

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

FDA Workshop to Address Food Defense

The Food and Drug Administration (FDA) has [announced](#) a November 7-8, 2012, public workshop at Oklahoma State University in Stillwater "to provide information about food defense as it relates to food facilities such as farms, manufacturers, processors, distributors, retailers and restaurants." Intended to help businesses better comply with the Public Health Security and Biodefense Preparedness Act of 2002, the workshop will cover the following topics: (i) "Food defense awareness and definitions"; (ii) "FDA food defense tools such as ALERT and Employees FIRST"; (iii) "Regulations mandated by the Biodefense Preparedness Act"; (iv) "Food Defense Guidance from the Food Safety and Inspection Service"; (v) "Investigating food-related incidents effectively"; (vi) "Physical plant security"; and (vii) "Crisis management." FDA has asked interested parties to register by October 31, 2012. *See Federal Register*, September 27, 2012.

FDA Extends Comment Deadline on Proposed Animal Drug Reporting Scheme

The Food and Drug Administration (FDA) has [extended](#) the comment period for an advanced notice of proposed rulemaking (ANPR) that announced potential changes to regulations governing new antimicrobial animal drug reporting. The ANPR proposed altering these regulations to incorporate the requirements of section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105).

FDA has requested public comments "on how best to compile and present the summary information as directed by ADUFA 105, and on alternative methods available to the Agency for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals." FDA has extended the comment period at the request of responders until November 26, 2012. *See Federal Register*, September 26, 2012.

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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.

NOP Interim Rule Addresses Continued Use of Vitamins, Minerals in Organic Handling

The U.S. Department of Agriculture's National Organic Program (NOP) has [issued](#) an interim rule extending the use of nutrient vitamins and minerals in organic handling while the agency considers a proposal to renew their exemption (use) on the National List of Allowed and Prohibited Substances (National List) for another five years. According to a September 27, 2012, *Federal Register* notice, the Agricultural Marketing Service (AMS) previously published a proposed rule during its 2012 sunset review that recommended continuing the use of nutrient vitamins and minerals "as ingredients in or on processed products labeled as 'organic' or 'made with organic (specified ingredients or food group(s))'" after their National List exemption expired on October 21, 2012. The proposed rule also sought to correct "an inaccurate cross-reference to U.S. Food and Drug Administration (FDA) regulations in the listing for vitamins and minerals on the National List."

The interim rule will allow handlers and processors to keep fortifying their organic products with vitamins and minerals while the proposed rule is under consideration. Meanwhile, the National Organic Standards Board has started reviewing petitions for the ingredient annotations that would be affected by the corrected cross-reference with FDA's fortification policy. As FDA apparently explained to NOP, the agency does not consider substances such as omega-3 and omega-6 fatty acids, inositol, choline, carnitine, and taurine as essential nutrients governed by its fortification policy at 21 CFR 104.20, which also does not cover infant formula.

"Once the NSOB has completed its review and has issued recommendations on all petitioned nutrients, the public will be able to more fully comment on the implications of correcting the FDA cross-reference as proposed," states AMS. The petitions currently under review pertain to (i) docosahexanoic acid (DHA) algal oil, (ii) arachidonic acid (ARA) single-cell oil, (iii) inositol, (iv) choline, (v) ascorbyl palmitate, (vi) synthetic beta-carotene, (vii) L-carnitine, (viii) lycopene, (ix) lutein, (x) L-methionine, (xi) nucleotides, (xii) taurine, and (xiii) amino acids for pet food. AMS will consider all comments received by December 26, 2012, before issuing its final rule.

Health Canada Backs Safety of BPA in Food Packaging

Health Canada has [released](#) an updated assessment of bisphenol A (BPA), concluding that dietary exposure through food sources "is not expected to pose a health risk." The September 2012 assessment takes into account surveys performed after the agency issued its first conclusions in 2008, when it found "Probable Daily Intakes (PDI) for BPA of 0.18 µg/kg bw/day for the general population and 1.35 µg/kg bw/day for infants." These surveys sought to measure concentrations of BPA in canned drink products, bottled water

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products, canned food products, and soft drink and beer products, as well as in total diet samples.

Based on Health Canada's probabilistic exposure assessment, the new survey results have revised the 2008 PDIs downward for both the general populations and infants. In particular, the agency reported a mean exposure to BPA of 0.055 µg/kg bw/day for the general population, "which is approximately 3 times lower than the intake calculated using migration studies conducted on epoxy-lined cans from the US market in 1995, and presented in the Department's previous health risk assessment published in August of 2008. This updated dietary exposure figure generally aligns with exposure estimates that are based on the results of population-based biomonitoring studies." In addition, the updated assessment noted that while BPA PDIs for infants could vary widely, "the BPA intake estimates for these age categories are, on average, approximately 3-fold lower than those previously derived as part of the 2008 assessment."

"Therefore, based on the overall weight of evidence, the findings of the previous assessment remain unchanged and Health Canada's Food Directorate continues to conclude that current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and young children," states the report. "This conclusion is consistent with those of other food regulatory agencies in other countries, including notably the United States, the European Union and Japan."

UK Agency Rules Almond Milk Claims Not Misleading

The U.K. Advertising Standards Authority (ASA) has [ruled](#) that print and Web advertisements for Alpro (UK) Ltd's almond milk are not misleading. ASA received two complaints alleging that the advertisements misled consumers because the product contains only 2 percent almonds and because the ads featured images implying that almonds could be "milked." Alpro countered, however, that "almond milk" is "commonly used as a descriptor for this type of product," with "the two leading international branded varieties both [having] an almond content of 2%."

"They explained the product was made by processing roasted almonds into a creamy paste, which was then blended with spring water and other ingredients and nutrients, but that no additional flavorings were added to the product," according to ASA. "They said the number of almonds used defined the texture and taste intensity of the product and that consumers liked the product with 2% roasted almonds, which equated to around 20 almonds per one liter pack."

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ASA ultimately agreed with Alpro, concluding that all almond milk varieties contain a relatively low percentage of almonds. “We considered that, whilst consumers might not be aware of exactly how almond milk was produced, they were likely to realize that almonds could not be ‘milked’ and that the production of almond milk would necessarily involve combining almonds with a suitable proportion of liquid to produce a ‘milky’ consistency,” concluded ASA’s adjudication, which found that neither ad in question breached CAP Code (Edition 12) rules 3.1 and 3.3 (Misleading advertising).

New York Bill Would Allow Toys in Fast-Food Meals Meeting Nutritional Requirements

New York State Senator Gustavo Rivera (D-Bronx) has introduced a bill ([S7849-2011](#)) that would require fast-food restaurants offering incentive items, such as toys, with children’s meals to meet certain nutritional guidelines. The standards, designed to limit the amount of fat, sugar, calories, and sodium per meal, would be established by the state health commissioner.

“Incentive items” under the proposal, which has been committed to the Committee on Rules, would also include games, trading cards, admission tickets, “or other consumer product, whether physical or digital, with particular appeal to children.” Such items would also include “any coupon, voucher, ticket, token, code or password which is provided directly by the restaurant and is redeemable for or grants digital or other access to any toy, game, trading card, admission ticket, or other consumer product” appealing to children.

The measure defines restaurant to include coffee shops, cafeterias, luncheonettes, sandwich stands, diners, short-order cafes, fast-food establishments, soda fountains, and any other eating or beverage establishments. Violations would be punishable by fines as high as \$2,500 for a third violation. The express justification for the proposal is that “Obesity in this country has grown into an alarming epidemic. . . . The food that is served in restaurants that is geared toward our children is often the culprit in this obesity epidemic. Studies have shown a positive association between eating out, higher caloric intakes, and higher body weights. Children often eat nearly twice as many calories (an average of 770) when they eat a meal at a restaurant than they do when they eat at home (an average of 420). . . . Restaurants are encouraging our children to make these unhealthy choices by linking them with a free toy or other incentive item.” Companion legislation has apparently been introduced in the State Assembly by Felix Ortiz (D-Brooklyn).

NYC Pushes Health Hospital Initiative Banning Junk Food

The New York City Department of Health and Mental Hygiene (DOHMH) has announced that more than 30 public and private hospitals have joined its voluntary Healthy Hospital Food Initiative, a new program seeking to make

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healthier food choices available in health care settings. Billed as part of the department's ongoing effort to curb obesity, the new initiative requires participating hospitals to implement the NYC Food Standards established in 2008 by Mayor Michael Bloomberg in four areas: "cafeterias, beverage vending machines, food vending machines and patient meals."

According to DOHMH, these standards are based on U.S. Department of Agriculture and Institute of Medicine nutritional guidelines and "use progressive strategies to make healthy foods easily available." Under the new initiative, hospital cafeterias must use a variety of techniques "to make the healthy choice the easy choice" by increasing the availability of fresh fruits, vegetables and whole grains; limiting the promotion of high calorie beverages; and eliminating fried foods. Participating hospitals must also pledge, among other things, to decrease the availability of high-calorie beverages in vending machines; provide nutritional information about vending machine food choices; and establish patient meal standards that meet nutritional requirements "for individual foods purchased, such as sodium limits for bread and cereal, and for meals served, such as two fruit or vegetable servings at lunch and dinner."

"Hospitals should set the standard for promoting healthy behaviors and with this initiative in New York City, they are doing just that," said Health Commissioner Thomas Farley in a September 25, 2012, DOHMH press release, which includes a list of the signatories. "The Healthy Hospital Food Initiative is the most comprehensive approach to improving food options inside our hospitals. I applaud the hospitals that are making changes to offer more healthy options throughout their facilities offering everyone, from patients to visitors, better choices."

LITIGATION

Federal Court Denies Four Loko Motion to Dismiss Putative Class Action

A federal court in New York has denied a motion to dismiss a consumer fraud action against the company that makes Four Loko®, a beverage allegedly containing high alcoholic and caffeine content and sold without disclosing "possible negative health effects." *Yourth v. Phusion Projects, LLC*, No. 1:11-CV-1261 (NAM/CFH) (U.S. Dist. Ct., N.D.N.Y., decided September 27, 2012). The defendant contended that the court lacked subject matter jurisdiction on the ground of mootness "because defendant has offered 'to fully refund any amounts that Plaintiff paid for Four Loko as well as any fees and costs he incurred.'"

Noting that the circuit courts have split over whether a defendant can moot a putative class action by offering to satisfy the plaintiff's demand before a motion for class certification is filed, the court concluded that "unless plain-

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tiff has unduly delayed in moving for certification, defendant's offer of full relief does not moot the action." According to the court, the plaintiff did not unreasonably delay moving for certification given that the dismissal motion was made two weeks after the plaintiff amended his complaint.

The defendant also argued that federal law expressly preempts the plaintiff's state law claims "that defendant failed properly to warn of the alleged harmful effects of caffeinated alcoholic beverages." Observing that the defendant had placed an appropriate warning label on its product, as required by federal law, relating to "any health hazards that may be associated with the consumption or abuse of alcoholic beverages," the court determined that this federal warning requirement was not intended "to preempt state law requiring warnings regarding a non-alcoholic ingredient that may have adverse health effects of its own." The court also stated, "[n]or is there any reason to construe the [Alcoholic Beverage Labeling Act (ABLA)] as intended to preempt state law requiring warnings regarding an adverse health effect of the combination of a non-alcoholic ingredient and alcohol, where the adverse health effect is distinct from that posed by alcohol alone."

The court further rejected the defendant's argument that compliance with ABLA labeling requirements entitles the company to the benefit of a safe harbor under the state's general business law. According to the court, "the deceptive practice alleged by plaintiff here is conduct that is not subject to the ABLA, because plaintiff does not complain of defendant's failure to warn of the health risks of alcohol consumption *per se*. Thus, [defendant's] compliance with the ABLA is no defense." The court also disagreed with the defendant's assertions that the plaintiff's deception and unjust enrichment claims were insufficiently pleaded.

Celebrity Chef Settles Restaurant Employee Wage Claims for \$1.15 Million

A federal court in New York has dismissed with prejudice claims that Mario Batali's Del Posto restaurant allegedly retained portions of workers' tips in violation of federal and state labor laws after approving an agreement requiring the defendants to pay \$1.15 million into a settlement fund and provide workers with training and paid vacation time and sick leave. *Amastal v. Pasta Resources, Inc.*, No. 1:10-cv-07748-RLE (U.S. Dist. Ct., S.D.N.Y., order entered September 24, 2012). Additional information about the lawsuit can be found in Issue [368](#) of this *Update*.

The 31 plaintiffs in this lawsuit had opted out of a similar class action involving captains, servers, waiters, bussers, runners, backwaiters, bartenders, and barbacks at Del Posto and seven other restaurants; the class action apparently concluded with a \$5.25-million settlement deal preliminarily approved in May. Details about the class action appear in Issues [361](#) and [430](#) of this *Update*.

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The deal also apparently releases claims against fellow defendants Lidia Matticchio Bastianich and Joseph Bastianich who were identified as owners and operators of Del Posto. According to a news source, several restaurant workers' discrimination claims, which were not part of the litigation, have been filed with the U.S. Equal Employment Opportunity Commission. See *Law360*, September 25, 2012.

Humane Society Sues to Stop IP Purchase Payments to National Pork Producers Council

The Humane Society of the United States (HSUS) has sued the U.S. Department of Agriculture (USDA) seeking to end payments made to the National Pork Producers Council (Pork Council) for the purchase of the registered mark "Pork, The Other White Meat." [*HSUS v. Vilsack, No. 1:12-cv-01582 \(U.S. Dist. Ct., D.D.C., filed September 24, 2012\)*](#).

According to the complaint, which details the circumstances leading to the mark's creation, development and use, the Pork Council should not have retained ownership of the mark, and the \$60-million, 20-year contract for its purchase should have been terminated when USDA decided to retire the mark and create a new one. HSUS contends that the contract is funded with pork-producer checkoff program dollars, which cannot be used for lobbying. Because the Pork Council is a lobbying organization, HSUS claims that the ongoing payments under the purchase agreement violate federal law.

HSUS seeks a declaration that these expenditures of checkoff funds are unlawful, recovery of the funds already distributed to the Pork Council, an injunction to stop USDA from further "unlawful authorizations or expenditures of checkoff funds related to the . . . marks," attorney's fees, and costs. Among other matters, HSUS claims that it has standing to bring the action because it is forced to spend money countering the Pork Council's lobbying and other activities, particularly regarding its own initiatives to halt the use of gestation cages in pork production. The complaint asserts in this regard, "Since HSUS resources would otherwise be spent on advocacy, legislation, and education related to improving the treatment of pigs and other animals, Defendant's unlawful conduct directly impedes Plaintiff's activities, and causes a significant drain on its resources and time." An individual plaintiff, Iowa pork-producer Harvey Dillenburg, is allegedly harmed by unlawful checkoff expenditures and the use of such money by a "lobbying organization that pushes for policies that Mr. Dillenburg considers harmful to his operations as an independent producer."

Chipotle Claims Jack in the Box Is Infringing Its Trademark

Chipotle Mexican Grill, Inc. has filed another infringement action against a retailer allegedly selling a chicken sandwich combo using the CHIPOTLE® trademark. *Chipotle Mexican Grill, Inc. v. Jack in the Box, Inc.*, No. 1:2012cv02511

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(U.S. Dist. Ct., D. Colo., filed September 21, 2012). Information about the trademark infringement lawsuit Chipotle filed in April against Kroger Co. appears in Issue [435](#) of this *Update*.

In the new action against Jack in the Box, Chipotle alleges that when asked to cease using the CHIPOTLE® marks to promote its chicken sandwich, the defendant responded that its use of the word did not infringe the marks and that it did not currently plan to use the mark, which was used in connection with a limited time offer, in the future. Still, according to the complaint, the defendant “suggested that it would use the CHIPOTLE Marks in the future.” Claiming that its marks have “acquired substantial goodwill and are an extremely valuable commercial asset,” Chipotle alleges trademark infringement, trademark dilution and false designation of origin in violation of the Lanham Act, as well as violation of Colorado’s consumer protection law.

Chipotle seeks temporary, preliminary and permanent injunctive relief to stop Jack in the Box from using the mark to promote its restaurant services or prepared food items; an accounting; compensatory and treble damages; attorney’s fees; costs; and interest.

Vintner Sues for Infringement of Naked Winery® Marks

Naked Wines LLC has filed an action against Nakedwines.com, Inc. and Groupon, Inc. alleging that they have infringed its “family of erotically-themed marks” including NAKED WINERY®, NAKED WINERY VIXEN®, NAKED WINERY NAUGHTY®, and NAKED WINERY DIVA®. *Naked Wines LLC v. Nakedwines.com, Inc.*, No. 3:12-cv-01717 (U.S. Dist. Ct., D. Or., filed September 21, 2012). According to the complaint, Oregon-based Naked Wines has used the marks since 2005 and has “developed and maintains customers throughout the United States.” The marks have purportedly “become an asset of substantial value as a symbol of Plaintiff and its products.”

Nakedwines.com, located in Napa, California, is allegedly “the U.S. arm of a UK-based, online company that sells and distributes wine from multiple producers.” According to the plaintiff, defendant Nakedwines.com, which is working with various producers to sell 400,000 cases of wine in the United States in 2013 and planning to open a winery in California under the name “Naked Wines Winery & Tasting Lounge” in October 2012, applied to the U.S. Patent and Trademark Office (USPTO) to register “NAKED WINES” for “alcoholic beverages (except beers).” The registration was allegedly refused due in part to a likelihood of confusion with the plaintiff’s Naked marks. USPTO deemed the application abandoned in August 2012.

Groupon, which hosts online “daily deals,” allegedly posted a deal for the defendant on August 7 titled “Naked Wines – Online Deal,” offering wine for a discount price. According to the plaintiff, a number of individuals contacted

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Naked Wines on that date “incorrectly believing that the Infringing Groupon was an offering from Plaintiff rather than from Defendant Nakedwines.com.” The plaintiff claims to have notified Groupon on August 7 that it had not authorized the use of its mark, reporting the confusion resulting from the “Infringing Groupon” and demanding that it be removed from Groupon’s Website. The plaintiff also demanded that Groupon “take steps to ensure that any sales made under [the infringing Groupon] are not consummated, as allowing this action will contribute to trademark infringement and unfair competition.”

While Groupon purportedly acknowledged the letter, it did not remove the Groupon from its Website, and when it expired on August 9, more than 410 infringing Groupons had allegedly been purchased. Thereafter, “additional Groupons for Defendant Nakedwines.com have been posted on, distributed through, or otherwise made available to the consuming public on Defendant Groupon’s” Website targeted to consumers in the Portland, New Orleans, Miami, Los Angeles, and Detroit markets.

The plaintiff alleges federal trademark infringement, false designation of origin and unfair competition under the Lanham Act, as well as unlawful trade practices under Oregon law against Nakedwines.com, and contributory trademark infringement under statutory and common law against Groupon. It seeks declaratory and injunctive relief; the destruction of infringing materials; actual, treble and punitive damages; interest; costs; and attorney’s fees.

OTHER DEVELOPMENTS

IASO Report Criticizes Industry Pledge to Reduce Youth Marketing

The International Association for the Study of Obesity (IASO) has released a [report](#) criticizing the food and beverage industry’s efforts to reduce marketing to children in the European Union. Part of the StanMark Project, which receives EU funding, *A Junk-Free Childhood 2012* focuses on the EU Pledge signed by 20 companies that agreed to stop marketing products to children younger than age 12 and to submit to independent monitoring. Citing data from the 2011 EU Pledge Monitoring Report, IASO notes a “disappointing” 29 percent decline in the number of advertisements for “non-compliant” products that were viewed by children between January and March 2011 as compared to those viewed between January and March 2005. “While for some countries there were significant decreases in advertising (e.g. in Poland, Ireland and France), in other countries significant increases were recorded, including Slovenia (up 26%) and the Netherlands (up 38%),” states the report.

“The problem is made worse because the companies are allowed to set their own standards for what they consider ‘junk food’ and they set the bar too

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low,” said the report’s author, Tim Lobstein. “Our report found over 30 fatty and sugary foods which are classified as unhealthy in government-approved schemes across Europe and the USA but which are considered healthy by the manufacturers and which they allow themselves to advertise.”

A Junk-Free Childhood 2012 also voices concerns about supposed gaps in self-regulation, including company-owned Websites, social media sites, the use of licensed characters, sports sponsorships, and child-to-child marketing. To address these issues, the StanMark Project ultimately aims to propose universal standards that take “a ‘risk-based’ approach to reducing exposure to the marketing of food and beverage products whose regular consumption is liable to increase the risk of noncommunicable diseases.” These standards would seek to ensure that (i) foods and beverages marketed to children meet international dietary standards established by the World Health Organization; (ii) products are promoted “only to those persons who have reached an age when they are legally considered to be competent enough to protect their own welfare”; (iii) regulation applies to “all media that carries marketing messages as well as those that cross national borders”; (iv) marketing techniques with special appeal to children are excluded; (v) brands “with recognizable links to food and beverage products” are treated as if they were promotions; (vi) all settings where children gather are free from advertising; and (vii) all parties are held accountable for the dissemination of marketing messages. See *IASO Press Release*, September 27, 2012.

NBER Paper Compares Changes in Smoking and Obesity Rates and Effects on Mortality

The National Bureau of Economic Research (NBER) has issued a [paper](#) titled “Projecting the Effect of Changes in Smoking and Obesity on Future Life Expectancy in the United States.” Funded by the Social Security Administration and a grant from the National Institute on Aging, the research applied Markov modeling to National Health and Nutrition Examination Surveys data from 1999 to 2008 to conclude that reductions in smoking rates coupled with increases in obesity will result in a gain of nearly one year of life expectancy for men and just a quarter of a year’s gain for women. According to the authors, “By 2040, male life expectancy at age 40 is expected to have gained 0.92 years from the combined effects. Among women, however, the two sets of effects largely offset one another throughout the projection period, with a small gain of 0.26 years expected by 2040.”

The researchers also project that by 2040, 47 percent of men and 51 percent of women will be obese with morbid obesity constituting “a majority of obese women by 2020 and thereafter.”

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MEDIA COVERAGE

***National Law Journal* Focuses on Obesity and ADA Claims**

Employment law practitioners are, according to a recent article, predicting an increase in the number of obesity-related claims filed against employers under the Americans with Disabilities Act (ADA). The 2008 amendments have made it easier for employees to prevail in these cases, and a trio of claims filed and resolved in recent months demonstrates that the Equal Employment Opportunity Commission and courts are recognizing obesity as a disability in itself, rather than focusing on some underlying physiological condition as the basis for the employees' disability. Settlements of obesity claims in Texas and Louisiana have resulted in payments of \$55,000 and \$125,000, respectively, while the Montana Supreme Court determined that a physiological disorder underlying morbid obesity is not necessary for a disability claim under a state law that mirrors the ADA. See *The National Law Journal*, September 24, 2012.

***New York Times* Blog Offers "Food Addiction" Quiz**

"Are you a food addict?," asks a September 20, 2012, *New York Times* "Well" blog post featuring a "food addiction" quiz. Citing several food studies allegedly suggesting "that food and drug addiction have much in common, particularly in the way that both disrupt the parts of the brain involved in pleasure and self-control," columnist Tara Parker-Pope offers a shortened version of the Yale Food Addiction Scale created by researchers at Yale University's Rudd Center for Food Policy and Obesity. The quiz asks readers to respond to such questions such as, "I find myself consuming certain foods even though I am no longer hungry" and "I keep consuming the same types or amounts of food despite significant emotional and/or physical problems related to my eating." Based on the inputted responses, the applet then provides a food addiction score ranging from "not addicted" to "possible food addiction" indicating that "you may meet the criteria for food addiction as defined by the Yale Food Addiction Scale."

SCIENTIFIC/TECHNICAL ITEMS

***NEJM* Focuses on Studies Examining Effects of Sugar-Sweetened Beverages**

The *New England Journal of Medicine* (NEJM) has published a series of studies and commentary on the purported health effects of consuming sugar-sweetened beverages. The American Beverage Association issued a statement contending that studies focusing "solely on sugar-sweetened beverages" as an alleged cause of obesity "or any single source of calories, do nothing meaningful to help address this serious issue. The fact remains: sugar-sweetened beverages are not driving obesity. By every measure, sugar-sweetened beverages play a small and declining role in the American diet."

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The studies included [Janne de Ruyter, et al., “A Trial of Sugar-free or Sugar-Sweetened Beverages and Body Weight in Children,”](#) (concluding, “[m]asked replacement of sugar-containing beverages with noncaloric beverages reduced weight gain and fat accumulation in normal-weight children.”); [Cara Ebbeling, et al., “A Randomized Trial of Sugar-Sweetened Beverages and Adolescent Body Weight,”](#) (concluding, “[a]mong overweight and obese adolescents, the increase in [body mass index] was smaller in the experimental group [which decreased sugar-sweetened beverage consumption] than in the control group after a 1-year intervention . . . but not at the 2-year follow-up.”); and [Qibin Qi, et al., “Sugar-Sweetened Beverages and Genetic Risk of Obesity,”](#) (concluding, “[t]he genetic association of adiposity appeared to be more pronounced with greater intake of sugar-sweetened beverages.”).

In an editorial titled “Calories from Soft-Drinks—Do They Matter?,” Sonia Caprio, with the Yale School of Medicine, Department of Pediatrics, contends that these three studies “provide new data showing that consumption of sugar-sweetened beverages may influence the development of obesity among children, adolescents, and adults.” She notes that Qi’s study “provides strong evidence that there is a significant interaction between an important dietary factor—intake of sugar-sweetened beverages—and a genetic-predisposition score, obesity, and the risk of obesity. Hence, participants with a greater genetic predisposition may be more susceptible to the adverse effects of sugar-sweetened beverages on obesity; this is a clear example of gene-environment interaction.” While Caprio acknowledges that mechanisms accounting for the “observed interaction” are not provided by the study, she contends that it “provides support for the need to test whether interventions aimed at reducing the intake of sugary drinks to reduce the risk of obesity might be more effective in persons with a high genetic-predisposition score.”

Caprio characterizes the two other studies as rigorously designed randomized, controlled trials, and concludes that all three studies “suggest that calories from sugar-sweetened beverages do matter.” She calls for policy decisions to address factors in addition to the consumption of sugar-sweetened beverages, including increasing physical activity “to stem the obesity epidemic and its effects.”

New York City Health Commissioner Thomas Farley and Cornell University Marketing Professor Brian Wansink, whose comments about government’s obligation to address the obesity epidemic were summarized in Issue [454](#) of this *Update*, provide further point-counterpoint commentary in this special *NEJM* issue. Farley supports the regulation of sugar-sweetened beverages, stating “If a harmful chemical in schools were causing our children to get sick, people would demand government regulation to protect them. It is therefore difficult to argue against a government response to an epidemic of obesity that kills more than 100,000 persons a year in the United States and has an environmental origin.”

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Wansink cites Prohibition as an example of government action to “wipe out the ills of alcohol” that “could not withstand the violent backlash, subversion, and illegal consequences that quickly followed.” He argues that (i) “consumption of other choices will not remain constant when we tinker with what is available to eat or drink,” (ii) “a preference for less healthful foods, including sugar-sweetened beverages, strengthens when it appears that a tax is being used to restrict consumption,” and (iii) “there is a way forward that has fewer risks and that can place children squarely in our corner. The use of simple behavioral nudges, such as making soft drinks less visible and less convenient, can have a big effect on consumption, while still allowing the children’s (or their parents’) own choice.” According to Wansink, “voluntary approaches are much more likely than regulations to create long-term behavioral habits and much less likely to create a class of soft-drink freedom fighters.”

In a related development, the American Public Health Association will be holding its 140th Annual Meeting & Expo, October 27-31, 2012, in San Francisco and has scheduled a number of [sessions](#) addressing food marketing to children, policy options for regulators, legislation seeking to limit obesity-related litigation, sodium content, and front-of-package labeling, among other matters.

October 29 sessions include:

- Michele Simon, “Food stamps, follow the money: Are corporations profiting from hungry Americans?”
- Sarah Mart, “Public health and alcohol: Corporate influence on regulation”
- Ruth Malone, “Public health: Becoming a tobacco industry competitor”
- Juliet Sims, et al., “We’re not buying it: An advocacy approach to exposing food marketing to children”
- Elizabeth Taylor Quilliam, et al., “Integrated tactics for marketing food to children: Below the belt and regulation radar”
- Lisa Powell, et al., “Nutritional content of food advertising directed to children on television”
- Kelly Brownell, “The food marketing environment: Barriers and opportunities to action to improve children’s health”
- Kelly Brownell, et al., “What are they thinking? Parents’ attitudes about food marketing to their children”
- Jennifer Pomeranz, “Policy options to regulate food marketing at the local level”
- Samantha Graff, “Policy strategies for improving the nutritional profile of fast food purchases”

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October 30 sessions include:

- Michele Simon and Ryan Treffers, "Control state politics: Is Costco victory in Washington a wake-up call for public health?"
- Tara Ramanathan, "Assessing the use of law on reducing sodium in the food supply"

October 31 sessions include:

- Lainie Rutkow and Jennifer Pomeranz, "Front-of-package labeling, food advertising, and the legal environment"
- Cara Wilking, "Cheeseburger bills: State laws to limit future obesity-related public health litigation."

fMRI Study Claims Youthful Brains Recognize Food Logos

Researchers with the University of Missouri-Kansas City and the University of Kansas Medical Center have [published](#) a study claiming that children's brain scans registered increased activation in the orbitofrontal precortex and inferior prefrontal cortex when the subjects were shown familiar food logos. Amanda Bruce, et al., "Branding and a child's brain: an fMRI study of neural responses to logos," *Social Cognitive and Affective Neuroscience*, September 2012. The study's authors apparently used functional magnetic resonance imaging (fMRI) with 17 healthy-weight children to gauge their neural reactions to 60 food and 60 non-food logos as opposed to a baseline image created to approximate the logos' visual properties of color composition and brightness.

"Food logos compared to baseline were associated with increased activation in orbitofrontal cortex and inferior prefrontal cortex," concluded the report. "Compared to nonfood logos, food logos elicited increased activation in the posterior cingulate cortex. Results confirmed that food logos activate some brain regions in children known to be associated with motivation."

The study's authors urge further investigation into how children respond "at the neural level" to marketing efforts. "Food logos may attract children's attention more than non-food logos," they remarked. "This is significant considering the vast majority of foods marketed to children are for unhealthy, calorically dense foods... However, results from this preliminary study should not be interpreted using reverse inference, but instead used to guide future studies. Researchers should directly compare neural responses to food logos compared to actual images of food."

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Commentary Cites Lack of Evidence Linking HFCS to Obesity Epidemic

A recent commentary published in the *International Journal of Obesity* has dubbed high-fructose corn syrup (HFCS) “one of the most misunderstood ingredients,” arguing that studies linking the sweetener’s use to increasing obesity rates tend to rely on temporal associations, “an ecologic fallacy in which group data are extrapolated to individuals.” D.M. Klurfeld et al., “Lack of evidence for high fructose corn syrup as the cause of the obesity epidemic,” *International Journal of Obesity*, September 2012. In particular, the article’s authors claim that not only did earlier hypotheses fuel misconceptions about “the metabolism and health effects of HFCS,” but more recent research has failed to identify a mechanism by which HFCS affects the body differently than sucrose, “the leading source of fructose in the American diet.” They also note that obesity and diabetes rates have not declined even as HFCS consumption has decreased and that these rates have persisted in areas such as Mexico, Australia and Europe where there is little or no HFCS available.

“While the scientific debate is largely over, the public debate related to HFCS and obesity has, by no means, concluded. There are literally thousands of postings on the Internet related to putative links between HFCS and obesity as well as a variety of other metabolic abnormalities,” conclude the authors, who warn that a similar story is unfolding for sugar-sweetened beverages despite the current state of the literature. “Moreover, a number of manufacturers have yielded to adverse publicity and removed HFCS from their products and replaced it with sucrose despite overwhelming scientific evidence that the two sugars are metabolically equivalent. These sequellae of the initial scientific debate, which persist long after the scientific debate is over, remind us that issues that are important to the public may persist and be misinterpreted long after scientific debate has been concluded.”

BPA Allegedly Linked to Reproductive Abnormalities in Monkeys

A recent study has allegedly linked low doses of bisphenol A (BPA) to reproductive abnormalities in rhesus monkeys. Patricia A. Hunt, et al., “Bisphenol A alters early oogenesis and follicle formation in the fetal ovary of the rhesus monkey,” *Proceedings of the National Academy of Sciences*, September 2012. Seeking to determine whether BPA exposure “could influence [] reproductive longevity and success,” researchers from University of California, Davis, and Washington State University (WSU) sought to approximate human exposure levels by administering BPA to gestating rhesus monkeys via one daily oral dose or a continuous subdermal implant. Their results evidently showed that the egg cell failed to divide properly in both groups of monkeys exposed to BPA, with those in the continuous-dosing group exhibiting further complications in the third trimester as fetal eggs “were not packaged appropriately in follicles, structures in which they develop,” according to a September 24, 2012, WSU press release.

“The concern is exposure to this chemical that we’re all exposed to could increase the risk of miscarriages and the risk of babies born with birth defects like Down Syndrome,” the lead author was quoted as saying. “The really stunning thing about

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the effect is we're dosing grandma, it's crossing the placenta and hitting her developing fetus, and if that fetus is a female, it's changing the likelihood that that female is going to ovulate normal eggs. It's a three-for-one hit."

Study Investigates Dark Side of Chocolate Temptation

A recent animal study has reportedly identified a new mechanism by which the brain increases the desire to overconsume sweet and fatty treats like chocolate. Alexandra DiFeliceantonio, et al., "Enkephalin Surges in Dorsal Neostriatum as a Signal to Eat," *Current Biology*, October 2012. Relying on advanced opioid microdialysis techniques to detect extracellular levels of a neurotransmitter called enkephalin, University of Michigan researchers injected a drug into the neostriatum of rats to stimulate the mu opioid receptors before the animals were permitted to eat M&M candies. The results evidently showed that mu opioid stimulation "potently enhanced consumption of palatable M&M chocolates," with injected rats "more than doubling total M&M intake." In addition, the authors' microdialysis study of the same brain region, which has primarily been linked to movement, purportedly revealed that naturally occurring enkephalin levels "rose to 150% of baseline when the rats were suddenly allowed to eat chocolates."

According to the study, these findings imply that "opioid signals in anteromedial dorsal neostriatum are able to code and cause motivation to consume sensory reward." As the lead author further explained to the press, "This means that the brain has more extensive systems to make individuals want to overconsume rewards than previously thought. It may be one reason why overconsumption is a problem today. The same brain area we tested here is active when obese people see food and when drug addicts see drug scenes. It seems likely that our enkephalin findings in rats mean that this neurotransmitter may drive some forms of overconsumption and addiction in people." See *ScienceDaily*, September 20, 2012.

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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.

