

ISSUE 521 | APRIL 25, 2014



### **CONTENTS**

Legislation,	Reau	lations	and	Stand	ards

FDA Issues Final Rule on Irradiation Use in Food Handling
FDA Releases Food Code Reference System1
USDA to Track Swine Viruses2
FSIS Issues Guidance for Meat and Poultry Product Allergens2
Advocacy Group Seeks Ban on Use of Apple Pesticide
EFSA Opens Public Consultation on Infant Formula Requirements3
ASA Dismisses Complaint Against Ad Linking Beer Consumption to Cancer3
ASA Censures Alcohol Ads Paired with Child-Friendly YouTube Videos4
Vermont Passes GM Labeling Legislation5
OEHHA Takes Action on Genistein and Warnings Revisions6

### Lif

and Warnings Revisions
tigation
Court Rules Plaintiff Cannot Prove HFCS Caused Teen's Type 2 Diabetes 6
Injunctive Relief Class Certified in Twinings Tea "Antioxidants" Suit
J.M Smucker Prevails on Class Certification Motion in Labeling Suit 3
Court Allows Obesity-Related Claims to Proceed
Court Denies Motion to Sever Charges Against Stewart Parnell
Former Employees File Putative Class Action Against T.G.I. Friday's for Labor Law Violations
Pasta Maker to Settle Product Labeling Claims for \$7.9 Million 1
ther Developments
Powdered Alcohol Garners

#### Scientific/Technical Items

Pomegranate Juice Allegedly Linked to Heightened Neurodegeneration in Parkinson's Disease
Caffeine Keeps Employees Ethical, Study Says

### LEGISLATION, REGULATIONS AND STANDARDS

### FDA Issues Final Rule on Irradiation Use in Food Handling

The U.S. Food and Drug Administration (FDA) has **issued** a final rule, effective April 14, 2014, amending its food additive regulations to allow the use of ionizing radiation on crustaceans (e.g., crab, shrimp, lobster, crayfish, and prawns) to control foodborne pathogens and extend shelf life.

In response to a petition first filed in 2001, FDA concluded that use of irradiation to treat chilled or frozen raw, cooked or partially cooked crustaceans, or dried crustaceans, with or without spices, minerals, inorganic salts, citrates, citric acid and/or calcium disodium EDTA used in accordance with applicable laws and regulations, is safe, provided that the absorbed dose does not exceed 6.0 kGy. At this dose, FDA notes, ionizing radiation will reduce but not entirely eliminate, the number of illness-causing microorganisms in or on crustaceans. The agency also observes that irradiation is not a substitute for proper food-handling practices and that crustaceans treated with ionizing radiation must be stored, handled and cooked in the same way as non-irradiated foods. In forming its assessment, the agency considered previous irradiation safety evaluations for other foods including poultry, meat, molluscan shellfish, iceberg lettuce, and fresh spinach. See Federal Register, April 14, 2014.

### FDA Releases Food Code Reference System

The U.S. Food and Drug Administration (FDA) has <u>released</u> its Food Code Reference System (FCRS), a searchable database that provides information for industry about FDA's positions and responses to questions related to the FDA Food Code.

With an aim "to promote nationwide consistency and increase transparency about the Food Code," FCRS contains entries that clarify issues such as (i) storing foods that require temperature control for safety; (ii) food establishment design and food equipment cleaning; (iii) bare-hand contact with ready-to-eat foods; and (iv) preventing food contamination.

FDA plans to add entries that are "important to the uniform application of the Food Code and that may have implications across all jurisdictions that regulate food establishments." These entries will reflect questions previously



ISSUE 521 | APRIL 25, 2014

answered by FDA as well as responses to future inquires that FDA receives. The Retail Food Protection Team in FDA's Center for Food Safety and Applied Nutrition (CFSAN) will develop and maintain the database information. *See CFSAN Constituent Update*, April 21, 2014.

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.

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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 (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

#### **USDA to Track Swine Viruses**

The U.S. Department of Agriculture (USDA) has announced that it will require reporting of Porcine Epidemic Diarrhea Virus (PEDv) and Swine Delta Coronavirus infections to curb the spread of the disease. In addition, USDA will track "movements of pigs, vehicles, and other equipment leaving affected premises." Hog farms in 29 states have already reported incidents of PEDv, which has killed more than six million piglets since it was first identified last spring. The virus poses no food safety concerns because it only affects pigs, but it has contributed to higher domestic pork prices. No PEDv vaccine is approved for use in the United States, but earlier this month, six senators from pork-producing states pressed Senate subcommittee leaders to provide funding to develop a vaccine for PEDv and Swine Delta Coronavirus. See Agriculture Secretary Tom Vilsack Announcement, April 18, 2014.

### **FSIS Issues Guidance for Meat and Poultry Product Allergens**

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has <u>issued</u> guidance for identifying, controlling and labeling allergens and other ingredients of public health concern through hazard analysis and critical control point (HACCP) plans, standard operating procedures (SOPs) or other prerequisite programs. Geared toward meat and poultry products, the guidance seeks to ensure "that product labels declare all ingredients, as required in the regulations, and that the product does not contain undeclared allergens or other undeclared ingredients."

In particular, the agency points to "a sustained increase in the number of recalls of FSIS-regulated products that contained undeclared allergens," noting that such recalls are "preventable, as many have been due to ingredient changes, product changes, products in the wrong package, or products with misprinted labels." In addition to establishing best practices for SOPs and HACCP plans, the recommendations clarify how to properly process, handle, store, and label a product with an allergenic ingredient or ingredient of public health concern. The agency has requested comments by June 20, 2014. See Federal Register, April 21, 2014.

#### Advocacy Group Seeks Ban on Use of Apple Pesticide

The Environmental Working Group (EWG) has <u>requested</u> that the U.S. Environmental Protection Agency (EPA) halt the use of a "post-harvest growth regulator"—diphenylamine (DPA)—on apples "until a rigorous analysis



ISSUE 521 | APRIL 25, 2014

(re-registration) by EPA of the chemical can prove that it poses a reasonable certainty of no harm to consumers." EWG cites in support of its request a 2012 European Food Safety Authority finding that "it could not confirm the safety of [DPA] because producers had not provided information about DPA on European apples and pears," the European Commission's (EC's) ban on the chemical's use on pears and apples in June 2012, and the EC's decision to reduce the allowable level of DPA on imports to 0.1 part per million. According to EWG, some 80 percent of domestic apples tested had measurable levels of the chemical on them, with the average level four times the European import limit. DPA is apparently applied after harvest to prevent "storage scald"—fruit skin browning, associated with long-term cold storage. See EWG Press Release, April 24, 2014.

### **EFSA Opens Public Consultation on Infant Formula Requirements**

The European Food Safety Authority (EFSA) has <u>launched</u> a public consultation on its draft scientific opinion determining "the essential composition of infant and infant follow-on formulae." Drawing on new evidence as well as dietary intake guidelines for infants and young children, the draft opinion addresses requirements for protein, fat, carbohydrates, micronutrients, and other ingredients found in formula. It also notes that nutrients should be added to formula only "in amounts that serve a nutritional or other benefit."

Among other things, the agency concluded that (i) "cow's milk, goat's milk and isolated soy protein are safe and suitable sources of protein for use in infant and infant follow-on formula based on intact protein"; (ii) "formulae containing protein hydrolysates are insufficiently characterized by the declared protein content even if they fulfill regulatory criteria concerning amino acid patterns and contents"; (iii) "infant and follow-on formula should provide indispensable and conditionally indispensable amino acids in amounts at least equal to those found in breast milk, irrespective of the protein source"; (iv) "it is not necessary to add arachidonic acid, eicosapentaenoic acid, chromium, taurine, nucleotides, non-digestible oligosaccharides, 'probiotics' or 'synbiotics' to infant and follow-on formula"; and (v) "for follow-on formula, unlike with infant formula, the addition of l-carnitine, inositol and choline is not necessary." EFSA will accept comments on the draft opinion until May 29, 2014. See EFSA News Release, April 24, 2014.

### ASA Dismisses Complaint Against Ad Linking Beer Consumption to Cancer

The U.K. Advertising Standards Authority (ASA) has reportedly <u>dismissed</u> a complaint about a controversial National Health Service advertisement showing a tumor growing in the bottom of a beer glass with the tag line "the more often you drink, the more you increase your risk of developing cancer."



ISSUE 521 | APRIL 25, 2014

Promoted by the alcohol awareness charity Balance and shown in a section of England reported to have the country's highest rates of alcohol-related health problems, the advertisement depicts a man preparing a meal and pouring a beer into a glass. As the man drinks the beer, a tumor appears to slowly grow at the bottom of the glass and slide toward his mouth. A voiceover then states, "The World Health Organization classifies alcohol as a group one carcinogen ... The more you drink and the more often you drink, the more you increase your risk of developing cancer."

Calling the ad "misleading and irresponsible, the British Beer and Pub Association, the Campaign For Real Ale, the Society of Independent Brewers, and others stated that it amounted to "scaremongering" and implied that drinking a small amount or drinking moderately would increase the risk of developing cancer.

According to Balance, however, the ad "conveyed the impression that the man featured consumed alcohol on a regular and routine basis, and at no point did the ad state or imply that the man featured was only consuming one glass of beer on that particular occasion." The group apparently intended the consumption of one drink to be interpreted as a proxy for routine drinking, also noting that the voice-over clearly stated, "... the more you drink and the more often you drink ...," further enforcing the impression that routine or regular drinking would enhance the risk of developing cancer.

Speaking on behalf of Balance, ASA stated that "the ad aimed to depict routine drinking, whereby a man consumed a bottle of beer as part of a typical every day task; cooking dinner for his children." In its dismissal of the complaint, ASA said, "We considered that the overarching message of the ad was that the consumption of alcohol could cause cancer, the more alcohol an individual consumed the greater that risk, and that viewers should reflect on, and potentially reduce, their alcohol intake. We did not consider that the ad over-emphasized the risk of developing alcohol related cancers, or suggested that viewers should significantly reduce their intake or abstain from the consumption of alcohol completely. In addition, we noted that the ad encouraged viewers to visit the website www.reducemyrisk.tv and find out more about the Government's recommended guidelines and for guidance regarding their own drinking habits. Therefore, we concluded that the ad was not misleading or irresponsible."

### ASA Censures Alcohol Ads Paired with Child-Friendly YouTube Videos

The U.K. Advertising Standards Authority (ASA) has <u>upheld</u> a complaint claiming that alcohol ads were shown during YouTube videos intended for children. According to the agency, a series of children's nursery rhyme videos featured advertisements for liquors sold by Wm Morrison Supermarkets PLC (Morrisons) even though both the company and YouTube took action



ISSUE 521 | APRIL 25, 2014

"to prevent alcohol content from being served during content that was family-friendly."

Despite these precautions and YouTube's warning that users should not access accounts "that declared they were over 18 years of age if they were watching YouTube with a minor," ASA ruled that the ads in question violated CAP Code rules governing social responsibility, children and alcohol. "The ASA noted that both Morrisons and YouTube had processes in place that were intended to ensure that ads for alcohol were not directed at those under 18 years of age," it explained. "However, we considered that the YouTube video in question was very unlikely to be viewed by an adult unless they were watching with a young child. We concluded that although Morrisons had taken all reasonable steps to ensure that the ad was targeted responsibly, it had not been targeted responsibly and therefore the ad breached the Code."

### **Vermont Passes GM Labeling Legislation**

Vermont lawmakers have reportedly passed the nation's first state bill (H.B. 112) to require mandatory labeling of foods made with genetically modified (GM) ingredients. Passed in the Vermont House of Representatives, 114-30, and in the state Senate, 28-2, the bill would require foods containing GM ingredients sold in retail outlets to be labeled as either "partially produced with genetic engineering," "produced with genetic engineering," or "may be produced with genetic engineering." The legislation would also make it illegal to describe any food product containing GM ingredients as "natural" or "all natural."

Backers of the legislation reportedly expect Governor Peter Shumlin (D) to sign it within the next few weeks, with the law taking effect July 1, 2016. "I am proud of Vermont for being the first state in the nation to ensure that Vermonters will know what is in their food," Shumlin was quoted as saying. "The even more thrilling aspect of this bill passage is that it makes the United States known across the globe as a nation that is beginning to take a stance against genetically modified organisms."

Consumer advocates have been ratcheting up pressure on states and federal government to require labeling of foods containing GM ingredients, claiming that consumers have a right to such information. Lawmakers have already passed similar bills in Maine and Connecticut, although the labeling laws will take effect only if neighboring states adopt comparable measures. The food industry, however, has argued that GM ingredients are safe and labeling costs would be passed onto consumers. In anticipation of a legal battle, state lawmakers included in the bill a fund for legal defense. "I'll be very surprised if we are not sued if the legislature goes ahead and enacts a mandatory GMO labeling statute," said state Attorney General Bill Sorrell. "A lot of people might not realize that this is arguably a free speech issue." See NPR's The Salt and Ecorazzi.com, April 24, 2014.



ISSUE 521 | APRIL 25, 2014

### **OEHHA Takes Action on Genistein and Warnings Revisions**

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has <u>determined</u> that the evidence is insufficient to proceed with the Proposition 65 listing process for genistein, a constituent of soy infant formula. Under the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) regulations, to identify the reproductive toxicity endpoint, "it is considered necessary that the evidence for developmental toxicity has resulted entirely or predominantly from prenatal exposure," OEHHA states. "That is not the case for genistein." The National Toxicology Program monograph on soy infant formula apparently found "clear evidence of adverse effects of genistein in studies with gestational, lactational, and post-weaning treatment, but does not conclude that the effects could result entirely or predominantly from prenatal exposure." See OEHHA News Release, April 16, 2014.

As to OEHHA's consideration of potential amendments to Proposition 65's clear and reasonable warning regulations, the agency has agreed to extend the public comment period at the request of the California Chamber of Commerce to June 13, 2014. Additional information about this initiative appears in Issue 517 of this Update.

#### LITIGATION

### Court Rules Plaintiff Cannot Prove HFCS Caused Teen's Type 2 Diabetes

A federal court in New York has dismissed an amended complaint filed against high-fructose corn syrup (HFCS) manufacturers, alleging that the HFCS in foods and beverages, such as McDonald's hamburger buns and Pepsi, was a substantial factor in causing a 14-year-old girl to develop Type 2 diabetes. S.F. v. Archer-Daniels-Midland Co., No. 13-634, decided April 21, 2014). The plaintiff alleged market-share liability under the tort doctrines of strict liability, negligence and failure to warn.

The court agreed with the defendants that Type 2 diabetes is a multifactorial disease, stating "[n]o expert opinion is required to arrive at this conclusion." And even accepting the allegations as true, the court said, "[T]here is little in it to suggest that Plaintiff could prove that her consumption of some foods containing HFCS over the course of her life was a substantial factor in causing Type 2 diabetes. . . . [A] side from idly listing various common foods she has eaten, Plaintiff offers limited facts that might lead this Court to believe that she could ultimately show that it was her consumption of these foods, and specifically the HFCS found within these foods (manufactured by these defendants) that led to her disease."

While the court found it may be "possible" to establish proximate cause, it asked whether this is "plausible" under Pelman ex rel. Pelman v. McDonald's



ISSUE 521 | APRIL 25, 2014

Corp., No. 02 CIV. 7821 (RWS), 2003 WL 22052778 (S.D.N.Y. Sept. 3, 2003), rev'd, 396 F.3d 508 (2d Cir. 2005)—the court questioned the continuing viability of the Second Circuit's ruling because it was decided before Twombly and *Iqbal*—and decisions establishing the "plausibility pleading" standard.

Assuming that she could surpass this hurdle, the court ruled that marketshare liability does not apply because a number of key factors are absent, i.e., "there is no claim that the 'manifestations of injury were far removed from the time of ingestion of the product' and certainly there has been no legislation suggesting an overriding public interest in allowing claims like this to proceed in this manner." The court also found no "signature injury" related to HFCS or that the HFCS manufacturers exercised exclusive control over the ingredient. Regarding the latter, the court stated, "There is no dispute that the makers of end-products—not the defendants—decide 'what quantities' of HFCS to use, just as the manufacturers of the paint—and not the manufacturers of the lead—decide how much lead to use."

The court further noted that liability must be premised on an allegation that the product is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it." In the court's view, "[i]f there is no difference between HFCS and simple fructose, HFCS can hardly be said to be unreasonably dangerous."

In this regard, the court found that the complaint must be dismissed because the plaintiff failed to plead that HFCS is unreasonably dangerous. She alleged that the high concentration of HFCS was the source of her illness and alleged that HFCS is "more dangerous than sugar because of the way fructose is processed in the body. But," the court said, "fructose is a naturally occurring compound, found in everyday, commonly consumed fruits like grapes and pears. Certainly Plaintiff is not suggesting that these fruits are 'toxic' substances. Yet this is precisely what Plaintiff appears to suggest: she does not distinguish between fructose found in fruit and fructose found in HFCS; rather, she alleges that '[f]ructose'—not high-fructose corn syrup—'is a major cause of metabolic syndrome and type 2 diabetes." The court found particularly relevant to this point that the defendants "do not control how much HFCS is used in the finished products that Plaintiff consumed."

The court found a third reason to dismiss the complaint—the plaintiff's failure to plead defective design under New York law. According to the court, "she does not attempt to allege how HFCS could be made safer... Instead she argues that all HFCS—even those formulations with a lower fructose-toglucose ratio than sugar—is unsafe, regardless of its composition." Not only did this allegation contradict the plaintiff's earlier claim that HFCS is more dangerous than sugar because of its elevated levels of fructose, the court also said that if she were to succeed by imposing state law tort liability on the manufacture and sale of HFCS now on the market, this would virtually ban the



ISSUE 521 | APRIL 25, 2014

ingredient. "Thus, if the only alternative is an outright ban, no design-defect claim will stand."

### Injunctive Relief Class Certified in Twinings Tea "Antioxidants" Suit

A federal court in California has certified a statewide class of those who purchased Twinings North America's green, black and white tea products labeled as a "Natural Source of Antioxidants." *Lanovaz v. Twinings N. Am., Inc.*, No. 12-2646 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered April 24, 2014). Details about a previous ruling narrowing the claims appear in Issue 509 of this *Update*.

So ruling, the court rejected the defendant's argument that the proposed class lacked ascertainability "because few, if any, company records exist to identify purchasers or which products they bought, and consumers did not keep receipts or product containers." According to the court, many classes similar to this one had been certified by courts in the Ninth Circuit to the extent that the "class definition describes a set of common characteristics sufficient to allow a prospective plaintiff to identify himself or herself as having a right to recover based on the description." The court also found the plaintiff's claims typical of the class, even though she had purchased just six of the 51 products at issue. In the court's view, all of the products here have the "natural source of antioxidants" label statements and are made from the same type of tea plant.

The certification order is limited to injunctive relief under Rule 23(b)(2), in part, because the plaintiff was unable to present "a legally relevant damages model under Rule 23(b)(3)." Her expert, Dr. Oral Capps, had proposed three models: refunding the entire purchase or "register" price of the tea, which the court found was not a proper measure of damages; comparing the price of the product under a "benefit of the bargain" rule or price-premium model, which the court rejected because the expert "has no way of linking the price difference, if any, to the antioxidant label or controlling for other reasons why 'comparable' products may have different prices"; and applying an "economic or regression analysis," which the court found could be legally relevant, but had been abandoned after the expert found that the antioxidants statement had been on the product packages during the entire class period. "Hence," the expert opined, "it is not possible in this case to invoke a regression analysis because of the lack of any variable in sales or units sold attributed to the antioxidant claims."

### J.M Smucker Prevails on Class Certification Motion in Labeling Suit

A federal court in California has denied the motion to certify statewide monetary or injunctive relief classes in litigation alleging that J.M. Smucker's labels for Uncrustables and Crisco Original and Butter Flavor Shortening



ISSUE 521 | APRIL 25, 2014

products "mislead[] consumers into believing that they are healthful, when in reality they both contain trans fat and Uncrustables also contain[] high fructose corn syrup." *Caldera v. The J.M. Smucker Co.*, No. 12-4936 (U.S. Dist. Ct., C.D. Cal., decided April 15, 2014). As to monetary relief, the court dismissed the motion to certify with prejudice.

The court agreed with the defendant that the plaintiff could not satisfy the predominance requirement as to her claims for monetary relief because she failed to identify any method of proving damages on a class-wide basis other than relying on the defendant's California sales data. According to the court, this is insufficient to support a claim for restitution, because "this is not a case where class members would necessarily be entitled to a full refund of their purchase price. . . . As evidenced by Plaintiff's own deposition testimony, class members undeniably received some benefit from the products." Cautioning that "[t[his is not to say that damages can never be determined on a classwide basis under California's consumer protection statutes," the court noted that the plaintiff "had failed to offer any evidence, let alone expert testimony, that damages can be calculated based on the difference between the market price and the true value of the products." Thus she failed to meet her burden that damages could be proven on a class-wide basis, and the court ordered her to proceed as an individual with respect to her claims for monetary relief.

As to the plaintiff's apparent alternate request for certification of injunctive relief classes, the court observed that the plaintiff did not "explain why certification of her injunctive relief claims under Rule 23(b)(2) would be appropriate." It also appeared to the court that she could pursue the injunctive relief she sought as an individual. The court denied her request to certify injunctive relief classes without prejudice and ordered the plaintiff to show cause within 14 days "why certification of her injunctive relief classes is warranted or even necessary." Her failure to do so "will be deemed her abandonment of her request to certify her injunctive relief classes, in which case this action will proceed as to Plaintiff's individual action only with respect to her claims for injunctive relief as well."

### **Court Allows Obesity-Related Claims to Proceed**

A federal court in Missouri has determined that a man who alleges employment discrimination and retaliation in violation of the Americans with Disabilities Act (ADA) on the basis of his severe obesity has sufficiently stated his claims and may proceed with his action. Whittaker v. America's Car-Mart, Inc., No. 13-0108 (U.S. Dist. Ct., E.D. Mo., Se. Div., order entered April 24, 2014). The plaintiff allegedly began working for the defendant in August 2005 and was discharged from his general manager position in November 2012, purportedly because of his disability. He claims that the defendant regarded him as having a physical impairment under the ADA and "as being substantially limited in a major life activity, walking, as a result of his obesity."



ISSUE 521 | APRIL 25, 2014

To support its argument that the alleged disability "is not an actual disability under the ADA unless it is related to an underlying physiological disorder or condition and that plaintiff fails to allege that his obesity is related to an underlying physiological disorder or condition," the defendant cited case law predating congressional ADA amendments intended to reject the U.S. Supreme Court's "unduly restrictive approach" to the law's disability definition. The defendant further relied on EEOC interpretive guidance that has been revised since the law was amended to omit the statement "except in rare circumstances, obesity is not considered a disabling impairment." Given Congress's mandate that the ADA's disability definition be construed "in favor of broad coverage of individuals . . . to the maximum extent permitted" by the law, the court found that the plaintiff's claims survived a motion to dismiss.

### **Court Denies Motion to Sever Charges Against Stewart Parnell**

A federal court in Georgia has denied a motion to sever the criminal charges filed against the former owner of the Peanut Corp. of America, linked to a 2009 nationwide Salmonella outbreak, from charges filed against other company employees. United States v. Parnell, No. 13cr12 (U.S. Dist. Ct., M.D. Ga., order entered April 24, 2014). Information about a hearing conducted to assess the reliability of the defendant's proffered expert—retained to testify about Stewart Parnell's purported Attention Deficit Hyperactivity Disorder appears in Issue 517 of this *Update*. The court has also continued an April 28 status conference in light of a previous ruling rescheduling the trial.

### Former Employees File Putative Class Action Against T.G.I. Friday's for Labor **Law Violations**

Four former employees of T.G.I. Friday's, Inc. have filed a putative class action against the restaurant and its parent company, Carlson Restaurants, Inc., to recover unpaid wages, including overtime compensation and unlawful deductions. Flood v. Carlson Restaurants Inc., No. 14-2740 (U.S. Dist. Ct., S.D.N.Y., filed April 17, 2014). The former employees claim that T.G.I. Friday's managers required them to work in violation of the Fair Labor Standards Act and New York Labor Law.

In the complaint, the employees allege that managers required tip-earning workers to do "side work" like rolling silverware, cleaning the restaurant and other tasks that did not merit them tips while the restaurant paid them at the reduced minimum wage reserved for tipped workers. They further allege that managers prevented the employees from receiving their earned overtime pay by lowering the amount of time the employees were on the clock each week to below 40 hours and that the restaurant implemented an unlawful policy requiring tipped employees to pay customer's bills when the customers failed to pay for their meals.



ISSUE 521 | APRIL 25, 2014

### Pasta Maker to Settle Product Labeling Claims for \$7.9 Million

To settle claims that it allegedly deceived consumers by advertising and labeling its Dreamfields pasta products as a low-glycemic index and low-carbohydrate alternative to traditional pasta, Dakota Growers Pasta Co. has agreed to establish a \$5-million settlement fund and pay an additional \$2.9 million to plaintiffs' counsel. *Mirakay v. Dakota Growers Pasta Co.*, No. 13-4429 (U.S. Dist. Ct., D.N.J., motion for preliminary settlement approval filed April 14, 2014). The company has also agreed to remove the allegedly false or misleading statements from Dreamfields packaging for at least one year.

Under the settlement, which requires certification of a nationwide class of consumers and approval by the court, those who purchased the pasta online will automatically receive \$1.99 for every box purchased. Class members who purchased the products in stores and submit a valid claim form will be limited to reimbursement for 15 boxes of pasta. Any funds remaining will be used to adjust each class member's recovery upward by as much as 50 percent; residual funds will be donated to the American Diabetes Association.

#### OTHER DEVELOPMENTS

### **Powdered Alcohol Garners Media Interest**

After the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) reportedly granted and then rescinded labeling approval for a powdered alcohol product created by Lipsmark LLC, the company has fielded a number of consumer and media questions about Palcohol's® marketing, safety and availability. Created by wine critic Mark Phillips, Palcohol® is described as "a powder version of vodka, rum and four cocktails" meant to be mixed with water or other liquids prior to consumption. Although it received approval for the new product "some time ago," the manufacturer was apparently "caught off guard by [TTB] making some of our approved labels public which we now know is standard procedure."

According to the product Website, the company has since surrendered its TTB-approved labels with the intention of revising and resubmitting them for final authorization. In the interim, however, the media attention has prompted Lipsmark to address concerns over "humorous and edgy" language and inaccurate labels displayed on a draft version of its Website not intended for release. "We know there are a lot of people opposed to Palcohol® and that's their right. All we're asking is that the media present a fair and balanced story," stated the company in an update. "Even though the old verbiage was a bit edgy, we clearly stated then, and still remain adamant, that Palcohol should be used in a responsible and legal manner."

11 I



ISSUE 521 | APRIL 25, 2014

#### SCIENTIFIC/TECHNICAL ITEMS

### Pomegranate Juice Allegedly Linked to Heightened Neurodegeneration in Parkinson's Disease

University of Pittsburgh and Purdue University researchers have purportedly found that pomegranate juice (PJ) heightened neurodegeneration in an animal model of Parkinson's disease (PD) by increasing nigrostriatal terminal depletion, dopamine neuron loss, the inflammatory response, and caspase activation. Victor Tapias, et al., "Pomegranate Juice Exacerbates Oxidative Stress and Nigrostriatal Degeneration in Parkinson's Disease," *Neurobiology of Aging*, May 2014. Designed to examine the beverage's potential neuroprotective effects, the study instead suggested that the polyphenols present in pomegranate juice exacerbated the nigrostriatal degeneration of rats with a rotenone-induced syndrome similar to PD.

"Several studies have demonstrated the efficacy of different types of polyphenols to attenuate or block neuronal death in animal models of neurodegeneration," reported the study's authors. "Although differences between PD models could explain a lack of beneficial efficacy of PJ in the rotenone model, the question remains as to why PJ would exacerbate rotenone toxicity—similarly to melatonin. A possible answer could be related to misconceptions about the antioxidant properties of PJ; polyphenolic phytochemicals are considered double-edged swords in cellular redox status."

In particular, the authors hypothesized that "the pro-oxidant nature of a large number of polyphenol compounds... may lead to an increase in lipid peroxidation, DNA damage, mitochondrial damage, and caspase-3 activation, and intracellular glutathione depletion and ROS [reactive oxygen species] scavenging enzyme inhibition." Concluding that their data "provide novel, strong evidence for a pro-oxidant effect of PJ in a PD model," they recommended further research "into the effects of PJ in neurodegeneration."

### **Caffeine Keeps Employees Ethical, Study Says**

A recent study has found that sleep deprivation can lead to unethical behavior, but caffeine can counteract the effect. David T. Welsh, et al., "Building a Self-Regulatory Model of Sleep Deprivation and Deception: The Role of Caffeine and Social Influence," *Journal of Applied Psychology*, March 2014. Researchers kept volunteers awake overnight then gave half of the participants a piece of gum laced with 200 mg of caffeine. The researchers then created situations emulating work environments in which a boss or a peer pressured the participants to "cut ethical corners at work" by lying to earn extra money. The caffeinated subjects consistently refused to lie, while the non-caffeinated subjects were significantly more willing to participate



ISSUE 521 | APRIL 25, 2014

in the deception. "Our results support supplying employees with caffeinated products," the researchers report, although they warn that caffeine consumption is not a replacement for sleep.

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### **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.





