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LEGISLATION, REGULATIONS AND STANDARDS

Advocacy Group Seeks Files in FDA "Soy Milk" Definition

The <u>Good Food Institute</u> (GFI) has filed a lawsuit seeking to compel the U.S. Food and Drug Administration (FDA) to disclose records "related to FDA's regulatory treatment of the common and usual name 'soy milk' or 'soymilk' to refer to a liquid food derived from the cooking and processing of whole soybeans with water." *Good Food Inst. v. FDA*, No. 16-1052 (D.D.C., filed June 6, 2016).

The organization asserts that FDA has been inconsistent in its opinion of "soy milk," citing two warning letters to soy-milk producers requesting them to use "soy beverage" or "soy drink" instead. "Notwithstanding FDA's varying positions on the matter, many major brands of soy milk continue to label their products as 'soy milk' or 'soymilk.' This has resulted in consumer confusion and an uneven competitive landscape," the complaint argues. GFI submitted Freedom of Information Act requests to FDA in April 2016 and asserts that it only received a partial response; its lawsuit now seeks to compel full disclosure of the documents requested.

Philadelphia to Adopt First City-Wide Soda Tax

The Philadelphia City Council Committee of the Whole has backed a 1.5-cents-per-ounce tax on sugar-added and artificially sweetened soft drinks, a measure that the council anticipates will raise \$91 million over the next year. If approved by final vote as expected, the tax will "fund quality pre-K expansion, community schools, reinvestment in parks and recreation centers, and help pad the City's General Fund," according to a June 8, 2016, press release.

Philadelphia Mayor Jim Kenney (D) initially proposed a 3-cents-perounce levy on sugar sweetened beverages, but the council concluded that such an increase would raise more revenue than needed. Instead, the committee opted to reduce the tax to 1.5 cents per ounce while expanding the scope to include diet soft drinks. The council also advanced a bill "offering tax credits to merchants that opt to sell healthy beverages in their stores."

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"A 1.5-cent-per-ounce tax increase on soft drinks will have a smaller negative impact on businesses and consumers; be more widely spread among consumers at both ends of the income spectrum; raise the funds necessary to make historic reinvestments in our young people and public spaces; and protect the City from uncertainty by increasing the General Fund balance," said Third District Councilwoman Jannie Blackwell. *See The New York Times* and *NPR*, June 9, 2016.

LITIGATION

Court Delays San Francisco SSB-Warning Enforcement

Following a May 2016 refusal to invalidate a San Francisco regulation requiring warning labels on sugar-sweetened beverages (SSBs), a California court has granted an injunction on enforcement pending appeal. *Am. Beverage Ass'n v. City of San Francisco*, No. 15-3415 (N.D. Cal., order entered June 7, 2016). Details on the May 2016 decision appear in Issue <u>605</u> of this *Update*, while additional information on the lawsuit appears in Issues <u>573</u>, <u>586</u> and <u>592</u>.

The ordinance, set to take effect July 25, 2016, requires billboards and other public advertisements to include a warning that "[d]rinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay." The American Beverage Association (ABA) challenged the regulation on First Amendment grounds, but the court denied a preliminary injunction, finding the industry group's claims unlikely to succeed. "[A]n injunction pending appeal may be appropriate, even if the Court believed its analysis in denying preliminary injunctive relief is correct. This is such a case," the court noted in its decision granting the injunction. "In addition, there is a good chance that the injunction pending interlocutory appeal will be relatively brief because the appeal will likely be resolved on an expedited basis (given Ninth Circuit Rule 3-3, which allows for expedited briefing on preliminary injunction appeals and thus the hardship to the City may be limited)."

In a separate order, the court granted a joint motion to dismiss the ABA's constitutional claims related to the portion of the ordinance banning SSB advertising on city property, which has since been overturned.

Shook 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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If you have questions about this issue of the *Update* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

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Rebate Moots "All Natural" Putative Class Action

A Massachusetts federal court has dismissed a lawsuit alleging ACH Food Companies Inc. mislabeled its Weber® barbecue sauce as "All Natural" despite containing caramel coloring, finding that a \$75-rebate rendered the case moot. *Demmler v. ACH Food Cos. Inc.*, No. 15-13556 (D. Mass., order entered June 9, 2016). Details about the complaint appear in Issue 582 of this *Update*.

The court found ACH had tendered full relief to the plaintiff by sending him treble statutory damages. Further, "the \$75 check did not represent a settlement offer—ACH sent the check unprompted, and did not impose any preconditions on [the plaintiff] for doing so. This distinction makes all the difference," the court held. The plaintiff could not pursue damages when he had already been made whole, the court noted, and his "refusal to accept the \$75 is immaterial. The question under Article III is whether a live case or controversy exists, and the mere fact that [the plaintiff] did not accept unconditionally-provided remediation does not extend the life of the dispute."

The court also found the class claims to be no longer viable. "[The plaintiff] argues that the Court should infer that ACH sought to thwart judicial review by satisfying only [his] individual claims, and not those of the class members," the court said. "On this record such an inference is untenable. ACH discontinued, prior to [the plaintiff's] demand letter, the very product about which [he] complained, and made [him] whole in response to his initial demand."

P.F. Chang's Gluten Suit Voluntarily Dismissed

A California federal court has granted voluntary dismissal to the plaintiff in a putative class action alleging P.F. Chang's China Bistro Inc. discriminates against customers with a gluten allergy by adding a surcharge to gluten-free dishes. *Phillips v. P.F. Chang's China Bistro Inc.*, No. 15-0344 (N.D. Cal., San Jose Div., order entered June 6, 2016). The order granted dismissal to the plaintiff with prejudice but without prejudice as to the putative class, leaving the possibility that another plaintiff may step into the lead plaintiff role. The court also imposed the defendant's costs on the plaintiff. Details on the complaint appear in Issue 555 of this *Update*.

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Ad Agency Alleges PepsiCo Stole Super Bowl Commercial Idea

Betty Inc., a Connecticut-based advertising agency, has filed a lawsuit alleging PepsiCo Inc. used its idea for a Super Bowl commercial without payment or attribution. *Betty Inc. v. PepsiCo Inc.*, No. 16-4215 (S.D.N.Y., filed June 7, 2016). The complaint asserts that employees of Betty presented the idea for "All Kinds/Living Jukebox," a tour through different musical genres and styles of dance representing the "Joy of Pepsi®," in November 2015, then accepted PepsiCo's request to refine the idea for a payment of \$5,000.

Betty argues it refined the idea but told PepsiCo that the \$5,000 did not transfer any rights of use or ownership of the advertising concept. PepsiCo did not seek to further produce the concept after the refinement, but "[t]he Super Bowl halftime commercial PepsiCo aired during the 2016 Super Bowl copies, is fundamentally based on, and is derivative of, the 'All Kinds/Living Jukebox' advertising storyline Betty presented to PepsiCo," according to the complaint. Further, another advertising agency "has publicly taken credit for the Super Bowl halftime commercial." For allegations of copyright infringement, breach of contract, unjust enrichment, unfair competition and conversion, Betty seeks compensatory and punitive damages, costs and attorney's fees.

SCIENTIFIC/TECHNICAL ITEMS

NAS Report Discusses Benefits and Risks of Gene Drive Research

The National Academies of Sciences, Engineering and Medicine (NAS) has released a <u>study</u> examining research into man-made gene drives, a type of gene editing that allows for the spread of gene modifications "throughout a population of organisms intentionally." Titled *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values*, the report focuses on techniques that use segments of bacterial DNA—such as clustered regularly-interspaced short palindromic repeats (CRISPR)—paired with a guide protein (CRISPR-associated protein 9, or Cas9) "to make targeted cuts in an organism's genome." Organisms modified using CRISPR-Cas9 then pass these changes to their offspring through sexual reproduction, a process that allows scientists to alter whole populations in an effort to eradicate insect-borne infectious diseases, for example.

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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.





Calling these developments "both encouraging and concerning," the report seeks to provide "an independent, objective assessment of the state of knowledge and responsible practices for research, risk assessment, public engagement, and the development of public policies on gene drive technologies." In particular, the study addresses, among other things, (i) human values and welfare, (ii) environmental considerations, (iii) scientific approaches to reducing potential risks, (iv) the need for ecological risk assessments, (v) avenues for public and stakeholder engagement, and (vi) governance of gene drives.

To mitigate potential drawbacks to gene drives, the NAS committee advocates "a phased testing pathway, such as the one outlined by the World Health Organization (WHO) for testing genetically modified mosquitoes," as well as ecological risk assessments designed to "trace cause-and-effect pathways" and "quantify the probability of specific outcomes." The study also notes that, in addition to finding new avenues for public engagement, researchers and policymakers must develop best practices for ensuring biosafety while working to resolve regulatory overlaps and loopholes.

"In the United States, regulation of gene-drive modified organisms will most likely fall under the Coordinated Framework for the Regulation of Biotechnology, which includes the U.S. Food and Drug Administration, the U.S. Department of Agriculture, and the U.S. Environmental Protection Agency," explains the report summary. "The U.S. government will need to clarify the assignment of regulatory responsibilities for field releases of gene-drive modified organisms, including the roles of relevant agencies that are not currently included in the Coordinated Framework for the Regulation of Biotechnology."

Citing the likely benefits of gene-drive modified organisms, the report offers support for basic and applied research and highly-controlled field trials, while urging researchers to "establish open-access, online repositories of data on gene drives as well as standard operating procedures for gene drive research." As the report overview concludes, "It is important to note that a one-size-fits-all approach to governance is not likely to be appropriate... Governance and regulation of gene drive research will need to be proportionate to the hazards posed by the specific activity, and evaluated on a case-by-case basis. Because of the existing uncertainties associated with gene drives, regulation will be needed that facilitates fundamental, applied, and translational research so that the potential harms and benefits of gene drives can be explored responsibly in laboratory and field studies."