ISSUE 627 | MARCH 17, 2017

FOOD & BEVERAGE LITIGATION UPDATE

SHOOK HARDY & BACON

SPOTLIGHT

Stakeholders Voice Opinions About Modernizing "Healthy" at FDA Meeting

Concerns about how or whether the term "healthy" should be used in food labeling and packaging prompted the U.S. Food and Drug Administration (FDA) to hold a public comment meeting on the issue on March 9, 2017.

Current FDA regulations allow the use of the term "healthy," as well as similar terms, as implied nutrient-content claims. However, the criteria for use vary for different food categories, and the criteria themselves are linked to elements of the nutrition facts panel and serving size regulations—both of which have undergone significant changes in recent years. FDA also received a citizen petition in 2015 from Kind LLC, a producer and distributor of snack bars, requesting the agency amend its regulations defining the use of the term with respect to total fat intake and emphasizing whole foods and dietary patterns instead of specific nutrients. Accordingly, FDA's 2016 publication of "Use of the Term 'Healthy' in the Labeling of Human Food Products: Guidance to Industry" advised food manufacturers of "FDA's intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim 'healthy'" for some items and that the agency is "re-evaluating" the regulatory criteria for its use.

Given the current questions of clarity on the issue, the agency sought comment from stakeholders and interested members of the public at the meeting. Attendees agreed that the working definition of "healthy" should be revised and modernized to keep pace with the evolution of nutrition and consumer behavior science as well as changes in healthy diet pattern nutritional

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standards. A majority of attendees also appeared to favor a hybrid definition, which applies a "food group"-based definition with beneficial nutrient criteria supplementing the food group breakdown. But the more nuanced questions about which specific criteria should underpin a modernized "healthy" claim yielded a variety of responses. There was also considerable debate about harmonization and whether "healthy" claims should be tied to the *2015-2020 Dietary Guidelines for Americans* or some other nutrition guidance platform.

Food and grower industry representatives posited that "healthy" is an important claim that needs to remain available to the market. Industry panelists suggested a food-group/diet pattern-plus-nutrient-based premise; other panelists suggested a tiered approach that would consider food group association, beneficial nutrient content, and to a lesser extent, negative nutrient content. However, some attendees expressed concern over a focus on negative nutrient content, citing foods such as almonds, nuts and avocados as examples of foods commonly perceived as "healthy" but which might be disqualified from a "healthy" claim because of negative attributes such as total fat and cholesterol content. Finally, industry representatives asked FDA to consider packaging and label space, costs and nutritional fortification when determining a manufacturer's ability to use a "healthy" claim.

Consumer advocates and medical professionals—primarily dietitians and nutritionists—expressed concerns about the futility of revising the definition of "healthy." In particular, they raised concerns about the rapidly-changing science in the nutrition and health fields. Attendees were also concerned that a "healthy" claim could distract consumers from other important labeling information and nutritional facts. Finally, consumer advocates and members of the general public said they were worried about disqualifications for total fat and cholesterol. Several objected to tying the criteria to the *Dietary Guidelines*, saying the guidelines were outdated. FDA will accept written and electronic comments on the issue through April 26, 2017.

Additional reporting provided by Shook Senior Staff Attorney Kelly Dawson.

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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.

LEGISLATION, REGULATIONS & STANDARDS

Bill Addresses Foreign Acquisitions of U.S. Food and Agricultural Businesses

The U.S. Senate is considering a bill that would give food and agriculture officials greater oversight of mergers and acquisitions involving U.S. food companies and foreign entities and includes new criteria to determine whether a transaction could result in control of a U.S. business by a foreign company.

The bill would make the Secretary of Agriculture and the Secretary of Health and Human Services (HHS) permanent members of the Committee on Foreign Investment in the United States (CFIUS). The purpose of CFIUS is to assess whether transactions involving foreign entities may impair U.S. national security; the bill adds criteria to the CFIUS review process to ensure that transactions are reviewed specifically for their potential impact on U.S. food and agriculture systems, including the availability of food and its safety and quality.

Sens. Chuck Grassley (R-Iowa), Debbie Stabenow (D-Mich.) and Joni Ernst (R-Iowa) introduced Senate Bill 616, titled the "Food Security is National Security Act of 2017," as an amendment to the Defense Production Act of 1950. The bill has been referred to the Senate Committee on Banking, Housing and Urban Affairs.

"As foreign entities continue their aggressive acquisitions of U.S. food and agriculture companies, it's imperative that these transactions face additional scrutiny," said Stabenow. "This bill ensures that the U.S. has the appropriate tools and people in place to safeguard America's food security, food safety, biosecurity and the highly competitive U.S. farm sector as a whole."

Appy Juice Drinks' "Natural" Claim Ruled Unsubstantiated and Misleading

The U.K. Advertising Standards Authority (ASA) upheld a complaint about the "About Us" section of its website for Appy Food & Drinks, which contained a claim that all of the advertiser's juice drinks were "100% natural" despite containing calcium lactate and glucose-fructose syrup. Appy Foods asserted that calcium lactate is a salt obtained through a natural fermentation process and occurs naturally in dairy products, and glucose-fructose syrup is obtained through hydrolysis of cornstarch, also a natural process.

The watchdog agency reviewed Appy's production processes and found that Appy did not provide sufficient evidence to demonstrate that the calcium lactate production process was "natural," and further that the glucose-fructose syrup was produced by the addition of an enzyme isomerase to the

cornstarch, a “non-traditional” treatment falling outside the definition of “natural” in the Food Standards Agency guidelines.

Because the Appy juice drinks were not “single foods,” the ASA decided that the term “natural” could not be used to describe them without qualification and that the two ingredients fell outside the permitted processes for “natural” foods as applied to individual ingredients for compound foods. Accordingly, the agency ruled that the claim was “unsubstantiated and therefore misleading,” in breach of CAP Code.

LITIGATION

Environmental Groups Seek to Intervene on Seafood Traceability Rule Lawsuit

Three environmental and conservation advocacy groups have moved to intervene in a lawsuit filed by a group of seafood processing, distribution and retail companies to block implementation of the Seafood Import Monitoring Program. *Alfa Int’l Seafood, Inc. v. Sullivan*, No. 17-0031 (D.D.C., motion filed March 7, 2017).

Natural Resources Defense Council, Oceana and the Center for Biological Diversity are asking to defend the oversight program, known as the Seafood Traceability Rule, which gives the National Oceanic and Atmospheric Administration power over stringent reporting and recordkeeping of fish catches, vessel and species identification, names of buyers and other chain-of-custody information. The National Marine Fisheries Service published the rule in December 2016 to combat U.S. imports of seafood alleged to be the product of illegal, unreported and unregulated fishing, along with fraudulent practices such as mislabeling of species.

Wrongful Death Suit Filed Against Makers of Allegedly Contaminated Cheese

The widow of a Vermont man who died after eating raw-milk cheese allegedly contaminated with *Listeria monocytogenes* has filed suit against the manufacturer of the cheese, Vulto Creamery. *Friedman v. Vulto Creamery LLC*, No. 17-0283 (N.D.N.Y., filed March 10, 2017). Vulto issued a recall of its Ouleout, Miranda, Heinennellie and Willowemoc raw-milk cheeses in March 2017 after the U.S. Food and Drug Administration identified Ouleout as the source of a *Listeria* outbreak that began in September 2016.

The complaint asserts that multiple people became ill or died after eating Vulto's Ouleout. For alleged strict liability, breach of warranty, negligence and negligence per se, the plaintiff is seeking damages and attorney's fees.

Shareholder Suit Against Chipotle Over Foodborne Illnesses Dismissed by New York Court

A New York federal court has dismissed a putative class action against Chipotle Mexican Grill Inc. alleging the burrito chain violated the Securities and Exchange Act of 1934 by making material misrepresentations about the company's response to foodborne illnesses linked to its stores. *Ong v. Chipotle Mexican Grill, Inc.*, No. 16-0141 (S.D.N.Y., order entered March 8, 2017). The court has granted the plaintiffs, led by Metzler Investment GmbH and Construction Laborers Pension Trust of Greater St. Louis, leave to amend.

Chipotle's stock price dropped in 2015 after outbreaks of foodborne illnesses, including norovirus, *E. coli* and *Salmonella*, were linked to its stores. As a result, Chipotle profits declined by 95 percent in 2016 as compared to the year before. The plaintiffs alleged that Chipotle and three of its executives misled shareholders and the public in the statements and reports it released about the outbreaks, although Chipotle predicted poor performance in 2016 projections submitted to the SEC.

The court disagreed, holding that plaintiffs failed to show knowledge of wrongdoing, or intention to deceive, manipulate or defraud in the defendants' public statements. "[It is] not enough for plaintiff to show motives that are common to most corporate officers, such as the desire for the corporation to appear profitable and the desire to keep stock prices high," the court said. "There is no indication in the complaint that Chipotle's projections were inconsistent with or did not account for the company's assessments of the impact of the food-borne illness outbreaks."

Putative Class Action Filed Against Ferrara Candy over Slack Fill Claims

A consumer has filed a putative class action against Ferrara Candy Co. claiming that its packaging of Jujyfruits® and other candies misleads consumers by misrepresenting the amount of candy contained in each box. *Iglesias v. Ferrara Candy Co.*, No. 17-0849

(N.D. Cal., filed February 21, 2017). The plaintiff claims that Ferrara "shortchanges consumers" by under-filling its opaque candy boxes. In movie theaters, where boxed candies are sold, the boxes are kept behind glass showcases, the complaint asserts, and consumers have no opportunity to examine net weight, serving disclosures or other labeling until after paying for the candy. Moreover, the plaintiff claims that consumers' purchasing decisions are heavily dependent on product packaging and that "consumers are apt to choose the larger box because they think it's a better value." The action includes other candy lines manufactured by Ferrara, including Lemonhead®, RedHots®, Chuckles®, Brach's® and Atomic Fireball® products. For alleged violations of California's Consumers Legal Remedies Act, False Advertising and Unfair Competition laws, the plaintiff seeks class certification, damages and attorney's fees.

Rachael Ray's Dog Foods Misrepresented as "Natural," Putative Class Action Alleges

A consumer has filed a putative class action against the manufacturers of Rachael Ray's dog foods, alleging that the products are labeled as "natural" despite containing artificial or synthetic chemicals. *Grimm v. APN, Inc.,* No. 17-0356 (C.D. Cal., filed February 28, 2017). The plaintiff claims that she only bought the dog foods, sold under the Nutrish®, Dish, Zero Grain and Just 6® labels, because they were labeled as natural and free of preservatives and would have purchased other products had she known the foods contained "artificial preservatives and unnatural ingredients."

The plaintiff alleges the defendant manufacturers "capitalized" on consumer preferences for natural food products. The product labels indicate that the dog foods contain L-ascorbyl-2-polyphosphate, menadione sodium bisulphate complex, thiamine mononitrate, and caramel color. For alleged negligent representation, violations of California's Legal Remedies Act, False Advertising Law and Unfair Competition Law, breach of warranties and quasi-contract, the plaintiff is seeking corrective advertising, statutory and punitive damages and attorney's fees.

Putative Class Action Filed After DNA Test Reportedly Finds Subway Chicken Sandwiches Are Half-Soy

A Connecticut plaintiff filed a projected class action against Subway after DNA testing of the chain's chicken sandwiches allegedly showed the meat was only 42 to 53 percent chicken and the remainder was processed soy. *Moskowitz v. Doctor's Associates Inc.*, No. 17-0387 (D. Conn., filed March 1, 2017). Researchers affiliated with the Canadian Broadcasting Company's "Marketplace" news show apparently found that the meat used in Subway's oven-roasted chicken items was only 53.6 percent chicken, while the meat used in the sweet onion teriyaki items was only 42.8 percent chicken.

The plaintiff claims that Subway is "disseminating false and misleading information via advertising, marketing, its website, and menu intended to trick unsuspecting customers, into believing they are purchasing chicken for their money, rather than Sandwiches and Chicken Strips containing a multitude of ingredients." The complaint alleges violations of the federal Magnuson-Moss Warranty Act, the Connecticut Unfair Trade Practices Act, breach of warranties and unjust enrichment. The plaintiff seeks damages, corrective advertising and attorney's fees.

Georgia Court Dismisses Olive Oil Suit Against Dr. Oz

A Georgia court has dismissed with prejudice a complaint against television personality Mehmet Oz accusing the physician of making false claims about the quality of olive oil in the United States, finding that Oz's statements were protected under a state anti-SLAPP (strategic lawsuit against public participation) law protecting speech made in connection with an issue of public concern. *N. Am. Olive Oil Assoc. v. Oz*, No. 2016-283156, (Sup. Ct. Ga., Fulton Cty., order entered March 3, 2017.)

The North American Olive Oil Association alleged that Oz and his guests made "false statements regarding the quality and purity" of olive oil sold in U.S. supermarkets. One of the guests was employed by olive oil producer California Olive Ranch, but the guest's ties to the company were allegedly not disclosed on the show. The court said it had "grave concerns that the motivation for the present action falls directly within the purpose of the anti-SLAPP statute as an attempt to chill speech, in this case, in the competitive marketplace."

The court found that Oz's statements were a matter of public concern because they were made "contemporaneously" with a U.S. House Appropriations committee report expressing concerns about "the prevalence of adulterated and fraudulently labeled olive oil imported into the United States and sold to American

consumers. In addition, some products labeled as olive oil may contain seed oil, which poses a serious health risk to consumers who are allergic to seed oil." The "tone and tenor of the show concerns the quality of olive oil, presented in the interest of ensuring viewers get what they pay for," the court concluded.

Golden Ticket Chocolate Beer Unwraps Trademark Opposition From Willy Wonka Filmmaker

Warner Brothers, the film studio that owns the rights to the Willy Wonka movies, has asked the Trademark Trial and Appeal Board of the U.S. Patent and Trademark Office to stop a Georgia craft brewer's use of "Golden Ticket" as the name for a chocolate stout beer, claiming that the name could lead some to believe the filmmaker is promoting underage drinking. *Warner Bros. Entm't Inc. v. S. Sky Brewing Co.*, No. 91233169 (T.T.A.B., filed March 1, 2017).

In the Willy Wonka movies, children who found golden tickets tucked inside chocolate-bar packaging won a tour of the chocolate factory and a chance to win a grand prize. Warner Brothers claims the name "Golden Ticket" is an "intent to capitalize" on the popularity of the films, alleging that Southern Sky's beer is advertised as "reminiscent of a chocolate hazelnut candy bar and as creamy as chocolate milk," reinforcing the "mental association" with Willy Wonka.

Warner Brothers asserts that it maintains active licensing of Willy Wonka-related products and that "[c]hildren, parents and others are likely to believe mistakenly that the display of applicant's 'Golden Ticket' mark on an alcoholic beverage is an attempt … to promote the sale of alcohol to minors."

SCIENTIFIC/TECHNICAL ITEMS

Study Claims Honeybee Gut Bacteria "Perturbed" by Antibiotics

A study has purportedly suggested that antibiotic treatments for foulbrood and other pathogens can disrupt the gut microbiota of honeybees, increasing their susceptibility to opportunistic bacterial infections. Kasie Raymann, et al., "Antibiotic exposure perturbs the gut microbiota and elevates mortality in honeybees," *PLoS Biology,* March 2017. To examine the effects of common bee

antibiotics, University of Texas researchers followed specimens from a single hive that received either sugar water or tetracycline.

Their results evidently showed “that honeybees treated with antibiotics and returned to the hive had decreased survivorship when compared to untreated bees.” The authors further note, “Control bees had, on average, five times more bacterial cells in their guts than bees treated with tetracycline.” Tetracycline also failed to eliminate the targeted bacterial species in the treated bees, raising questions among the researchers about antibiotic resistance in domestic bee populations.

“The aim of the study was for us to better understand the role of the microbiota in the biology of bees, and more generally understand the consequences of disrupting the microbiome in an animal host,” said the lead author. *See Popular Science,* March 15, 2017.