



FIRM NEWS

Gates Calderon Joins FDLI Conference Panel to Discuss Plant-Based Foods

Partner [Katie Gates Calderon](#) was a panelist at the Food and Drug Law Institute (FDLI) [Food Advertising, Labeling and Litigation Conference](#) in Washington, D.C., September 13-14, 2017. She joined Jessica Almy, policy director at The Good Food Institute, and moderator Stuart M. Pape of Polsinelli PC in a discussion of “Naming of Plant-Based Food Products and Standards of Identity.” The panel explored legal issues in naming and the role of standards of identity in the ever-growing world of alternative products.

LEGISLATION, REGULATIONS & STANDARDS

FDA Announces Final FSMA Produce Safety Rule

The U.S. Food and Drug Administration (FDA) has announced that the produce safety rule of the Food Safety and Modernization Act of 2010 (FSMA) is now final, establishing minimum standards for the growing, harvesting, packing and holding of raw produce for human consumption. Compliance dates are staggered but will affect large operations first.

The key requirements include: (i) establishment of criteria for microbial water quality based on the presence of *E. coli*; (ii) rules governing the use of raw manure and compost; (iii) testing and corrective-action requirements for cultivation of sprouts; (iv) rules for assessment of contamination by domestic livestock and wild animals; (v) measures for worker training, health and hygiene; and (vi) standards for equipment, tools and buildings. Qualified exemptions and variances are also included for small farms, tribes and foreign countries that export food to the United States.

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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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NAD Rules Ragú Sauce Provided “Reasonable Basis” for Customer Preference Ad Claim

The National Advertising Division (NAD) has ruled that Mizkan America, Inc. provided a reasonable basis for its advertising claim that “consumers prefer the taste of Ragú Homestyle Traditional over Prego Traditional.” The Campbell Soup Co., which makes Prego, challenged the ad on the grounds that Mizkan’s consumer survey methodology was flawed. Both parties conducted a taste test of the products; the Mizkan test reportedly showed a consumer preference for Ragú while the Campbell test showed no preference. The Mizkan test included testing of all tomato-based sauces, while Campbell limited its test to traditional-style sauces. NAD found the Campbell test “overly restrictive” and that its results were not “stronger or more persuasive” than those of Mizkan.

Netflix Sends Cease-and-Desist to “Stranger Things”-Themed Bar

Netflix has reportedly requested that a Chicago bar end its theming related to the company’s popular “Stranger Things” show. “The Upside Down” was intended to be a six-week installation run by neighboring Emporium Logan Square, an arcade-themed bar, but success led the creators to plan on extending the pop-up past its scheduled closing date of October 1, 2017. In a letter filled with references to the 1980s-set show featuring a group of children fighting a supernatural entity, Netflix asked the bar owners to close the temporary installation as planned.

“We’re not going to go full Dr. Brenner on you, but we ask that you please (1) not extend the pop-up beyond its 6 week run ending in September, and (2) reach out to us for permission if you plan to do something like this again,” the letter stated. “We love our fans more than anything, but you should know that the demogorgon is not always as forgiving. So please don’t make us call your mom.” See [DNAInfo](#), September 18, 2017.

LITIGATION

First Amendment Concerns Pause San Francisco SSB Tax’s Warning-Label Requirement

The Ninth Circuit Court of Appeals has reversed a lower court’s denial of a preliminary injunction stopping the warning-label portion of San Francisco’s sugar-sweetened beverage (SSB) tax from taking effect. *Am. Beverage Ass’n v. City & Cty. of San Francisco*, No. 16-16072 (9th Cir., entered September 19, 2017).

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.



Additional information about the complaint and denial appears in Issues [573](#) and [605](#) of this *Update*, and details on the enforcement delay and associated amicus briefs appear in Issues [592](#), [607](#) and [613](#).

San Francisco's warning-label ordinance would require a warning about the health effects of SSBs—specifically, "Drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay"—to occupy 20 percent of the visible portions of fixed SSB advertising, including billboards, structures and vehicles. After several industry associations challenged the requirement, the district court held that the warning was not misleading, would not place an undue burden on the plaintiffs' commercial interests and was rationally related to a government interest.

The Ninth Circuit first considered whether the statement is factually accurate and uncontroversial. The warning label "conveys the message that sugar-sweetened beverages contribute to these health conditions regardless of the quantity consumed or other lifestyle choices," the court found. "This is contrary to statements by the [U.S. Food and Drug Administration] that added sugars are 'generally recognized as safe,' [] and 'can be a part of a healthy dietary pattern when not consumed in excess amounts. ... Because San Francisco's warning does not state that overconsumption of sugar-sweetened beverages contributes to obesity, diabetes, and tooth decay, or that consumption of sugar-sweetened beverages may contribute to obesity, diabetes, and tooth decay, the accuracy of the warning is in reasonable dispute." The court further noted that the warning would be misleading because it is "required exclusively on advertisements for sugar-sweetened beverages, and not on advertisements for other products with equal or greater amounts of added sugars and calories. By focusing on a single product, the warning conveys the message that sugar-sweetened beverages are less healthy than other sources of added sugars and calories and are more likely to contribute to obesity, diabetes, and tooth decay than other foods."

The court then considered whether the compelled disclosure would be "unjustified or unduly burdensome" and whether it would chill protected speech. The plaintiffs argued that the label "effectively takes over their message" and would chill their speech "because it renders their speech on covered media so ineffective as to make it impractical to advertise on covered media." The court agreed, finding that the warning box "overwhelms" other visual elements in the plaintiffs' examples of ads complying with the ordinance. The warning label also "burdens the First Amendment right to be silent," the court held. "Moreover, even though advertisers would be free to engage in counter-speech, countering San Francisco's misleading message would leave them little room to communicate their intended message. This would defeat the purpose of the advertisement, turning it into a vehicle for a debate about the health effects of sugar-sweetened beverages," the court held. Accordingly, the Ninth Circuit reversed the lower court's denial of a preliminary injunction and remanded the case for further proceedings.

Industry Group Sues USDA Over Delay of Organic Livestock Rule

The Organic Trade Association has filed a lawsuit to compel the U.S. Department of Agriculture (USDA) to implement the Organic Livestock Rule, which was scheduled to take effect on March 18, 2017. *Organic Trade Ass'n v. U.S. Dep't of Agric.*, No. 17-1875 (D.D.C., filed September 13, 2017). After 10 years of public process and hearing, USDA published the final rule in January 2017 along with formal recommendations from the National Organic Standards Board (NOSB) resulting from consultations required by the Organic Foods Production Act (OFPA).

On January 20, 2017, former White House Chief of Staff Reince Priebus issued a memorandum to federal agencies directing them to temporarily postpone effective dates for regulations that had been published but had not yet taken effect. The complaint alleges that public comment should have been permitted on whether the Priebus memo applied to the Organic Livestock Rule because its standards affect only those who opt into the program and impose no duty or obligation on entities that do not.

The complaint asserts that USDA twice delayed the effective date of the rule without prior notice, opportunity for public comment or consultation with NOSB. The advocacy group further argues that on May 10, 2017, USDA published a new proposed rule that would either (i) allow the Organic Livestock Rule to become effective on November 14, 2017; (ii) suspend the rule indefinitely; (iii) further delay the effective date; or (iv) withdraw it, “unwinding years of public process by mere fiat.”

Claiming violations of the OFPA and the Administrative Procedures Act, the Organic Trade Association seeks declaratory and injunctive relief, including an order to enjoin USDA from further delay of the rule's implementation.

EU Member States Cannot Restrict GMOs Without Valid Safety Concerns, ECJ Rules

The European Court of Justice (ECJ) has determined that member states cannot invoke the “precautionary principle” to restrict the cultivation and sale of crops developed from genetically modified organisms (GMOs) if the European Commission has not determined that the crops “are likely to constitute a serious risk to human health, animal health or the environment.” Case C-111/16, *Italy v. Fidenato* (E.C.J., entered September 13, 2017). The ruling responded to a request from an Italian court overseeing the prosecution of three farmers accused of growing GMO maize in violation of Italian law. The district court judge stayed the criminal proceedings to ask the ECJ whether Italy had the authority to ban the crop despite EC approval of its cultivation and sale.

In 2013, Italy asked the European Commission to adopt emergency measures allowing member states to apply a

“precautionary principle” and implement risk-management measures where “the possibility of harmful effects on health is identified but scientific uncertainty persists.” In response, the European Commission asked the European Food Safety Authority (EFSA) to evaluate the scientific studies Italy had submitted in support of its request. Despite EFSA’s finding that the materials provided no new science-based evidence, the Italian government banned the defendant’s GMO maize strain and criminalized its cultivation and sale.

The ECJ held that Italy and other member states cannot adopt emergency measures to restrict GMO crops unless a risk to life or health exists and scientific uncertainty about the crops’ safety persists; even in that instance, the restrictions must be proportionate and undergo review in “a reasonable period of time.” Member states can also implement emergency measures if the EC fails to act. But here, the court noted, the EC had already authorized the maize, and it was “clear and obvious that the European Commission has made the assessment that the substantive conditions for the adoption of emergency measures for food or feed are not met.”

Ninth Circuit Rejects Preemption Argument, Upholds California Ban on Foie Gras

The Ninth Circuit has upheld California’s ban on force-feeding ducks and geese to produce foie gras, finding the state’s law is not preempted by the Poultry Products Inspection Act (PPIA). *Assoc. des Éleveurs de Canards et d’Oies du Québec v. Becerra*, No. 15-55192 (9th Cir., opinion filed September 15, 2017). In 2013, the Ninth Circuit rejected a constitutional challenge to the ban filed by the same plaintiffs.

The court reversed a grant of summary judgment in favor of the plaintiffs, who challenged the state’s ban on sales or production of foie gras made from force-fed birds. First, the court held the ban is not expressly preempted by the PPIA because the federal statute’s “ingredient” requirement addresses the components of poultry products, not husbandry or feeding practices, and California’s law does not ban all foie gras—only that made from force-fed birds. “Nothing in the federal law ... limits a state’s ability to regulate the types of poultry that may be sold for human consumption,” the court said.

The court also ruled that the PPIA does not preempt the state law under the doctrines of field or obstacle preemption because it does not preclude a state’s role in poultry regulation and the plaintiffs did not show how the state law created an obstacle to the objectives of the PPIA, which are to provide “wholesome, not adulterated, and properly marked, labeled and packaged” poultry products. Additional details about the continuing dispute over force-fed foie gras appear in Issues [497](#), [542](#), [550](#), [554](#), [584](#), [587](#) and [626](#) of this *Update*.

FDA, Advocacy Groups Agree to Stay Lawsuit Over Menu Labeling Compliance Delay

The U.S. Food and Drug Administration (FDA), the Center for Science in the Public Interest (CSPI) and the National Consumers League have filed a joint motion to stay a lawsuit intended to compel the agency to implement the delayed menu labeling rule required by the Affordable Care Act. *Ctr. for Sci. in the Pub. Interest v. Price*, No. 17-1085 (D.D.C., filed September 15, 2017). FDA has agreed to: (i) confirm in the *Federal Register* on or before December 31, 2017, that the compliance date of the rule is May 7, 2018; (ii) publish draft or final guidance by December 31, 2017; and (iii) announce by “rule, guidance, public statement, publically-available document, or otherwise,” if the compliance date could or will be extended past May 2018. If FDA fails to meet those terms, the advocacy groups may move for, and FDA will not oppose, expedited hearing of the lawsuit. Additional details appear in Issues [633](#), [637](#) and [645](#) of this *Update*.

“Bourbon Barrel Aged” Wine Not Infringing, Court Rules

Following a bench trial, a California federal court has ruled that Fetzer Vineyards, Inc.’s “bourbon barrel aged” 1000 Stories red zinfandel wine, which features a sketch of a buffalo on its label, does not infringe the trademark or trade dress of Sazerac Co.’s Buffalo Trace bourbon. *Sazerac Co. v. Fetzer Vineyards, Inc.*, No. 15-4618 (N.D. Cal., entered September 19, 2017). “This case was not close,” the court said. Sazerac “did not establish that Buffalo Trace’s bourbon trade dress was similar to 1000 Stories wine’s. It did not establish that Fetzer intended to infringe at the creation of its product or in its marketing. There was no evidence of actual confusion between the products ... and no indication that consumers of 1000 Stories are even aware of Buffalo Trace.” The court had already limited Sazerac’s potential recovery to attorney’s fees after the company failed to provide damage calculations on a timely basis. Additional details appear in Issue [633](#) of this *Update*.

Plaintiff Challenges "ColdPressed" Label Claim

A consumer has filed a putative class action alleging the Hain Celestial Group's “ColdPressed” juice products are mislabeled because a third-party company, which manufactures some of the product, heats the juice during high-pressure processing, causing a “compositional change.” *Davis v. Hain Celestial Grp.*, No. 17-5191 (E.D.N.Y., filed September 3, 2017). The complaint challenges two product lines, BluePrint ColdPressed Juice and

BluePrint Organic fruit drinks, which the plaintiff claims are represented as “raw and organic” and “never heated.” The plaintiff asserts that high-pressure processing heats the juice, causing changes in the “microbial, enzymatic and bacterial activity and intact cellular structures,” resulting in the products no longer being raw or fresh. Claiming violations of New York consumer-protection laws along with fraudulent misrepresentation, implied warranty of merchantability and unjust enrichment, the plaintiff seeks class certification, injunctive relief, damages and attorney’s fees.

Burger Chain Faces Food-Safety Allegations from Former Employee

A former employee of Shake Shack Inc. has alleged he was fired after complaining about health and safety violations at one of the company’s New York City locations. *Via v. Shake Shack Inc.*, No. 17-7049 (S.D.N.Y., filed September 14, 2017). The plaintiff alleges that managers of one location fired him after he complained that, among other allegations, they (i) failed to train employees about food allergies; (ii) allowed visibly sick workers to prepare food; and (iii) failed to properly clean the kitchen and equipment. Recent New York City health inspections cited the location for the presence of food/refuse/sewage-associated flies found in food and non-food areas, contaminated and cross-contaminated food and food contact surfaces that had not been sanitized. Claiming retaliation in violation of state laws, the plaintiff seeks \$1 million in damages.

UC Davis and Professors Settle Strawberry Patent Dispute

After a jury unanimously found in May 2017 that two former University of California, Davis professors willfully infringed the university’s patents on a strawberry breed they developed in the school’s program, both sides have agreed on a settlement that will dispose of all other claims against each other. *Regents of Univ. of Cal. v. Cal. Berry Cultivars*, No. 16-2477 (N.D. Cal., filed September 18, 2017). The professors, who left the university to form a private strawberry-breeding company, have agreed to return breeding materials to the school and relinquish \$2.5 million in future royalties related to pre-existing patent-share agreements but will retain interests in some of the varieties they bred. Additional details appear in Issues [604](#), [633](#) and [636](#) of this *Update*.

Baking Mixes Have Too Much Slack Fill, Consumer Alleges

A plaintiff has filed a proposed class action alleging ACH Food Companies sells its Fleischmann’s® Simply Homemade Baking

Mix products in opaque boxes that contain approximately 50 percent slack fill. *Buso v. ACH Food Cos.*, No. 17-1872 (S.D. Cal., filed September 14, 2017). The complaint asserts that the plaintiff would not have purchased the products had he known the container was substantially empty. Alleging violations of California consumer-protection laws, the plaintiff seeks class certification, injunctive relief, exemplary, compensatory and punitive damages, restitution and attorney's fees.

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