

FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Public Citizen Legal Team Veteran to Head FTC Bureau of Consumer Protection

Federal Trade Commission (FTC) Chair Jon Leibowitz has reportedly named David Vladeck as director of the commission's Bureau of Consumer Protection. Vladeck, who leaves the Georgetown University Law Center faculty, is apparently a 30-year veteran of the Public Citizen Litigation Group and, as such, is expected to pursue a consumer-protection agenda. Representatives of other public advocacy organizations are applauding the selection and have expressed their hope that "he will pay special attention to advertising and marketing to children."

Vladeck co-authored a [law review article](#) with former Food and Drug Administration Commissioner David Kessler to criticize the preamble to the FDA's 2006 prescription drug labeling rule, which set forth a pro-preemption policy. In the article, titled "A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims," the authors conclude, "it would be a mistake to preempt state-law failure-to-warn cases, which impose a complementary discipline on the marketplace." See *Advertising Age* and *FTC Press Release*, April 14, 2009.

USDA to Host Meeting on Proposed Rule Regarding GE Organisms

The U.S. Department of Agriculture's (USDA) Animal Plant Health Inspection Service has [announced](#) a public meeting on April 29 and 30, 2009, in Riverdale, Maryland, to address a proposed rule involving the interstate movement and environmental release of certain genetically engineered (GE) organisms. The comment period on the proposed rule has been extended to June 29, 2009. See *Federal Register*, April 13, 2009.

USDA, HHS Announce Third Meeting Regarding Updated Dietary Guidelines

The U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) have [announced](#) the third meeting of the Dietary Guidelines Advisory Committee charged with revising the *Dietary Guidelines for Americans 2005*. Slated for April 29 and 30, 2009, the online meeting will include (i) presentations on topics such as "eating environment, economics, nutrient adequacy, and effects of various macronutrient meal plans on weight status"; (ii) progress updates

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from individual subcommittees; and (iii) plans for future work of the committee. Written comments pertinent to this meeting must be received by 5 p.m. on April 23, although comments will be accepted throughout the committee's deliberation process. *See Federal Register*, April 14, 2009.

USDA Announces Meeting on Codex Agenda Targeting Veterinary Drug Residues

The Office of the Acting Deputy Undersecretary for Food Safety, U.S. Department of Agriculture and U.S. Food and Drug Administration have [announced](#) a public meeting on April 29, 2009, to discuss draft U.S. positions for the 18th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) slated for May 11-15, 2009, in Natal, Brazil. CCRVDF works to (i) establish "priorities for the consideration of residues of veterinary drugs in foods"; (ii) "recommend maximum levels of such substances"; (iii) "develop codes of practice as may be required"; and (iv) consider methods of sampling and analysis for the determination of veterinary drug residues in foods."

The session will include agenda items related to (i) the "registration of veterinary medicinal products"; (ii) "draft guidelines for the design and implementation of national regulatory food safety assurance programs"; and (iii) a "draft priority list of veterinary drugs requiring evaluation or reevaluation." *See Federal Register*, April 10, 2009.

FTC Considers Holding Paid Web Bloggers Liable for False Brand Claims

The Federal Trade Commission (FTC) has apparently proposed amending its advertising guidelines to hold companies and paid word-of-mouth marketers, including bloggers and those on social networking sites, liable for making false statements to promote products. According to an FTC spokesperson, the proposal would bring the commission up to speed with evolving marketing practices. "The commission is attempting to update guidelines that are 30 years old so that they address current marketing techniques and in particular to address the issue of whether or not the safe harbor that's currently allowed for 'result not typical'-type disclaimers is still warranted," he was quoted as saying.

Meanwhile, a public comment submitted by the American Association of Advertising Agencies has reportedly urged FTC to reconsider "overly stringent amendments that will likely result in advertisers abandoning longstanding legitimate advertising techniques, such as consumer testimonials, and rejecting new media forms, such as blogs and viral marketing." The commission will vote on the revisions this summer after reviewing public comments. *See Advertising Age*, April 13, 2009.

Groups to Focus on Food Safety Implications of Nanotechnology

The United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO) has announced a joint expert [meeting](#) titled Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, to be held June 1-5, 2009, in Rome, Italy. The gathering will reportedly

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address the potential food safety risks that may arise from nanoparticles, particularly in the areas of (i) nanotechnology applications in plant and animal food production; and (ii) nanotechnology applications in food processing, packaging and distribution.

Health Canada Expected to Declare BPA Hazardous to Human Health

According to a news source, Health Canada is about to become the first country to formally place bisphenol A (BPA) on its toxic substances list and prohibit its use in baby bottles. An official announcement in the *Canada Gazette* is reportedly imminent, although nothing on the government agency's Web site confirms this report. Health Minister Tony Clement said in 2008 that the government planned to take such action, calling the move "precautionary and prudent." See *Canada.com*, April 14, 2009.

Meanwhile, a legislative committee in Connecticut has apparently approved a bill (Raised Bill No. 6572) that would prohibit BPA's use in products for children younger than age 3, such as baby bottles, infant formula cans and spill-proof cups, as well as in reusable food or beverage containers, beginning in October 2009. Jars, cans, bottles, or other food product containers could not contain BPA after October 2012. While the proposal still faces approval by the full General Assembly and the state's governor, it passed unanimously in committee. According to the bill's sponsor, Representative Beth Bye (D), "Our first worry was about babies, because bisphenol A is found in the highest proportions in the youngest children." See *Greenwire*, April 15, 2009.

In a related development, an international consortium of scientists has reportedly rejected as incomplete and unreliable the Food and Drug Administration's (FDA's) assertion that BPA is safe. According to a news source, nearly 60 industry, academic and government scientists, who met recently in Germany to discuss the issue, plan to release a consensus statement in coming weeks. They were apparently critical of the two studies that FDA relied on to declare the chemical safe and are expected to call for a broader look at the scientific literature. A Tufts University developmental biologist was quoted as saying, "The FDA's standard is reasonable certainty. It is no longer reasonable to say that BPA is safe." The group also reportedly questioned the European Food Safety Authority's BPA assessment. See *JS (Journal Sentinel) Online*, April 11, 2009.

Prop. 65 Public Comment Period Extended for Chemical Found in Cooked Wines and Sauces

California's Office of Environmental Health Hazard Assessment (OEHHA) has [extended](#) the deadline for public comment on its notice of intent to list 4-methylimidazole (4-MEI) as a chemical known to the state to cause cancer under Proposition 65 (Prop. 65). The new deadline is May 29, 2009.

According to a news source, the proposed intent to list has generated significant opposition from grocers and other food industry representatives who argue that the chemical, which is found in foods such as wine, soy sauce and Worcestershire sauce

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after cooking, “is just the latest in a series of near-ubiquitous chemicals created as an unavoidable consequence of heating the natural constituents of foods.” Once a chemical is listed under Prop. 65, products containing the chemical cannot be sold without warnings. The industry groups reportedly contend, “listing 4-MEI can be expected to impact a wide swath of foods by producing warnings, changes in cooking methods, changes in diets, litigation and other consequences—intended or otherwise.”

OEHHA rejected these arguments in March 2009, relying on the National Toxicology Program’s (NTP’s) formal identification of 4-MEI as a carcinogen. A 2007 NTP technical report apparently “concluded that there is clear evidence of the carcinogenic activity of 4-MEI in both male and female B6C3F₁ mice.” OEHHA has also stated, “4-MEI has been shown to be present in certain foods, though its use as a chemical intermediate in the production of certain pharmaceuticals, agricultural chemicals, dyes and pigments, and as a component of imidazole-phenoxyalkanal oven cleaners and other products indicates that exposure to the chemical extends beyond food.” See *Inside EPA*, April 10, 2009.

LITIGATION

Federal Appeals Court Upholds Dairy’s Right to Challenge Marketing Law Amendments

The D.C. Circuit Court of Appeals has determined that the owners of a dairy are not required to first exhaust administrative remedies before bringing a constitutional challenge to Agricultural Marketing Agreement Act amendments. [*Hettinga v. U.S., No. 07-5403 \(D.C. Cir., decided April 3, 2009\)*](#). The amendments codified certain rule changes that the Secretary of Agriculture made to a program that regulates payments from milk handlers (processors and distributors) to milk producers (farmers) and is intended to protect producers from price fluctuations.

The plaintiffs sought an injunction against enforcement of the secretary’s rule, and, while that proceeding was pending before a federal court in Texas, Congress amended the law. The plaintiffs then filed a complaint in a D.C. district court alleging that “the Amendments are unconstitutional as a bill of attainder and a denial of due process and equal protection because only the Hettingas are subject to them.” The district court dismissed the complaint for lack of subject matter jurisdiction, characterizing a challenge to the amendments’ validity as “essentially a challenge to [an] order by the Secretary,” and thus that plaintiffs were required to exhaust their administrative remedies before seeking relief in the courts.

The milk marketing law contains a mandatory administrative exhaustion requirement on milk handlers “seeking to challenge the provisions of a milk marketing order.” Because the plaintiffs were not challenging an order in the D.C. district court, the appeals court found that their constitutional challenges to the amendments were not subject to exhaustion as a jurisdictional matter.

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The court also refused to find an exhaustion requirement as a prudential matter, observing, "it would make little sense to require exhaustion where an agency 'lacks institutional competence to resolve the particular type of issue presented, such as the constitutionality of a statute' or where 'an agency may be competent to adjudicate the issue presented, but still lack[s] authority to grant the type of relief requested.'" The court remanded the claims for proceedings on their merits.

Chocolate Price-Fixing Case Certified for Appeal to Federal Appeals Court

A federal court in Pennsylvania has certified for immediate appeal its denial of the defendants' motion to dismiss in multidistrict litigation (MDL) alleging price-fixing by chocolate manufacturers. [*In re Chocolate Confectionary Antitrust Litig.*, MDL No. 1935 \(U.S. Dist. Ct., M.D. Pa., April 8, 2009\)](#).

The defendants in these 87 consolidated lawsuits reportedly supply 75 percent of the chocolate candy consumed by Americans each year. The lawsuits allege that the companies conspired to raise prices in 2002, 2004 and 2007 by as much as 10 percent and rely on information generated by government investigations in the United States and Canada to bolster their conspiracy allegations. At least one company spokesperson has been quoted as saying, "You can't just infer the existence of a price-fixing conspiracy from the fact that independent competitors in concentrated industries independently choose to raise their prices."

The question certified to the Third Circuit Court of Appeals is whether the U.S. Supreme Court's ruling in *Bell Atlantic Co. v. Twombly*, 550 U.S. 544 (2007), which established a new standard for pleading in antitrust cases, authorizes "a court in a [price-fixing conspiracy] case to draw an inference of conspiracy from the collective effect of repeated parallel price increases, averments of anticompetitive activity in closely related foreign markets, transnational management of corporate subsidiaries, opportunity for collusion, and descriptions of anti-competitive conduct that are economically sensible in light of mature market characteristics."

The district court notes in the memorandum accompanying its grant of defendants' interlocutory appeal that *Twombly* arguably presents "varied analytical cues" that "expose it to multiple interpretations." Before *Twombly*, a court asked to dismiss a complaint for failure to state a claim would not dismiss the complaint "unless it appear[ed] beyond doubt that the plaintiff c[ould] prove no set of facts in support of his claim which would entitle him to relief." While *Twombly* rejected a requirement of "heightened fact pleading of specifics," it did require plaintiffs to set forth plausible averments that possess "enough heft to 'sho[w] that the pleader is entitled to relief.'" The U.S. Supreme Court has refined this standard since *Twombly* was decided and reaffirmed that "a complaint must simply 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests."

According to the court, "a narrow reading of *Twombly* construes it as a formalistic change designed to give voice to a pleading standard that was already commonplace in many courts. Under a robust interpretation, however, *Twombly* requires a court to scrutinize the plausibility of a complaint's allegations and dismiss claims that lack sufficient factual underpinning for the relief requested."

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Because the Third Circuit has not yet applied *Twombly* in the context of antitrust claims, and because antitrust “plaintiffs often lack direct evidence of a conspiratorial agreement and must rely upon circumstantial allegations to surmount a Rule 12(b)(6) challenge,” the court determined that an immediate appeal giving the appeals court the opportunity to explore *Twombly*’s parameters was warranted. Still, the court reiterated its belief that it correctly denied defendants’ motion to dismiss. In its order, the court directs that jurisdictional discovery continue during the pendency of any appeal accepted by the Third Circuit. See *The American Lawyer*, April 13, 2009.

Ninth Circuit Orders New Trial in Idaho Milk Permeate Litigation

Finding that a trial court erred in admitting evidence and instructing the jury in a lawsuit involving claims that milk permeate sickened or killed calves that were fed the product as a source of dietary energy, protein and minerals, the Ninth Circuit Court of Appeals has returned a breach-of-warranties lawsuit to the lower court for a new trial. [*Millenkamp v. Davisco Foods Int’l, Inc., Nos. 07-35299 & -35318 \(9th Cir., decided April 14, 2009\)*](#).

The defendant allegedly advised the owners of a cattle operation about the use of milk permeate as a food source for their calves and then sold the product to them. When their calves fell ill and some died, the plaintiffs learned that they had stored the product at an improper temperature, “which allowed lactose to ferment into a harmful lactic acid that caused the calves to fall prey to rumen acidosis.”

The plaintiffs sued for breach of express and implied warranties, negligence and negligence per se and proceeded to trial on the warranty claims only. The jury awarded damages to the plaintiffs, and the defendant sought a new trial, objecting to several evidentiary rulings and jury instructions. The appeals court rejected any of defendant’s jury-instruction challenges that would have provided a defense to negligence claims, because those claims were not before the jury. The court did, however, find that the trial court erred when it instructed the jury that the defendant’s failure to comply with Idaho’s Milk Permeate Labeling Requirement was a basis for finding breach of express and implied warranties. According to the court, Idaho law recognizes that a state statute may create the basis for tort liability but not for breach of warranty.

The appeals court also determined, among other matters, that the trial court erred in admitting the testimony of plaintiffs’ expert, who testified concerning the same issue, i.e., that “the American Feed Control Officials’ model feed law required sellers to label milk permeate.” Because this was not relevant to determine liability for breach of warranties and was prejudicial to the defendant, the court found that the trial court abused its discretion in admitting it. Still, the appeals court agreed with the trial court’s decision to allow the expert to testify as to the cause of the calves’ illness, finding it relevant and sufficiently reliable under the Federal Rules of Evidence.

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Fair Credit Transactions Litigation Can Proceed

The Eleventh Circuit Court of Appeals has turned aside a constitutional challenge to the statutory damages provisions of the Fair and Accurate Credit Transactions Act in litigation against a food establishment that allegedly printed more than the last five digits of a customer's credit card number on an electronically generated receipt. [*Harris v. Mexican Specialty Foods, Inc., Nos. 08-13510 & -13616 \(11th Cir., decided April 9, 2009\)*](#). The district court had granted the merchants' motions for summary judgment and dismissed the claims with prejudice, after finding the statutory damages provision unconstitutionally vague and excessive.

According to the appeals court, which addressed only the facial challenge to the law, by providing for a range of damages (from \$100 to \$1,000), the law does not deprive potential defendants of notice of the consequences of violations or result in arbitrarily assessed damages awards. The court remanded the litigation for further proceedings.

OTHER DEVELOPMENTS

Chewing Gum Claims Generate Dispute Before BBB Advertising Arm

According to the National Advertising Division of the Council of Better Business Bureaus (BBB), Wrigley should modify or discontinue some of the claims it makes for its Eclipse® brand chewing gum. Following a challenge by Cadbury Adams USA, which makes competing products, the BBB's advertising division examined Wrigley claims that its gum "kills germs and cures bad breath." The division determined that such claims "convey the message that Eclipse with MBE [magnolia bark extract] is different from other gums based on its germ killing capabilities which is attributable to the addition of MBE."

Because scientific studies did not provide the support necessary to substantiate the claims due to purported methodological flaws, the division "recommended that the print advertising and packaging claims be discontinued or modified to indicate that there is emerging evidence as to MBE's germ killing capability without expressly or by implication communicating that there is credible scientific evidence that the gum has been proven to kill the germs that cause bad breath or provides fresh breath based on any germ-killing ability."

Wrigley has apparently taken issue with the division's evaluation of its testing and with the division's findings and has indicated that it will take an appeal to the National Advertising Review Board, "which serves as the appellate body of the advertising industry's system of self-regulation." See *NAD News*, April 8, 2009.

Consumer Advocates Protest Chicken Imports from China

The consumer advocacy group Food & Water Watch (FWWatch) recently launched a campaign to block chicken imports from China, where several U.S. companies are reportedly building plants. Alleging that these corporations are "putting pressure" on lawmakers, FWWatch has asked Congress to uphold its 2008 ban on imported

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processed poultry in light of “specific problems” with China’s food safety standards and inspection system. In particular, the group pointed to the rejection of other Chinese imports due to “contamination with melamine or banned chemicals like chloramphenicol; pesticide residues and unsafe additives; and conditions inspectors described as ‘poisonous’ and ‘filthy.’” “Even worse,” according to FWWatch, “China has experienced several outbreaks of the very contagious bird flu that has not only infected poultry but also been fatally transmitted to humans.” See *Food & Water Watch Action Alert*, April 14, 2009.

Childhood Obesity Conference Set for June 18-19 in Washington, D.C.

The Physicians Committee for Responsible Medicine (PCRM) is sponsoring a [National Conference on Childhood Obesity](#) on June 18-19, 2009, in Washington, D.C. The event will address (i) evidence-based links between diet, obesity and chronic disease, (ii) opportunities in clinical practice for preventing and treating obesity and related chronic diseases, (iii) the ways that school food programs and government policies affect children, and (iv) upcoming changes to nutrition guidelines and related government policies.

MEDIA COVERAGE

Kelly D. Brownell and Thomas R. Freiden, “Ounces of Prevention – The Public Policy Case for Taxes on Sugared Beverages,” *The New England Journal of Medicine*, April 30, 2009

“Because excess consumption of unhealthful foods underlies many leading causes of death, food taxes at the local, state and national levels are likely to remain part of political and public discourse,” claims this editorial co-authored by Yale University’s Rudd Center for Food Policy and Obesity Director Kelly Brownell and New York City Health Commissioner Thomas Freiden, who write in favor of a penny-per-ounce excise tax on sugar-sweetened beverages. Describing these products as “the single largest driver of the obesity epidemic,” the article compares a soft drink tax to similar taxes on tobacco “that have been highly effective in reducing consumption.”

The authors specifically argue that an excise tax would help (i) reduce health care and other societal costs for obesity and diet-related diseases; (ii) correct an “informational asymmetry” between marketers and younger audiences, “who often cannot distinguish a television program from an advertisement”; and (iii) generate revenue, “which can further increase the societal benefits of a tax on soft drinks.” They also note that while a regressive sales tax would merely prompt consumers to switch to cheaper brands, “excise taxes structured as a fixed cost per ounce provide an incentive to buy less and hence would be much more effective in reducing consumption and improving health.” According to Brownell and Freiden, their proposed penny-per-ounce tax would ultimately “reduce consumption of sugared beverages by more than 10 percent,” leading them to conclude that such government intervention is preferable to “education alone.”

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Meanwhile, the legitimacy of taxing food items has drawn criticism from the public, politicians and industry stakeholders. American Beverage Association President Susan Neely reportedly questioned the impact of sugar-sweetened beverages on obesity rates, which continue to rise despite a decline in soft drink sales. "We agree that obesity is a serious and complex problem. It defies both science and common sense, however, to think singling out one product as a unique contributor to obesity will make a dent in the problem," Neely was quoted as saying. See *The New York Times*, April 9, 2009.

James E. McWilliams, "Free-Range Trichinosis," *The New York Times*, April 10, 2009

"Free range is not necessarily natural. In fact, free-range is like piggy day care, a thoughtfully arranged system designed to meet the needs of consumers who despise industrial agriculture and adore the idea of wildness," writes James McWilliams in this op-ed article questioning claims that free-range products confer "indisputable" health benefits. According to McWilliams, a recent study published in *Foodborne Pathogens and Disease* found that free-range pigs had higher rates of *Salmonella* and *Toxoplasmosis* than conventional livestock and that two specimens carried the parasite responsible for *Trichinosis*, a potentially fatal infection all but eliminated in the commercial pork supply. McWilliams notes that a desire for the "superior taste" of free-range pork has led many connoisseurs to conflate "the highly controlled grazing of pigs" with "wild animals in a state of nature," an assumption that obfuscates the "arbitrary point between the wild and the domesticate." "Even if the texture conferred on pork by this choice does lead to improved tenderloin, the enhanced taste must be weighed against the increased health risks," McWilliams concludes. "If we have learned anything from our sustained critique of industrial agriculture, it is that eating well should not require making such calculations."

Meanwhile, several consumer advocates have criticized McWilliams for failing to disclose that the National Pork Board funded the study of free-range pigs, an omission later rectified by a *New York Times* editorial note. One *Ethicurean* contributor also responded that "pastured-pork fans" are not motivated by the "naïve idea of 'happy' pigs," but refuse to support "the industrial meat system, which is titanicly destructive to any nearby land, water and air; to the people with the misfortune to work in it; and to the sentient animals it turns into protein widgets." In addition, the *Agricultural Law* blog argued that large confined hog operations have purportedly led to (i) "serious health problems," including respiratory illness, among farm workers; (ii) an increase in antibiotic resistant infections such as methicillin-resistant *Staphylococcus aureus* (MRSA); and (iii) the "contamination of groundwater with nitrate." "Contrary to the tone of McWilliams' analysis, today's free range production is not a new system that was invented by chefs who seek the taste of wild game," opines the blog author. "Rather, [free-range] is a system of production that has been used by farmers worldwide for generations." See *Agricultural Law*, April 11, 2009; *Ethicurean.com*, April 14, 2009.

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SCIENTIFIC/TECHNICAL ITEMS

Study Claims Fat Intake Associated with Cognitive Decline in Diabetics

A recent study has reportedly linked cognitive decline in some diabetic women to high intakes of saturated and *trans* fats and low intakes of polyunsaturated fats during midlife. Elizabeth E. Devore, "Dietary Fat Intake and Cognitive Decline in Women With Type 2 Diabetes," *Diabetes Care*, April 2009. Harvard Medical School researchers apparently assessed the cognitive functioning of approximately 1,500 women with type 2 diabetes enrolled in the Nurses' Health Study, finding that those in the highest tertile of *trans* fat intake scored 0.15 standard units lower on six cognitive function tests when compared to women in the lowest tertile.

"This mean difference was comparable with the difference we find in women 7 years apart in age," stated the authors, who noted a need for "further research to confirm these findings and explore additional strategies for maintaining cognitive health in diabetes – especially in women, who can have a higher lifetime prevalence of both type 2 diabetes and cognitive impairments than men." See *Reuters Health*, April 8, 2009; *Physicians for Responsible Medicine Press Release*, April 9, 2009.

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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.

