



LEGISLATION, REGULATIONS & STANDARDS

FDA Commissioner Offers Look at Agency's Direction

In a speech at the National Food Policy Conference in Washington, D.C., U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb reportedly summarized the agency's plans, including (i) defining "healthy" for use with a food-labeling icon, (ii) implementing delayed updates to nutrition labels, and (iii) creating a strategy for reduction in salt consumption.

Gottlieb reportedly said FDA will explore possible changes to nutrient-content claims. "People eat foods, not nutrients," he is quoted as saying. "This is why we're asking the important question of whether a modernized definition of 'healthy' should go beyond nutrients to better reflect dietary patterns and food groups, like whole grains, lowfat dairy, fruits and vegetables and healthy oils."

FDA will also propose short-term, voluntary targets for salt and sodium reduction from the current average daily intake of 3,400 milligrams to no more than 3,000 milligrams. "There remains no single more effective public health action related to nutrition than the reduction of sodium in the diet," Gottlieb reportedly said. "Excess sodium in the diet results in hypertension, which increases the risk of strokes and heart attacks." He also asserted that reducing sodium intake by one-half teaspoon per day could prevent nearly 100,000 premature deaths each year as well as 120,000 cases of coronary heart disease, 66,000 strokes and 99,000 heart attacks. The agency may also change labeling rules to better communicate that products contain salt. "We've been petitioned to allow the use of alternative names for potassium

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chloride, to make it clear that this product is a salt, and we're actively considering the request," Gottlieb said.

Gottlieb also announced that FDA will implement changes to nutrition labels previously scheduled to take effect in July 2018.

DeLauro Asks GAO To Review Regulatory Framework for Lab-Grown Foods

U.S. Rep. Rosa DeLauro (D-Conn.) has sent a letter asking the U.S. Government Accountability Office (GAO) to examine the regulatory framework for cell-cultured food products. According to the letter, such food products include lab-grown meat and "animal-free" milk that can be produced from fermented yeast and proteins in cow's milk. DeLauro requested a "comprehensive review" of the unique challenges in safety oversight, the regulations and labeling requirements that may already exist, and a determination on whether federal agencies have begun preparing for the product's commercialization.

"While not yet commercially available, the potential introduction of this new type of product into the nation's food supply and economy raises many important questions," DeLauro said in the letter. "To date, it remains unclear exactly how cell-cultured food products should be regulated . . . More information is needed for Congress to address this emerging sector in the United States and to ensure it is properly overseen by the relevant agencies."

LITIGATION

Guinness False-Source Claims to Continue

A Massachusetts federal court has dismissed half of the claims in a lawsuit alleging Diageo-Guinness misrepresents where its Guinness Stout beer is brewed. *O'Hara v. Diageo-Guinness USA Inc.*, No. 15-14139 (D. Mass., entered March 27, 2018). The plaintiff alleged that the "Frequently Asked Questions" page of Guinness' website stated that "All Guinness sold in the UK, Ireland, and North America is brewed in Ireland at the historic St. James's Gate Brewery in Dublin," while a disclosure on Guinness bottles sold in the United States indicate that the product is "Imported by DIAGEO – Guinness USA, Stamford, CT. Brewed and bottled by Guinness Brewing Company, New Brunswick, Canada. Product of Canada." The court dismissed three of the six



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ABOUT SHOOK

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.

Shook 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.



causes of action because the bottling and packaging labels were approved by the U.S. Alcohol and Tobacco Tax and Trade Bureau. A misrepresentation claim and two claims for violations of state consumer-protection laws will continue.

Second Circuit Affirms Organic Baby Food Suit Dismissal

The Second Circuit has affirmed the dismissal of a putative class action that alleged Abbott Laboratories Inc. falsely represented its Similac Advance Organic Infant Formula as organic, ruling the plaintiffs' state-law claims are barred by the Organic Foods Production Act (OFPA). *Marentette v. Abbott Labs. Inc.*, No. 17-0062 (2d Cir., entered March 23, 2018). The plaintiffs alleged that Abbott misled consumers because the product contained ingredients not permitted by the OFPA.

The appeals court asked the U.S. Department of Agriculture (USDA) to submit an amicus brief addressing (i) whether the certification process requires the certifying agent to review and approve the ingredients of the final product to be labeled organic and (ii) whether products made in accordance with a properly certified plan will necessarily comply with the OFPA. According to the decision, USDA stated that "certifying agents review and approve both the process and the ingredients of the final product to be labeled organic, but generally do not inspect or certify batches of products." The agency also explained that "certification is intended to be coextensive with compliance, but that it may not be if a plan is improperly certified or if a producer changes the plan after certification."

The court found that the plaintiffs' position "necessarily undermines Congress' purpose in enacting the OFPA, because it demands adjudication of a product's organic status separate and apart from the scheme set out in the law . . . [the p]arents' claims strike at the very heart of the OFPA certification process and are therefore preempted by it."

Consumer Challenges Pabst's Olympia Beer Source

A consumer has filed a putative class action alleging Pabst Brewing Company LLC's Olympia beer labels falsely imply the product is brewed from artesian water in Washington despite being brewed in a facility in Los Angeles. *Peacock v. Pabst Brewing Co. LLC*, No. 18-0568 (E.D. Cal., filed March 15, 2018).

The complaint alleges that although Olympia was originally brewed with artesian water in Washington, Pabst shifted production to California after it acquired the company in 1999. The plaintiff further argues that the beer may be brewed using chlorinated municipal water, that the brewery's water supply has previously been contaminated with industrial solvents and that two Superfund sites are located within three miles of the brewery. According to the complaint, Olympia's website credits the Washington water for its premium taste. Alleging violations of California consumer-protection statutes, the plaintiff seeks class certification, injunctive relief, corrective advertising, damages and application of the common fund doctrine.

Eleventh Circuit Reverses Jury Verdict in Contaminated Oyster Case

Ruling that the jury instructions were misleading, the U.S. Court of Appeals for the Eleventh Circuit has reversed a jury verdict finding for a seafood restaurant in a lawsuit involving allegations of foodborne illness. *Rhodes v. Lazy Flamingo 2 Inc.*, No. 17-11338 (M.D. Fla., entered March 29, 2018). The plaintiffs alleged negligence per se after one ate Lazy Flamingo's oysters, which were contaminated with *Vibrio vulnificus* and caused an illness requiring five days of hospitalization. A Florida regulation requires foodservice establishments serving raw oysters to display a health-risk warning on menus or table placards; the jury was instructed that it could consider the text of the regulation as well as a Florida foodservice industry bulletin indicating the warning "may be on menus, table placards, or elsewhere in plain view of all customers." The appeals court found no evidence that the bulletin offered a "reasonable interpretation" of the regulation, reversed the verdict and remanded for a new trial.

Federal Court Dismisses Shareholder Suit Against Chipotle

A federal court in New York has dismissed with prejudice a shareholder suit against Chipotle Mexican Grill Inc., finding the plaintiffs were unable to allege that the company made "demonstrably false" statements about foodborne illness outbreaks linked to its restaurants. *Ong v. Chipotle Mexican Grill*, No. 16-0141 (S.D.N.Y., entered March 22, 2018). The plaintiffs alleged that Chipotle and three of its executives misled shareholders and the public in 2015 and 2016 statements after outbreaks of norovirus, *E. coli* and *Salmonella* were linked to its restaurants. In addition to finding Chipotle's annual reports

contained sufficient disclosures about its processes, the court found that the plaintiffs failed to adequately allege that executives who knew about the outbreaks' connection to Chipotle sold more than \$214 million in stock because the stock sales occurred months before the outbreaks were linked to the company.

Plaintiffs Allege Kombucha Drinks Contain More Sugar Than Advertised

A consumer has filed a putative class action alleging Health-Ade LLC's kombucha contains four to five times the amount of sugar listed on its label. *Gonzalez v. Health-Ade LLC*, 28-1836 (N.D. Cal., filed March 23, 2018). The complaint alleges that the nutrition panels for nine of Health-Ade's products state they contain from two to four grams of sugar per 8-ounce serving, but the plaintiffs' testing apparently indicates the beverages contain between 11 and 13 grams per serving. Claiming false and misleading advertising, unjust enrichment, breach of warranties and negligent misrepresentation, the plaintiffs seek certification of nationwide and California classes, injunctive relief, corrective advertising, damages and application of the common fund doctrine.

In-N-Out Burger Seeks Restraining Order Against YouTuber

In-N-Out Burger has reportedly requested a restraining order against a YouTube video creator who allegedly posed as the company's CEO at two of its restaurants. The man allegedly argued with employees, demanded that kitchen employees prepare him food for a "taste test," and took food out of a customer's hand, threw it on the floor and stepped on it. In a statement, a company executive reportedly said, "We have recently seen an increase of visitors to our stores, who are not customers but instead are intentionally disruptive and who then try to promote themselves through social media." The lawsuit also petitions the Los Angeles Superior Court to impose a \$1,000 fine for each violation of the restraining order and seeks damages of more than \$25,000 for fraud, trespass, nuisance and criminal violations.

SCIENTIFIC / TECHNICAL ITEMS

Study Links High Phthalate Levels and

Dining Out

A study has reportedly found that Americans who consumed more restaurant, fast-food and cafeteria meals had phthalate levels up to 35 percent higher than those who ate out less frequently. Julia R. Varshavsky, et al., “Dietary sources of cumulative phthalate exposure among the U.S. general population in NHANES 2005-2014,” *Environment International*, March 29, 2018. The data was collected from more than 10,000 participants in the National Health and Nutrition Examination Survey. While the researchers reportedly found a significant association between eating out and higher phthalate levels across all age groups, teenagers apparently showed the highest association, with 55 percent. A previous study purportedly found that participants who ate the highest amount of fast food had phthalate levels as much as 40 percent higher than participants who rarely ate such foods.

MEDIA COVERAGE

Livestock Producers Divided on Use of Antibiotics

The New York Times has published a report exploring the debate among meat producers, scientists and regulators on the role of antibiotics in cattle feed. The U.S. Food and Drug Administration has banned the use of antibiotics for livestock growth, but many producers continue to use the prescription-only substances for disease prevention. The debate centers on concern that overuse may create disease-resistant bacteria. According to the article, one feedlot has begun limiting the use of drugs, although it uses antibiotics to treat liver abscesses and intestinal diseases. An executive for the feedlot reportedly told the *Times*, “Antibiotic resistance is a fact of life, no two ways about it. We want to make sure that by virtue of our using these products we’re not contributing to it.” Other cattle producers and veterinarians reportedly said they have not seen “clear evidence” that antibiotics are causing increased bacterial resistance.

The *Times* also interviewed a researcher who tracks microbes in the human gut as well as antibiotic resistance. “Both on the farm and in human medicine, we’ve become addicted to antibiotics,” Martin Blaser, director of the Human Microbiome Program at New York University, is quoted as saying. “We’re using them as if there was no biological cost to using them. And there are costs.”

He further calls the use of antibiotic tylosin in animal feed “a genuinely bad idea because of cross-resistance.”

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