Bacteroidetes” that are “efficient at harvesting calories and nutrients from food

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 497 | SEPTEMBER 13, 2013

and have been associated with leanness.” As Jeffery Gordon, director of the Center for Genome Sciences & Systems Biology at Washington University, explained, “Eating a healthy diet encourages microbes associated with leanness to quickly become incorporated into the gut. But a diet high in saturated fat and low in fruits and vegetables thwarts the invasion of microbes associated with leanness. This is important as we look to develop next-generation probiotics as a treatment for obesity.” See *The New York Times*, September 5, 2013.

Meta-Analysis Allegedly Links SSBs to Weight Gain in Children and Adults

A recent systematic review and meta-analysis conducted by researchers with the Harvard School of Public Health has allegedly concluded that sugar-sweetened beverage (SSB) consumption “promotes weight gain in children and adults.” Vasanti Malik, et al., “Sugar-sweetened beverages and weight gain in children and adults: a systematic review and meta-analysis,” *American Journal of Clinical Nutrition*, October 2013. Focused on prospective cohort studies and randomized controlled trials (RCTs), the meta-analysis noted that a one-serving per day increase in SSB consumption was associated with (i) “a 0.06-unit increase in BMI over a [one-year period] among children and adolescents,” and (ii) “an additional weight gain of 0.12 to .22 kg (≈0.25-0.50 lb) over [one year] among adults.”

“SSBs can lead to weight gain through their high added-sugar content, low satiety, and an incomplete compensatory reduction in energy intake at subsequent meals after intake of liquid calories,” conclude the study’s authors. “Our results also suggest the need for targeted strategies to reduce SSB consumption among high-risk populations, particularly children who are already overweight to prevent further weight gain, and highlight the importance of sustained strategies... Our findings have broad implications for developing public health strategies and policies targeting SSBs for weight control and obesity prevention.”

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

FOOD & BEVERAGE LITIGATION UPDATE

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.

