Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Federal Audit Faults FSIS for Failure to Test Mechanically Tenderized Beef for *E. Coli*

A U.S. Department of Agriculture Office of Inspector General **audit report** titled "FSIS *E. coli* Testing of Boxed Beef" concludes that the Food Safety and Inspection Service (FSIS) must reevaluate its *E. coli* testing methodology and "take additional steps to ensure that beef to be ground throughout the production process—from Federally inspected slaughter establishments to local grocery stores—be subject to FSIS sampling and testing for *E. coli*." According to the report, "FSIS is not testing tenderized meat products for *E. coli* despite several recent recalls."

The Kansas City Star noted that the report was issued three months after the newspaper published a series of stories profiling individuals who had apparently been sickened with *E. coli* poisoning after consuming medium-rare, mechanically tenderized steaks in restaurants. The article highlighted that "the process of mechanically blading that meat uses automated needles or knives to tenderize tougher cuts of beef, forcing pathogens into the center," where the bacteria may survive if not adequately cooked. FSIS responded to the Inspector General's recommendations by stating that if it "determines that there is a significant amount of risk associated with the consumption of mechanically tenderized beef products, FSIS will develop a plan with milestones and reasonable timeframes for establishing a sampling and testing program for tenderized products or their components." The agency's risk analysis of tenderized beef is scheduled to be published in April 2013. *See The Kansas City Star*, April 2, 2013.

FSIS Orders Additional "Species Testing" on EU Meat Imports

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) recently issued a **notice** directing import inspectors to increase "species sampling and testing" on products from countries affected by the European Union's ongoing investigation into beef contaminated with horsemeat. According to the new order, FSIS has scheduled "increased species sampling

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for product from Iceland, Ireland, Poland, the United Kingdom, and Northern Ireland via PHIS [Public Health Information System]," but dropped Brazil from the list of those countries requiring special attention from inspectors.

"We are confident that the inspection system at ports of entry ensures the safety of products that come into our country every day," said FSIS spokesperson Catherine Cochran. "However, in response to recent events and consumer concerns, we are increasing species testing to enhance current safeguards and prevent fraudulently labeled products from entering the country." *See Bloomberg,* April 4, 2013.

AMS Issues Draft Guidance on Materials for Organic Crop Production

The U.S. Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) has **announced** the availability of draft guidance concerning (i) "the classification of materials under USDA organic regulations (7 CFR part 205)" and (ii) "materials for use in organic crop production." In particular, the first set of guidance "details the procedures and decision trees for classifying the materials used for organic crop production, livestock production, and handling," while the second set includes "an itemization of allowed natural and synthetic materials and a limited appendix of materials prohibited in organic crop production."

AMS has asked "accredited certifying agents, certified operations, material evaluation programs, and other organic industry stakeholders" to submit comments on these documents through June 3, 2013. The agency will eventually publish the finalized version as part of the National Organic Program's handbook for certifying agents and certified operations. *See Federal Register*, April 2, 2013.

FDA Issues Draft Compliance Policy Guide on Food Facility Registration

The Food and Drug Administration (FDA) has **announced** the availability of "Draft Compliance Policy Guide Sec.100.250 Food Facility Registration—Human and Animal Food" (draft CPG), which aims to "provide guidance for FDA staff regarding enforcement of the food facility registration provisions under a section [415] of the Federal Food, Drug, and Cosmetic Act ." To this end, the draft CPG outlines how FDA plans to implement provisions establishing food facility registration requirements as well as "FDA's authority to suspend a food facility's registration."

According to FDA, the finalized CPG "will replace 'Compliance Policy Guide Sec.110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'" Comments should be submitted by May 6, 2013. *See Federal Register*, April 4, 2013.

California Assembly Bill Would Provide Prop. 65 Safe Harbor

The California Assembly's Environmental Safety and Toxic Materials Committee has scheduled an April 16, 2013, hearing on a bill (**A.B. 227**) intended to give small business owners two weeks to correct a purported violation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65) without incurring any liability under the law.

The measure was introduced by Assemblyman Mike Gatto (D-Silver Lake) at the request of a coffeehouse owner who received a 60-day legal notice after he started serving alcoholic beverages without the requisite Prop. 65 warning to customers about chemicals, such as alcohol, known to the state to pose a cancer or reproductive health risk. If the letter recipient demonstrates to the satisfaction of a city attorney, local district attorney or state attorney general that the violation has been corrected, no further enforcement action could be taken.

As currently drafted, the bill would provide a safe harbor to any recipient of a 60-day Prop. 65 notice letter, although it was apparently intended to protect small business owners. According to a news source, this has raised concerns among consumer advocacy groups that it would apply too broadly and include product manufacturers, giving them an incentive to delay complying with the law immediately. Critics also reportedly complain that the bill would burden prosecutors who would be "inundated on all these sorts of questions" as to whether businesses or other entities have corrected the violation. Still, a number of industry trade groups support the proposal, calling it a "common-sense approach" to Prop. 65 enforcement and claiming that it would protect businesses from "shake-down lawsuits." *See Inside Cal/EPA*, March 28, 2013.

LITIGATION

D.C. Circuit Clarifies When FOIA Requesters May Sue Agencies in Court

The D.C. Circuit Court of Appeals has ruled that the Freedom of Information Act (FOIA) requires federal agencies to issue a determination about what will be produced to or withheld from a FOIA requester within statutory deadlines; a failure to do so is deemed the exhaustion of administrative remedies and allows the requester to bring an action in federal court to compel the production of responsive documents. ***Citizens for Responsibility & Ethics in Wash. v. Fed. Election Comm'n*, No. 12-5004 (D.C. Cir., decided April 2, 2013)**. The Federal Election Commission (FEC) contended that it could simply inform a FOIA requester within the 20-day deadline (or 30 days in "unusual circumstances") that it would produce non-exempt responsive documents and claim exemptions in the future.

According to the court, FEC's interpretation of the statute would allow an agency to "keep FOIA requests bottled up in limbo for months or years on end." FEC claimed that the requester had no basis for bringing an administrative appeal until several months beyond the statutory deadline, when it finally produced records and issued a letter indicating what exemptions would be claimed. The court agreed that the requester had no decision to appeal until the letter issued, "But that fact also necessarily shows that the FEC had not made a 'determination' in March, given that the statute indicates that a 'determination' must be subject to immediate appeal. By arguing that it made a 'determination' in March and simultaneously saying that nothing could be administratively appealed until June, the FEC's position on [the plaintiff's] request amply demonstrates the impermissible Catch-22 it seeks to enshrine in the law."

While acknowledging the burdens on federal agencies of complying with FOIA requests, the court stated, "It is true that the statute does not allow agencies to keep FOIA requests bottled up for months or years on end while avoiding any judicial oversight. But Congress made that decision. If the Executive Branch does not like it or disagrees with Congress's intent, it may so inform Congress and seek new legislation." The court reversed the district court's grant of the commission's motion for summary judgment and remanded for further proceedings.

Plaintiffs Fail to Show HFCS Is Not "All Natural," Class Decertified, Summary Judgment Entered

A federal court in California has decertified and entered summary judgment against a statewide class alleging that AriZona Iced Tea beverages with "All Natural," "100% Natural" and "Natural" labels violated state consumer protection laws because they contain high-fructose corn syrup (HFCS) and citric acid, ingredients alleged by the plaintiffs to be man-made. *Ries v. AriZona Beverages USA LLC*, No. 10-01139 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., decided March 28, 2013). Additional information about this case and similar litigation before a New Jersey court appears in issues **360**, **408** and **463** of this *Update*.

According to the court, the plaintiffs failed to produce any evidence or timely identify any expert who could prove that HFCS and citric acid are not natural. They claimed that they would be able to do so during the "merit state of discovery," but failed to produce such evidence within the court's discovery deadlines. Nor, according to the court, had the plaintiffs produced any evidence from which damages may be assessed.

The plaintiffs apparently asked the court to "take judicial notice of United States Patent law," to determine that HFCS is not natural "because patents have been issued for the process of producing it." Noting that "United States Patent law" is not a proper subject of judicial notice, the court denied the request and further observed, "plaintiffs have cited no legal authority

supporting their contention that if the process to produce an ingredient is patented, that fact, in and of itself, automatically renders it artificial. This is merely an extension of their rhetoric that HFCS is artificial because it 'cannot be grown in a garden or field, it cannot be plucked from a tree, and it cannot be found in the oceans or seas of this planet.' In the face of a motion for summary judgment, rhetoric is no substitute for evidence."

Given that the defendants did not object to the plaintiffs' apparent abandonment of their false labeling theory, the court considered whether the plaintiffs could prove their theory that the product labels are true but still confusing because consumers do not know what "all natural" means. In this regard, the court determined that the plaintiffs could not prevail because they failed to "demonstrate by extrinsic evidence, such as consumer survey evidence, that the challenged statements tend to mislead consumers. . . . They have neither intrinsic evidence that the labels are false (because HFCS and citric acid are not natural) *or* [sic] extrinsic evidence that a significant portion of the consuming public would be confused by them."

As for the plaintiffs' failure to introduce evidence on damages to prove "the difference between the value of an AriZona Iced Tea billed as all-natural and the value of a comparable beverage not marketed or sold at a premium due to such claims," the court ruled that this failure "alone provides an independent and sufficient basis to grant defendants summary judgment." The plaintiffs had not offered "a scintilla of evidence from which a finder of fact could determine the amount of restitution or disgorgement to which plaintiffs might be entitled if this case were to proceed to trial."

Finding that plaintiffs' counsel had been "dilatory" and "failed to prosecute this action adequately," the court was compelled to decertify the class for failure to meet the requirements for adequacy of representation under Rule 23(a)(4).

Federal Court Dismisses Parts of Consumer Fraud Action Against Frito-Lay & PepsiCo

A federal court in California has dismissed in part the first amended complaint in a putative class action against Frito-Lay and PepsiCo, alleging that the companies falsely advertised and labeled their products as "All Natural," "0 Grams Trans Fat," "No MSG," "low sodium," "healthy," and with other unspecified health claims. *Wilson v. Frito-Lay N. Am., Inc.*, No. 12-1586 (U.S. Dist. Ct., N.D. Cal., order entered April 1, 2013). Dismissed with prejudice were claims that the companies breached warranties under the Magnuson-Moss Warranty Act and the Song-Beverly Consumer Warranty Act. Among the claims that the plaintiffs will be allowed to amend are the allegations against PepsiCo, dismissed due to insufficient pleading; allegations involving products not specifically named or described in the complaint; and a claim for restitution based on unjust enrichment, which should have been pleaded in the alternative.

To the extent that the plaintiffs based their unfair, false and deceptive advertising claims on Website statements, the court was not convinced that the Website constitutes labeling under the Food, Drug, and Cosmetic Act, but allowed the plaintiffs to amend their complaint to show how the Website language "explains or supplements the individual Named Products such that the website could generally be found to 'accompany' the Named Products." The court refused to find that the "No MSG" claims were preempted. According to the court, a Food and Drug Administration statement—posted on the agency's Website after the motion to dismiss was filed— interpreting ambiguous MSG labeling regulations was entitled to deference and was binding even though it had not been promulgated with notice-and-comment rulemaking.

The court also refused to dismiss the "0 Grams Trans Fat" claims, distinguishing cases that found them preempted, because the plaintiffs here were not attempting to impose stricter requirements under state law than are imposed under federal law. Regarding the "Made with ALL NATURAL" ingredients labeling on the product packages, the court found that they could mislead consumers, rejecting the defendants' assertion that "the label only states that the product includes some all-natural ingredients, in this case potatoes and natural oil" and that "a reasonable consumer, as a matter of law, would read the statement in that context and sate any further curiosity by reading the nutrition box." The court cited *Williams v. Gerber Products Co.*, 552 F.3d 934 (9th Cir. 2008), for its holding that reasonable consumers should not be "expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box."

Trial Set for Prop. 65 Lawsuit over Lead in Food

According to a news source, trial begins April 8, 2013, in the Environmental Law Foundation's Proposition 65 (Prop. 65) lawsuit against 28 food manufacturers and retailers in a California state court, alleging failure to warn the public that their baby and toddler foods and fruit juices contain lead, a chemical known to the state to cause reproductive toxicity or cancer. *Envtl. Law Found. v. Beech-Nut Nutrition Corp.*, No. 11597384 (Cal. Super. Ct., Alameda Cnty., filed Sept. 28, 2011). Details about the case appear in Issue **412** of this *Update*. The trial will involve the manufacturing defendants and will resolve their affirmative defenses only. Trials over damages issues and claims against the retailers have not apparently been scheduled.

Among the defenses that the court will consider are whether (i) Prop. 65, as applied, is preempted under the Food, Drug, and Cosmetic Act and federal nutrition programs; (ii) exposure to the products' lead levels is sufficiently high to require warnings; and (iii) enough of the lead in the food products is "naturally occurring" and thus exempted from Prop. 65. With few Prop. 65 cases reaching trial, court watchers are reportedly following the matter

closely given its potential impact on other Prop. 65 litigation, particularly cases involving lead exposure. The plaintiff, which frequently files Prop. 65 lawsuits as part of its mission to "improve environmental quality" by enforcing environmental and community right-to-know laws, compiled a **list** of products tested to support the litigation. *See Law360*, April 4, 2013.

Law Firm Announces Filing of 4-MEI Lawsuits Under Prop. 65

A Connecticut-based law firm has filed Proposition 65 (Prop. 65) lawsuits against three companies that make food extracts and flavorings, alleging that they fail to disclose the presence of 4-Methylimidazole (4-MEI), a substance known to California to cause cancer. *Leeman v. Adams Extract & Spice Co., LLC*, No. 13-529493; *Leeman v. McCormick & Co., Inc.*, No. 13-529494; *Leeman v. Farmer Bros. Co.*, No. 13-529495 (Cal. Super. Ct., San Francisco Cnty., filed March 13, 2013). Named plaintiff Whitney Leeman claims to hold a doctorate in environmental engineering and seeks "to promote awareness of exposures to toxic chemicals in products sold in California." She provided 60-day notices of violation to the companies in December 2012 concerning their alleged failure to warn consumers about 4-MEI exposure.

The products specifically named in the complaints are Adams' "Extract Mapel Imitation Maple Flavor," McCormick's "Culinary Imitation Maple Flavor" and "Culinary Caramel Color," and Farmer's "Sierra Brand Premium Products Imitation Maple Flavor." The complaint states that California "identified and listed 4-MEI as a chemical known to cause cancer" on January 7, 2011, and that the defendants have violated Prop. 65 since that time. Information about California's approval of a no significant risk level for 4-MEI appears in Issue **424** of this *Update*. Leeman seeks preliminary and permanent injunctive relief to compel the defendants to provide the warnings and civil penalties of $2,500 per day for each violation. *See Chanler Group Blog Post*, April 2, 2013.

OTHER DEVELOPMENTS

Dietary Supplement Trade Association Issues Caffeine Guidelines

The Council for Responsible Nutrition has issued recommended **guidelines** for dietary supplement products containing caffeine, including energy drink products marketed as supplements.

According to the council, the guidelines expand "its self-regulatory initiatives that encourage best practices within the supplement industry and promote safe use of dietary supplements by consumers." Council President and CEO Steve Mister said, "This is one example of how responsible companies in our industry are taking proactive steps to educate consumers so they can make informed decisions about caffeine-containing supplements, and we trust consumers will be mindful of the amounts of caffeine they are getting from all sources."

The guidelines recommend (i) the disclosure of total caffeine content for products with added caffeine in amounts more than 25 mg per serving, "declared in milligrams per serving either in the Supplement Facts Box or in a separate statement elsewhere on the label"; (ii) advisories for conditions of use, such as statements that products with more than 100 mg of caffeine per serving warn against use by "children and those sensitive to caffeine" and that "pregnant or nursing women, those with a medical condition, and those taking medication should consult a healthcare professional before use"; (iii) labeling information about serving size and daily intake recommendations; and (iv) restraint against marketing caffeinated products "in combination with alcohol, or to counter the acute or immediate effects of alcohol."

According to the council, the guidelines took effect April 1, 2013, and dietary supplement makers are encouraged to comply with the guidelines for new product labels within 12 months. The Food and Drug Administration is currently reviewing the safety of such products. Sen. Dick Durbin (D-Ill.) received a letter from the agency in late 2012 in which it said, "it may be advisable for certain subpopulations, including children and pregnant women, to limit their caffeine consumption." Durbin responded to reports about the new self-regulatory guidelines by stating that they "made sense but still will not protect our children. I feel that energy drink companies need to go further and stop marketing their products to children." *See Council for Responsible Nutrition News Release*, April 3, 2013; *Law360*, April 4, 2013.

NEJM Publishes Commentary on Court's Invalidation of NYC Sugary Drink Limits

The *New England Journal of Medicine* (*NEJM*) has published two "Perspective" articles in its April 3, 2013, issue, commenting on the recent ruling by Judge Milton Tingling overturning the New York City Board of Health's restrictions on the size of sugary drinks sold at certain city establishments—the "Portion Cap Rule." Details about the ruling are included in Issue 475 of this *Update*.

Attorneys Wendy Mariner and George Annas with the Boston University School of Health opine in "**Limiting 'Sugary Drinks' to Reduce Obesity—Who Decides?**" that the court was likely correct in ruling that the Board of Health lacked the authority to adopt the rule given a court of appeals ruling overturning indoor smoking rules after examining "the difficult-to-define line between administrative rulemaking and legislative policymaking." They contend that higher taxes on all soda sales would be a reasonable alternative to the Portion Cap Rule, noting that "[h]igher prices often discourage consumption." Observing that the rules' enactment was widely ridiculed, including by comedian Jon Stewart, the authors conclude, "Agencies that overstep their bounds or adopt rules that are intrusive or just plain silly invite backlash, which can make effective public health regulation impossible. They make fools of themselves and heroes of the opponents of public health."

Meanwhile, Amy Fairchild, a professor of sociomedical sciences at Columbia University, explores in "**Half Empty or Half Full? New York's Soda Rule in Historical Perspective**" the history of public health initiatives that succeeded by focusing on both environmental and social conditions.

According to Fairchild, the city's tenements and neighborhoods were cleaned up in the late 19th and early 20th centuries when "an alliance of public health, labor, social, and housing reformers organized to get garbage, filth, and the accompanying microbes off city streets, out of water supplies, and out of the fetid halls of tenement buildings." They also "sought to confront unfair labor practices, hazardous working conditions, child labor, and 'slave wages' that made the poor as a class susceptible to disease."

The author reports that public health efforts then turned from social reform and industrial regulation to target "the germ" and "individual behavior." She sees this turning point and the "century-old struggle" between effecting change through an alternating focus on individual and corporate behavior "playing out again in the case of the giant-soda ban." While she agrees with Mariner and Annas that a tax on sugary beverages would "effectively limit our individual ability to drink ourselves silly," she characterizes Mayor Michael Bloomberg's initiative as an appropriate focus on corporate behavior. She states, "if Bloomberg is bent on appealing Tingling's ruling, it is time to start making a case with some muscle, which will require strong, active support from the medical and public health communities. If we can challenge the industries and businesses that profit by promoting bloated serving sizes, perhaps we can take on other corporate enterprises that similarly contaminate our social environment."

Coalition Urges USDA to Adopt COOL Rules

A coalition of more than 200 farm, consumer and environmental organizations has written a **letter** urging the U.S. Department of Agriculture (USDA) to support recently proposed changes to U.S. Country of Origin Labeling (COOL) requirements for meat products.

USDA proposed new labeling rules in March 2013 in response to a World Trade Organization (WTO) ruling that the old labels discriminated against imported livestock from other countries. The proposed rules would require that that all meat from animals born, raised and processed in the United States bear a "born, raised and slaughtered in the USA" label.

"The only acceptable way to respond to the WTO challenge is to make labels more informative for consumers, not water them down," states the letter. "U.S. farmers and ranchers are proud of what they produce and should be allowed to promote their products."

"Consumers want more information about the source of their food, not less," said Chris Waldrop, director of the Food Policy Institute at Consumer Federation of America in a news release. "Strengthening the Country of Origin Label provides consumers with more accurate and precise information about the source of beef and pork products they purchase." Additional details about the COOL requirements appear in Issue **475** of the *Update*. *See Consumer Federation of America News Release,* April 2, 2013.

Rudd Center Report Focuses on Children's Food and Beverage Marketing

Yale University's Rudd Center for Food Policy & Obesity has issued a March 2013 **report** highlighting "where children and adolescents viewed the food and beverage advertisements they saw on television in 2011." Using Nielsen data, the Rudd Center apparently sought to quantify "the average number of food and beverage TV ads viewed by age group (ages 2-5, 6-11, 12-14, 15-17) in total and by product category, as well as the channels and programs where these ads appeared."

According to the report, four youth-oriented channels accounted for one-half of food advertising viewed by children, with Viacom's Nickelodeon airing "over one-fourth of the food ads viewed by 2- to 11-year-olds." Overall, 24 percent of these ads evidently featured fast-food restaurants, 12 percent featured cereal, 11 percent featured other restaurants and 11 percent featured candy. In addition, the report noted that "[f]ive programs on the top-ten list of programs where children saw food advertising had a child-audience share of less than 30%, which falls outside the CFBAI [Children's Food and Beverage Advertising Initiative] definition of 'child-directed' advertising."

Based on these findings, the Rudd Center recommends that food companies (i) "expand CFBAI pledges to promote only healthier dietary choices in programming widely viewed by children, including 12- to 14-year olds"; (ii) "expand the definition of children's programming covered by the CFBAI to include programs viewed by large numbers of children, not just programs with a high proportion of children"; and (iii) "discontinue advertising in children's programming viewed by large numbers of children under age 6." The report also urges media companies to take the lead in setting children's food advertising standards. "Given the food industry's apparent reluctance to establish more effective standards to limit unhealthy food advertising to children, media companies could set guidelines that require food and beverage companies (regardless of whether they participate in the CFBAI) to advertise only products that meet meaningful nutrition standards," it concludes.

EC-Funded Research Suggests Approach to Insuring Nanomaterial Production Risk

In a *Nature Nanotechnology* commentary titled "The insurability of nanomaterial product risk," business and scientific researchers funded by the European Commission (EC) propose a framework for the insurance industry to assess risks for purposes of issuing policies that will ensure the "commercial viability and long-term sustainability" of the nanotechnology industry. Noting that Lloyd's of London and large insurers are "paying close attention to developments in the area of nanomaterials," the authors suggest that uncertainty about nanotech risks has led insurance companies to carry this risk on their books, because they have failed to explicitly cover nanotechnology risks in their policies. They recommend that control banding, which rates risks according to exposure and toxicity levels, could provide the means to harness the uncertainties and allow policies to explicitly include nanomaterials. The commentary concludes, "In the absence of effective regulatory controls and a lack of legal clarity, control banding will allow nanoparticle production to be put on a more sustainable footing as the science in this emerging area develops." *See Nature Nanotechnology*, April 2013.

"Fast Food Forward" Stages Second Strike in Six Months

Fast Food Forward has apparently coordinated its second strike in six months as part of its long-term effort to unionize fast-food employees in New York City. According to media sources, hundreds of workers employed by approximately 65 fast-food restaurants throughout New York City walked off the job on April 4, 2013, to show support for Fast Food Forward's latest campaign, which seeks to increase worker wages to $15 per hour. The effort has apparently drawn public support from UnitedNY.org, the Black Institute and the Service Employees International Union, among other organizations.

"What happened in November was a very big thing in terms of seeing whether workers were ready and able to go out and strike and take risks in a way that has not happened in the fast-food industry before," said New York Communities for Change Executive Director Jonathan Westin of Fast Food Forward's previous strike. "A lot of people have been emboldened by what happened last time." Additional details about Fast Food Forward's first strike appear in Issue 463 of this *Update*. *See The New York Times and NPR,* April 4, 2013.

SCIENTIFIC/TECHNICAL ITEMS

Studies Seek to Pinpoint Animal-Human Transmission of Antibiotic-Resistant Infections

A recent study has reportedly used whole genome sequencing (WGS) to retrospectively trace the transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) from animal to human for the first time. Ewan Harrison, et al.,

"Whole genome sequencing identifies zoonotic transmission of MRSA isolates with the novel *mecA* homologue *mecC*," *EMBO Molecular Medicine,* April 2013. According to a March 25, 2013, University of Cambridge press release, U.K. and Danish researchers used WGS to examine two separate cases of MRSA infection in Danish farmers and their animals. The results evidently showed that the MRSA strains under investigation carried the novel *mecC* gene, which allowed researchers to compare the human infections with those found in the livestock and determine that animals were most likely the source of the new strains.

"Having found this new MRSA in both people and animals on the same farm it was likely that it is being transmitted between animals and people. By looking at the single differences in nucleotides, or SNPs, in the DNA sequences of each isolate, it became obvious that in both farms we looked at the human and animal MRSA were almost identical," said the study's lead author. "In one case, the results also clearly showed that the most likely direction of transmission was from animal to human."

According to the authors, their use of WGS not only clarified that MRSA can travel from animal to human—as opposed to the reverse—but raised questions about the use of antibiotics in livestock production. "Our findings demonstrate that the MRSA strains we studied are capable of transmission between animals and humans, which highlights the role of livestock as a potential reservoir of antibiotic resistant bacteria," said one of the researchers.

Meanwhile, former Food and Drug Administration (FDA) Commissioner David Kessler authored a March 27, 2013, op-ed article urging the agency and Congress to implement a comprehensive system for tracking antibiotic use in livestock production. "In 2011, drugmakers sold nearly 30 million pounds of antibiotics for livestock—the largest amount yet recorded and about 80 percent of all reported antibiotic sales that year," writes Kessler. "We don't know much more except that, rather than healing sick animals, these drugs are often fed to animals at low levels to make them grow faster."

In particular, Kessler supports two recently proposed bills—the Animal Drug User Fee Act and the Delivering Antimicrobial Transparency in Animals Act—that would empower FDA to collect and disclose data about the distribution of animal drugs and how food producers are using those drugs in their daily operations. Opining that "we have more than enough scientific evidence to justify curbing the rampant use of antibiotics for livestock," Kessler notes that combating resistance will require FDA to track "both the prevalence of antibiotic-resistance bacteria in our food, as well as the use of antibiotics in our livestock."

"Why are lawmakers so reluctant to find out how 80 percent of our antibiotics are used?," he asks. "We cannot avoid tough questions because we're afraid of the answers. Lawmakers must let the public know how the drugs they need to stay well are being used to produce cheaper meat."

Energy Drink Maker Commissions Scientific White Paper on Ingredient Safety

Las Vegas, Nevada-based Rockstar, Inc. recently released a "scientific white paper" prepared for the energy drink maker by Intertek Cantox. Signed by University of Kansas Medical Center Department of Pharmacology Professor John Doull, a member of an "Expert Panel convened to evaluate the conditions of use of caffeine in Rockstar products," the paper reviews scientific literature on the purported health effects of caffeine in adults and youths, and concludes that the estimated daily dietary intakes of the caffeine in Rockstar energy drinks is safe and generally recognized as safe (GRAS) "based on scientific procedures." The paper also reviews literature on other ingredients, including guarana extract, taurine, milk thistle extract, and ginseng extract, and reports that "the Expert Panel unanimously concluded" that these ingredients are also safe and GRAS.

Among other matters, the paper further notes that (i) there is no apparent basis for the claim that the American Academy of Pediatrics recommends no more than 100 mg of caffeine per day for adolescents; (ii) Rockstar energy drink beverages, with up to 240 mg of caffeine per 16-ounce can, contain less caffeine than certain Starbucks coffee products; and (iii) "[a]dverse event reports do not establish a cause and effect relationship, and the number of such reports for Rockstar is very low in comparison to retail sales of approximately 3 billion cans of Rockstar energy drink products in the USA since Rockstar brand inception in 2001."

As to the adverse event reports, the paper contends that more than one-half of the reports compiled by the SAMHSA Drug Abuse Warning Network of hospital visits allegedly associated with energy drinks among patients aged 18 to 25 also involved drug or alcohol use with the energy drinks. Any reported deaths, none of which has apparently been linked to a Rockstar product, purportedly involved confounders, such as suicide, falls and pneumonia. The paper also notes that the filing of such a report "is not sufficient to prove cause and effect." Details about the SAMHSA research appear in Issue 467 of this *Update*.

Details about the letters sent by two U.S. senators to energy drink makers taking them to task for marketing to children and adolescents appear in Issue 477 of this *Update*.

Harvard Study Links Walnut Consumption to Reduced Risk of Type 2 Diabetes

A recent study has reportedly found that "frequent intake of walnuts was associated with a lower risk of incident type 2 diabetes in women." An Pan, at al., "Walnut Consumption is Associated with Lower Risk of Type 2 Diabetes in Women," *Journal of Nutrition,* February 2013. Scientists at the Harvard School of Public Health apparently tracked nearly 140,000 nurses (from the Nurses' Health Study) aged 35 to 77 during a 10-year period to determine how many

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developed type 2 diabetes—which comprises "90 percent of all diabetes cases"—concluding that compared to those who rarely or never ate them, (i) women who consumed a serving (28g) of walnuts at least twice a week reduced the risk of type 2 diabetes by 24 percent; (ii) women who consumed a serving of walnuts at least once a week reduced the risk of type 2 diabetes by 13 percent; and (iii) women who consumed a serving of walnuts one to three times a month reduced the risk of type 2 diabetes by 4 percent.

Compared with other nuts, the study notes, "walnuts are unique because they are rich in PUFAs [polyunsaturated fats] . . . and because of their fatty acid composition, [they] increase circulating concentrations of PUFAs, particularly linolenic acid and *α*-linolenic acid, which may favorably influence insulin resistance."

OFFICE LOCATIONS

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