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LEGISLATION, REGULATIONS AND STANDARDS

FDA Seeks Comments on FSMA Amendments

The U.S. Food and Drug Administration (FDA) has <u>issued</u> an advance notice of proposed rulemaking under the Food Safety Modernization Act (FSMA) that seeks information to help the agency "implement and enforce" amendments to the reportable food registry (RFR) provisions of the Federal Food, Drug, and Cosmetic Act. Among other things, the new provisions permit FDA to (i) require that parties submit to FDA "consumer-oriented" information regarding certain reportable foods—defined as foods for "which there is a reasonable probability that use of, or exposure to, such food will cause serious adverse health consequences or death to humans or animals"; (ii) use such information to create consumer notification summaries for the agency's Website; and (iii) obligate certain grocery stores that sell reportable food to display the notification summaries.

FDA has requested input from the food industry, consumer organizations and other parties on certain topics, including (i) "what information should be required in consumer notifications so that consumers can determine whether a food in their possession is a reportable food"; (ii) "the format in which the information should be presented"; (iii) what types of retail establishments should be considered "grocery stores" subject to the consumer notification requirements; (iv) the impact on grocery stores from posting the information; and (v) whether FDA should require industry to submit consumer-oriented information for foods that will not be sold in retail stores. Comments will be accepted through June 9, 2014. *See Federal Register*, March 26, 2014.

FDA Secures Strong Response on Reducing Antibiotic Use in Animal Husbandry

The U.S. Food and Drug Administration (FDA) has <u>secured</u> the participation of all but one animal drug company in the agency's plan to phase out the use of medically important antimicrobials in food animals for food production purposes, such as artificial weight gain. Each company has "committed in writing to seek withdrawal of approvals for any production uses of affected drug applications and change the remaining therapeutic uses of their products from over-the-counter (OTC) to use by Veterinary Feed Directive (VFD) or prescription." See FDA News Release, March 26, 2014.



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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.

Upcoming Codex Meeting to Address Pesticide Residues

The U.S. Department of Agriculture's Food Safety and Inspection Service and the U.S Environmental Protection Agency have announced an April 10, 2014, public meeting in Arlington, Virginia, to provide information and receive public comments on agenda items and draft U.S. positions for discussion during the 46th Session of the Codex Committee on Pesticide Residues of the Codex Alimentarius Commission in Hong Kong, China, on May 5-17, 2014.

Agenda items include (i) revision to the Codex classification of food and feed for step 6-selected vegetable commodity groups (roots and tubers); (ii) draft discussion paper on guidance for setting maximum residue limits (MRLs) for pesticides for minor uses and specialty crops; (iii) revision of the committee's risk analysis principles on pesticide residues; (iv) priority list for establishing MRLs for pesticides; and (v) guidance for assessing pesticide residue analysis methods. See Federal Register, March 26, 2014.

French Senate Report Calls for Junk-Food Tax

A French Senate committee has issued a report, "Taxation and Public Health: Evaluation of Behavioral Taxation," urging lawmakers to implement a "behavioral tax" to counteract poor dietary habits and help cover health care expenditures associated with consumption of "unhealthy" foods. While emphasizing the need for a sugar-sweetened beverage tax, the report also advocates harmonizing tax rates on vegetable oils, aligning cigarette and other tobacco product taxes, and repealing value-added tax breaks for certain foods and drinks linked to increased health care costs. See Tax-News.com, March 20, 2014.

OEHHA Adds Methyl Isobutyl Ketone to Prop. 65 List of Reproductive Toxicants

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has added methyl isobutyl ketone to the list of chemicals known to the state to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). The chemical is used as a solvent for vinyl, epoxy, acrylic and natural resins, and as a synthetic flavoring adjuvant and a fruit flavoring. According to OEHHA, the listing is based on the authoritative body listing mechanism because the U.S. Environmental Protection Agency has identified it as a chemical that causes reproductive toxicity. The listing is effective March 28, 2014, and will require exposure warnings to consumers. See OEHHA News Release, March 28, 2014.



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LITIGATION

D.C. Circuit Upholds COOL Regulations in Preliminary Injunction Context

The D.C. Circuit Court of Appeals has affirmed a lower court ruling denying the motion for preliminary injunction filed by meat producer interests in litigation challenging U.S. Department of Agriculture (USDA) regulations requiring retailers of "muscle cuts" of meat to list the countries of origin and production (country-of-origin labeling or COOL) as to each step of production—born, raised or slaughtered. <u>Am. Meat Inst. v. USDA</u>, No. 13-5281 (D.C. <u>Cir., decided March 28, 2014</u>).

The regulations at issue were adopted in 2013 in response to a World Trade Organization (WTO) ruling finding their predecessor to violate the WTO Agreement on Technical Barriers to Trade. They "increased the required level of precision" to address each production step and also "eliminated the special allowance for commingled meat." The plaintiffs argued that the amended rules ban commingling and thus alter "production practices over which the COOL statute gives the Secretary no authority," and that the "production-step labeling is both outside of and contrary to the plain language of the COOL statute."

According to the court, the 2013 regulations do "not actually ban any element of the production process," rather they "require[] that meat cuts be accurately labeled with the three phases of production named in the statute. It appears that under current practices meat packers cannot achieve that degree of accuracy with commingled production" and this may be costly for the packers. Still the rules do not "force the segregated handling of animals with varying geographical histories," except in the sense that compliance with any regulation may induce changes in unregulated production techniques that a profit-seeking producer would not otherwise make." The court concluded that USDA's interpretation of the statute was reasonable and thus entitled to be upheld.

The court also rejected the plaintiffs' First Amendment compelled speech claims, distinguishing their concerns from cases involving disclosures of hormone treatment (rBST) of dairy cows. In this regard, the court stated, "Although the government later seeks to justify the COOL requirements as possibly reassuring to consumers who are anxious about potentially lax foreign practices, it seems a good deal less likely that consumers would draw negative hints from COOL information than from the required declarations about use of rBST....[T]he appearance of countries of origin on packages of meat seems susceptible to quite benign inferences, including simply that the retailers take pride in identifying the source of their products."



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Finding that the labeling "enables a consumer to apply patriotic or protectionist criteria in the choice of meat[, and] it enables one who believes that United States practices and regulation are better at assuring food safety than those of other countries, or indeed the reverse, to act on that premise," the court ruled that these goals were not "so trivial or misguided as to fall below the threshold needed to justify the 'minimal' intrusion on [the plaintiffs'] First Amendment interests." The court concluded that the plaintiffs had failed to show a likelihood of success on the merits.

Court Decertifies Consumer Fraud Class in POM Wonderful MDL

A federal multidistrict litigation (MDL) court in California has granted POM Wonderful's motion to decertify a class of claimants alleging that they were misled by health-benefit representations for the company's pomegranate juice. *In re POM Wonderful LLC Mktg. & Sales Practices Litig.*, MDL No. 2199 (U.S. Dist. Ct., C.D. Cal., order entered March 25, 2014). Details about the motion appear in Issue <u>516</u> of this *Update*. According to a news source, the court found that (i) the plaintiffs' two damages models failed to support a class action, and (ii) claims that consumers allegedly paid an inflated price for the company's juice failed to explain how the company's health-benefit representations caused damage.

As to the practical effects of proceeding as a class action, the court reportedly stated, "Here, Plaintiffs acknowledge that, based on the volume of product sold, every adult in the United States is a potential class member. These millions of consumers paid only a few dollars per bottle, and likely made their purchases for a variety of reasons. No bottle, label, or package included any of the alleged misrepresentations. Few, if any, consumers are likely to have retained receipts during the class period, which closed years before the filing of this action." Thus, "there is no way to reliably determine who purchased Defendant's products or when they did so." *See The National Law Journal*, March 25, 2014.

Court Dismisses Claim for Injunctive Relief Against Yogurt Maker

While a federal court in California has dismissed a request for injunctive relief in a consumer fraud action against Wallaby Yogurt Co. for lack of standing, it will allow the first amended complaint's remaining claims to proceed. *Morgan v. Wallaby Yogurt Co., Inc.,* No. 13-0296 (U.S. Dist. Ct., N.D. Cal., order entered March 13, 2014). Additional details about the court's ruling on the plaintiff's original complaint appear in Issue <u>500</u> of this *Update*.

As to the request for prospective injunctive relief, the court agreed with the defendant that the plaintiffs will not be deceived as to future product purchases because they now know that "evaporated cane juice" is added sugar. So ruling, the court acknowledged a split among the district courts



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in the circuit on this issue. The court also expressly disagreed with *Kane v. Chobani, Inc.*, No. 12-2425 (N.D. Cal. Sept. 19, 2013), to the extent that the court (i) found that the plaintiffs lacked standing because they could not plausibly allege that they relied on the term "evaporated cane juice" due to their failure to allege what they believed the substance to be "if not a form of sugar"; and (ii) determined that consumers are not likely to be deceived into consuming unwanted sugar when the name of an ingredient "discloses that it is derived from cane."

The court here found that (i) the plaintiffs have standing because it is plausible that a reasonable consumer, concerned about consuming added sugar, does not realize that "evaporated cane juice" is added sugar; and (ii) the plaintiffs had sufficiently pleaded a violation of the "fraudulent" prong of the Unfair Competition Law because they "do not need to identify what they believed evaporated cane juice to be if not sugar, or what other forms of cane there are besides sugar cane. There is no need for the plaintiffs to have any understanding of 'evaporated cane juice' at all—it is sufficient to plead that they did not think, and a reasonable consumer would not know, that it was really just added sugar."

No Class Certification in Labor Code Suit Against Starbucks

A federal court in California has refused to certify four classes of Starbucks employees in litigation alleging that its rest break policy and scheduling practices, and meal period policy and practices violated the state's Labor Code and Unfair Competition Law. *Cummings v. Starbucks Corp.*, No. 12-6345 (U.S. Dist. Ct., C.D. Cal., decided March 24, 2014).

As to the proposed meal break class, the court found that the plaintiff's "second theory of liability—that Starbucks had a practice of failing to provide timely meal breaks—does not present a common question of law" because "there is no common answer as to why employees took a late meal break, and individualized inquiries into each late meal break would be required." The court also found as to this proposed class that the plaintiff's claims did not meet the typicality requirement because her alleged late meal break claims were due not to a defective policy, but "because of unique circumstances in the store."

Regarding the predominance requirement, the court found "conflicting case law as to whether Starbucks's liability can result solely from its unlawful policy, as the California Court of Appeal cases suggest, or whether liability results from the actual failure to provide a rest break, as the [federal] district court cases suggest." The unlawful policy was the company's apparent failure to include certain language—"or major fraction thereof"—in its policy as required under California law. Relying on Ninth Circuit precedent which applied the reasoning from the state law cases but noted that "it is an



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abuse of discretion for the district court to rely on uniform policies 'to the near exclusion of other relevant factors touching on predominance," the court acknowledged the "possibility that the predominance requirement may not be met, despite the existence of a facially defective policy." In this regard, the court found that the evidence "does not indicate that Starbucks's facially defective rest period policy was consistently applied to deprive class members of a second rest period." Thus the court found the plaintiff's rest break claims not amenable to class certification because they did not satisfy the predominance requirement.

Because the Unfair Competition Law claims were derivative of the Labor Code claims, the court also found this class not amenable to class certification.

ECJ-Tea Lawsuit Removed to Federal Court

The defendant in litigation alleging that it conceals the sugar added to its tea-like yerba mate products by listing the ingredient as "organic evaporated cane juice" has removed the action to federal court. *Cowan v. Guayaki Sustainable Rainforest Prods., Inc.*, No. 14-1248 (U.S. Dist. Ct., N.D. Cal., removed March 17, 2014). The plaintiff, a California resident with a family history of diabetes, alleges that she purchased the products relying on the ingredients listed on the product labels and paid more for them "because she believed the Class Products contained lesser amounts of sugar and was [sic] healthier for her" than comparable products.

Seeking to represent a nationwide class of consumers, the plaintiff claims that Guayaki releases misbranded products into the stream of commerce and that the company violates the Unfair Business Practices Act, California False Advertising Act and Consumers Legal Remedies Act. She also brings causes of action for negligent misrepresentation and breach of quasi-contract. In addition to restitution and punitive and statutory damages, the plaintiff requests an order declaring the product labels unlawful, and requiring the company to change its product packaging and engage in corrective advertising.

Challenges to Ag-Gag Bills on the Dockets in Idaho and Utah

The University of Denver law professors who filed a challenge to Utah's law barring audio or video recordings of purported animal abuse in agricultural operations have filed a second challenge to a similar law that recently took effect in Idaho. *Animal Legal Def. Fund v. Otter*, No. 14-0104 (U.S. Dist. Ct., D. Idaho, filed March 17, 2014). Both lawsuits challenge the so-called "ag-gag" laws on constitutional grounds. Utah's attorney general has requested that the lawsuit filed in that state in 2013 be dismissed on standing grounds; the issue will be argued on May 15.

Filed against the governor on behalf of animal rights organizations, the American Civil Liberties Union, Center for Food Safety, journalists, historians,



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and an "agricultural investigations expert," the Idaho lawsuit contends that the statute "defines 'agricultural production facility' so broadly" that it would apply to "public parks, restaurants, nursing homes, grocery stores, pet stores, and virtually every public accommodation and private residence in the state." The plaintiffs claim that the law, which has not yet been used to charge anyone, (i) "criminalizes efforts to document criminal behavior in a workplace"; (ii) "limits speech in the form of sound and image production, and it does so in a content-based manner"; (iii) was intended to "punish animal rights groups and curtail a form of political speech of great public interest"; and (iv) "renders impossible the creation of non-industry-approved speech about matters of great public importance."

The plaintiffs seek declaratory and injunctive relief, alleging causes of action sounding in First Amendment overbreadth and content and viewpoint-based discrimination; Supremacy Clause preemption under the False Claims Act, Food Safety Modernization Act and Clean Water Act; and Fourteenth Amendment equal protection and due process.

Putative Class Claims Vinegar Not "All Natural"

A California resident has filed a putative statewide class action against H.J. Heinz Co. alleging that its Distilled White Vinegar is falsely advertised as "all natural" because it is made with genetically modified (GM) crops. *Banafsheha v. H.J. Heinz Co.*, No. 14-2023 (U.S. Dist. Ct., C.D. Cal., filed March 17, 2014).

Alleging that she paid more for the product due to the "all natural" labeling and would not have purchased the product had she known that it contains GM ingredients, the plaintiff claims, "Over 70% of U.S. corn crops are GM. Defendant sources its ingredients from U.S. commodity suppliers who supply GM crops. Large volume food manufacturers who wish to use non-GM ingredients must specifically source their crops, typically from Europe, or undertake the additional step and expense of verifying the supply from non-GM growers through identity preservation programs. In most instances, manufacturers who purchase only non-GM crops for their products specifically label the products 'non-GMO."

Alleging violations of California's Consumers Legal Remedies Act, Unfair Competition Law and False Advertising Law, and breach of express warranty, the plaintiff seeks actual, punitive and statutory damages; injunctive relief; attorney's fees; costs; and interest.

Four Loko Maker Settles AG Claims

According to New York Attorney General (AG) Eric Schneiderman, Phusion Projects, LLC, the company that makes Four Loko flavored malt beverages, has agreed to settle allegations by 20 attorneys general and the San Francisco city attorney that the company marketed and sold its products in violation



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of consumer protection and trade practice statutes. *In re Investigation by Eric T. Schneiderman, N.Y. AG of Phusion Projects, LLC*, No. AOD 14-075 (N.Y. AG, Bureau of Consumer Frauds & Protection, March 25, 2014).

Without admitting any liability, the company has agreed not to (i) promote the misuse of alcohol or mixing flavored malt beverages with caffeinated products; (ii) manufacture, market, sell, or distribute any caffeinated alcohol beverages; (iii) provide materials to wholesalers, distributors or retailers promoting mixing flavored malt beverages with caffeinated products; (iv) sell, distribute or promote alcohol beverages to underage persons or hire underage persons to promote these products; (v) use college-related logos to promote its products; or (vi) use Santa Claus in its promotional materials. The company also agreed to monitor social media and remove any postings depicting the consumption of caffeinated alcohol beverages or condoning the misuse of alcohol.

The company will pay \$400,000 to cover attorney's fees, costs and consumer education programs or for other purposes at the AG and city attorney's discretion. *See AG Eric Schneiderman Press Release*, March 25, 2014.

OTHER DEVELOPMENTS

Consumer Reports Finds 4-MEI in Pancake Syrups

Following up its testing of soft drinks for the caramel-coloring ingredient 4-methylimidazole (4-MEI) by testing for its presence in pancake syrups, *Consumer Reports* tested several products, including pure maple syrup which had just 0.7 micrograms in a one-quarter cup serving, and found relatively low levels in light of the amount of syrup generally consumed in the United States. Still, because 4 percent of children between the ages of 1 and 5 consume pancake syrup daily, *Consumer Reports* claims "the [cancer] risk would be 10 times higher than negligible, or one excess case of cancer in 100,000 people who ate that amount daily over a lifetime, that's the point where risk becomes significant." Because some syrups tested had little 4-MEI, *Consumer Reports* concludes that manufacturers that use caramel color can minimize the 4-MEI levels in their products and will urge the U.S. Food and Drug Administration "to set standards for 4-MEI in foods." It also calls for companies to disclose the types of caramel color they use, so that consumers can avoid 4-MEI. *See Consumer Reports*, May 2014.

Roosevelt House to Host Book Release Event Focused on Corporations and Public Health

The Roosevelt House Public Policy Institute at Hunter College has announced an April 8, 2014, event touting the release of *Lethal But Legal: Corporations, Consumption and Protecting Public Health* by City University of New York's School of Public Health Professor Nicholas Freudenberg. Moderated by former New York City Department of Health and Mental Hygiene Commissioner Thomas Farley, the



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conversation with Freudenberg and Brooklyn Food Coalition's Nancy Romer "will examine the ways in which corporations have affected public health over the last century, and the long-term impact of corporate influence on public health in industrialized countries and now in developing regions." Additional details about Freudenberg's new book appear in Issue <u>515</u> of this *Update*.

Incomplete Products Linked to Increased Consumption

The University of Pennsylvania Wharton School of Business recently interviewed Marketing Professor and Jay H. Baker Retailing Center Director Barbara Kahn about her research on food consumption habits for the March 20, 2014, edition of its Knowledge@Wharton series. Describing how product shape and size affect consumer perception, Kahn noted that individuals will eat more of a particular food item if they perceive it as "incomplete," that is, if the product is broken into pieces or presented with holes in it. A study co-authored by Kahn and published in the America Marketing Association's *Journal of Marketing Research* apparently supported these findings, suggesting that consumers "overweight the completeness" of a product in their decision-making process.

"[P]eople are not normative decision-makers," explained Kahn. "They don't eat what they think they need to eat to feel full. They eat what they perceive is the right amount, and they use these implicit rules for deciding how much to eat."

In addition, Kahn has investigated the impact of visual and verbal displays on consumer choice, including the best ways to present a wide variety of products to shoppers. "We do show that you can manipulate what the expectation is, and change people's behavior," she concluded, pointing to a study in which consumers were offered rolls and cheeses with holes in them. "When we called it a roll or cheese, people thought the ones with the holes were less compete. They tended to consume more of the holey bread. On the other hand, if we set the expectation that it was a bagel, or that it was Swiss cheese, their thought was: 'A whole bagel has a hole in it.' That reversed the findings."

UK Campaign Calls for Extended Junk-Food Ad Ban

A recent analysis conducted by University of Liverpool researchers and commissioned by the campaign group Action on Junk Food Marketing has suggested that children in the United Kingdom are "bombarded" with as many as 11 junk-food advertisements during one hour of prime-time, family-oriented TV. Noting that almost one out of four TV ads shown between 8 and 9 p.m. promote unhealthy supermarket products, fast food, candy, and chocolate, the advocacy group, which includes the Children's Food Campaign and British Heart Foundation, also observed that one-third of the ads conclude by showing a Website or a Twitter hashtag—a reportedly popular way of targeting teenagers. Campaigners have asked the government to ban junk-food ads until after 9 p.m. and establish rules to prohibit Internet marketing. *See BBC.com*, March 20, 2014.



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SCIENTIFIC/TECHNICAL ITEMS

BMJ Examines Fast Food and Obesity

The *British Medical Journal* (BMJ) recently published two research articles related to fast food and obesity, including a study claiming that "individuals who are genetically predisposed to obesity may be more susceptible to the adverse effects of eating fried foods." Qibin Qi, et al., "Fried food consumption, genetic risk, and body mass index: gene-diet interaction in three US cohort studies," *BMJ*, March 2014. Relying on food consumption data from three cohort studies involving 37,000 men and women, researchers with the Harvard School of Public Health, Brigham and Women's Hospital and Harvard Medical School also assigned participants "a genetic risk score based on 32 known genetic variants associated with BMI and obesity." The results evidently showed that "eating fried food more than four times a week had twice the effect on BMI for those in the highest third of genetic risk as those in the lowest third."

"This work provides formal proof of interaction between a combined genetic risk score and environment in obesity," explains a concurrent editorial, which notes that the public health implications of the study are most applicable to those individuals with undiagnosed inherited forms of obesity. "There is a danger that issues surrounding blame and 'personal responsibility' in obesity might lead to lack of appropriate support for extremely obese people, who often have complex care needs... In summary, use of combined genetic risk scores in gene-environment interaction studies allows joint analysis of factors influencing obesity."

Meanwhile, the second study has purportedly concluded that "exposure to takeaway food outlets in home, work, and commuting environments combined was associated with marginally higher consumption of takeaway food, greater body mass index, and greater odds of obesity." Thomas Burgoine, et al., "Associations between exposure to takeaway food outlets, takeaway food consumption, and body weight in Cambridgeshire, UK: population based, cross sectional study," *BMJ*, March 2014. Using the Fenland Study of 5,442 working adults to estimate exposure to and consumption of foods such as hamburgers, pizza, fried food, and chips, University of Cambridge scientists reportedly "found evidence of an environmental contribution to the consumption of takeaway food and body mass index in all exposure domains studied," observing the "strongest and most significant environmental associations when combining the exposures at home, at work and along commuting routes."

As a Columbia University senior research scientist further editorialized, "Instead of restricting takeaway food, we should seek to transform it. Healthy takeaway food should not only be available, it should be as visible, tasty, and cheap as unhealthy food. Healthy eating should, in fact, be the default option... To affect public health, food policy must go beyond action that promotes some types



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of outlets and curbs others. In the food environment, what matters is the menu—what food is offered, at what price—not the venue." *See BMJ Editorial,* March 19, 2014.

Study Claims High Sodium Intake Accelerates Cellular Aging in Overweight Teens

A research abstract presented at the American Heart Association's (AHA's) Epidemiology and Prevention/Nutrition, Physical Activity and Metabolism Scientific Sessions 2014 has claimed that "overweight or obese teenagers who eat lots of salty foods may show signs of fast cell aging." According to a March 20, 2014, AHA press release, researchers with the Medical College of Georgia at Georgia Regents University analyzed the telomere-to-single-copygene ratios of 766 participants ages 14-18 who were divided into two groups representing low-sodium intake (an average of 2,388 mg/day) and high sodium intake (an average of 4,142 mg/day). The abstract's authors noted that overweight and obese teens in the high-intake group had telomeres "that were significantly shorter" than the telomeres of normal weight teens in the same intake group.

"Even in these relatively healthy young people, we can already see the effect of high sodium intake, suggesting that high sodium intake and obesity may act synergistically to accelerate cellular aging," one study author was quoted as saying. "Lowering sodium intake, especially if you are overweight or obese, may slow down the cellular aging process that plays an important role in the development of heart disease."

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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.





