Shook, Hardy & Bacon L.L.P.

ISSUE 409 | SEPTEMBER 16, 2011

FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

GAO Highlights Security Challenges for Food and Agriculture Sector

The U.S. Government Accountability Office (GAO) recently delivered its **evaluation** of how well federal agencies have implemented the nation's food and agricultural defense policy known as Homeland Security Presidential Directive (HSPD)-9. Established to protect the food supply "against terrorist attacks, major disasters, and other emergencies," HSPD-9 divides emergency response activities among several agencies, including the Departments of Agriculture (USDA), Health and Human Services, and Homeland Security, the latter of which has designated a system of emergency support functions (ESFs) within a National Response Framework. According to the August 2011 GAO report, however, "There is no centralized coordination to oversee the federal government's overall progress implementing… HSPD-9."

In **testimony** before a subcommittee of the U.S. Senate Committee on Homeland Security and Governmental Affairs, GAO Natural Resources and Environmental Director Lisa Shames explained that because this general oversight is lacking, the agencies responsible for HSPD-9 cannot guarantee their "cross-cutting" efforts are "well-designed and effectively implemented in order to reduce vulnerability to, and the impact of, terrorist attacks, major disasters, and other emergencies." In particular, Shames noted that not only has USDA failed to deploy a department-wide strategy for implementing its HSPD-9 responsibilities, but that the agency faces numerous challenges when coordinating federal (ESF-11) natural disaster responses.

To this end, GAO has urged DHS to better coordinate HSPD-9 activities, while also calling on USDA to discharge its own HSPD-9 responsibilities and ensure that after-action ESF-11 reports are completed. "In our report, we are making nine recommendations to help ensure that the federal government is effectively implementing the nation's food and agriculture defense policy and to ensure that the nation is adequately prepared to respond to and recover from emergencies affecting food and agriculture," concludes Shames. "In addition, in an e-mail received July 22, 2011, the National Security Staff's Deputy Legal Advisor stated that the National Security Staff agrees that a review of HSPD-9 is appropriate and that they will look for an opportunity to do so."

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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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GAO Faults Agency Progress on Antibiotic Use in Animals

The U.S. Government Accountability Office (GAO) has issued a September 2011 **report** claiming that the Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) have failed to obtain credible data on the use of antibiotics in food animals, as well as the presence of resistant bacteria in animals and retail meat. After examining the extent to which U.S. agencies have addressed this area of concern, GAO apparently found major gaps in the information needed to understand how livestock antibiotics can contribute "to the emergence of resistant bacteria that may affect humans." In particular, the report faulted the Food and Drug Administration (FDA) for failing to adequately monitor a 2010 voluntary strategy designed to limit "approved uses of antibiotics" and increase "veterinary supervision of use." According to GAO, "FDA does not collect the antibiotic use data, including the purpose of use, needed to measure the strategy's effectiveness."

The report also points to proactive measures taken by the European Union, which banned the use of antibiotics to promote animal growth in 1995, while praising the extensive data collection activities that have allowed Danish officials to track antibiotic resistance in retail meat, food animals and humans. "Some of their experiences may offer lessons for the United States," concludes the report's executive summary. "GAO recommends that HHS and USDA (1) identify and evaluate approaches to collecting detailed data on antibiotic use in animals and use these data to evaluate FDA's voluntary strategy, (2) collect more representative data on resistance, and (3) assess previous efforts on alternatives to identify where more research is needed."

USDA Intends to Ban Six *E. Coli* Strains in Raw Beef Products

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) recently **announced** its intention to prohibit six serogroups of Shiga toxin-producing *E. coli* (STEC) in addition to *E. coli* O157:H7. According to FSIS, the agency plans to begin testing for the additional STEC on March 5, 2012, at which time those six strains will be deemed adulterants and barred from commerce under the Federal Meat Inspection Act if detected in raw ground beef, its components or tenderized steak.

"As a result of today's action, if the *E. coli* serogroups O26, O103, O45, O111, O121 and O145 are found in raw ground beef or its precursors, those products will be prohibited from entering commerce," stated a September 13, 2011, USDA press release, which also solicits comments on the policy change for 60 days after publication in the *Federal Register*.

FDA and FSIS to Collect Information on Dietary Sodium Intake

The Food and Drug Administration (FDA) and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) have **established** new dockets "to obtain comments, data and evidence relevant to the dietary intake of sodium as well as current and emerging approaches designed to promote sodium reduction." FDA and FSIS have warned that current sodium consumption "is substantially higher than what has been recommended by scientific and public health agencies and organizations," including the Institute of Medicine and the USDA in its 2010 Dietary Guidelines for Americans. According to the September 15, 2011, *Federal Register* notice, "The Centers for Disease Control and Prevention (CDC) reported in 2010 that over 80 percent of adults (>=20 years) recommended to consume less than 2,300 mg/d [milligrams per diem] of sodium in fact consumed more than 2,300 mg/d."

The new dockets invite stakeholders and other interested persons to provide information about (i) "current and emerging practices by the private sector in sodium reduction"; (ii) "current consumer understanding of the role of sodium in hypertension and other chronic illnesses"; (iii) "sodium consumption practices"; (iv) "motivation and barriers in reducing sodium in their food intakes"; and (v) "issues associated with the development of targets for sodium reduction in foods to promote reduction in excess sodium intake." In addition, FDA and FSIS have solicited comments and research addressing industry-led sodium reduction initiatives, strategies for reducing sodium in packaged or prepared foods, and the potential food safety consequences of sodium reduction, among other topics.

"Many food companies recognize that reduction of sodium in the American diet is an important public health issue," state the agencies. "Some major food manufacturers have publicly committed to reducing the sodium content of their products over time. Certain companies have voluntarily identified specific product goals for sodium reduction. Many have demonstrated that substantial reductions in sodium can be achieved in certain food products and have established research programs to address key issues such as taste preference, technological advances, safety, and consumer acceptance in working through challenges and gaps in knowledge."

LITIGATION

WTO Nixes "Dolphin-Safe" Labels on U.S. Tuna

Concluding that "dolphin-safe" tuna product labels authorized by the U.S. Commerce Department "are more trade-restrictive than necessary to achieve a legitimate objective," a World Trade Organization (WTO) panel has given a **partial victory** to Mexico, which filed a complaint in 2009 claiming that the

labels were illegal because they excluded Mexican yellowfin tuna from the U.S. market and shut down one-third of its tuna fleet.

The WTO panel rejected Mexico's claim that the U.S. labeling provisions discriminate against its tuna products, finding "that Mexican tuna products are not afforded less favourable treatment than tuna products of the US and other origins in respect of the US dolphin safe labeling provisions on the basis of their origin." Still, the panel recommended that the United States be asked "to bring its measures into conformity with its obligations" under the Technical Barriers to Trade agreement.

Mexican Economy Secretary Bruno Ferrari reportedly responded to news of the ruling by stating that it is "a crushing blow to the label 'dolphin-safe' and opens the way for Mexican producers to enter the U.S. market without restrictions, as is their right." The United States may appeal the ruling, and Ferrari speculated that, if it did, a final ruling would not be issued until late in the first quarter of 2012. "If such an appeal is again unfavorable and the country chooses not to abide by an adverse ruling, Mexico would have the right, under the rules of the organization, to impose trade retaliation," he said.

The U.S. advocacy group Public Citizen apparently predicted a WTO backlash; a spokesperson said that a prohibition on these labels "is among the few things likely to unite Americans across the political spectrum." *See Associated Press*, September 15, 2011.

Florida EVOO Lawsuits Dismissed for Inadequate Pleading

Two putative class actions alleging that companies making and selling extra virgin olive oil (EVOO) sell their products at a premium despite their failure to meet certain EVOO standards have been dismissed by a federal court in Florida because the plaintiffs did not adequately plead their claims under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009). *Meyer v. Colavita USA, Inc.,* No. 10-61781, *Nachio v. Am. Rice Inc.*, No. 10-61793 (U.S. Dist. Ct., S.D. Fla., decided September 13, 2011). The defendants claimed in their motions to dismiss that the complaints were based on a flawed UC Davis study that analyzed a small sample of olive oil purchased in California and that the plaintiffs failed to either allege that the products they purchased were not EVOO as the companies claimed or that they had been harmed.

The court agreed that the UC Davis results were inconclusive and possibly flawed and that the plaintiffs failed "to plead anything other than unwarranted deductions of fact in support of their claims that Defendants have engaged in a deceptive act or unfair practice. Plaintiffs do not allege facts suggesting that the olive oil they purchased was not actually extra virgin olive oil. They do not plead facts indicating when, where, and what type of olive oil they purchased and whether the actual olive oil they purchased conformed

with the identified standards. Rather, Plaintiffs support their claims with speculation and unwarranted extrapolation from the UC Davis Study's findings." The court also noted, "There are no allegations that anyone in Florida purchased extra virgin olive oil that tasted bad, or was tested and failed to meet certain standards, or was in any other way 'fake.'"

Because the plaintiffs also failed to notify the defendants about their breach of warranty claims before filing suit, the court determined that those claims must be dismissed for failure to state a claim.

"Percent Fat Free" Litigation Against Deli Meat Makers Dismissed in Florida

A federal court in Florida has dismissed with prejudice most of the claims asserted in a putative class action alleging that "percent fat free" labels on the packages of deli meats are misleading and deceptive. *Kuenzig v. Kraft Foods, Inc.*, No. 11-838 (U.S. Dist. Ct., M.D. Fla., Tampa Div., decided September 12, 2011). Additional information about the case appears in **Issue 391** of this *Update*. The court found all but one of the plaintiff's claims preempted by federal food-labeling law and also found that all but one of his claims failed to state a claim because they were frivolous or disingenuous.

As to defendant Hormel Foods Corp., the plaintiff had alleged that while the company's labels do not indicate the number of calories per serving next to the "percent fat free" claim on the front of its product packaging, the labels are "somehow misleading by association, since Hormel's products are on grocery shelves next to Kraft's products." The court found as a matter of law that Hormel's labels do not misrepresent that the "percent fat free" claims are based on calories. As to defendant Kraft Foods, the court determined that the front-of-package labeling, which did pair "percent fat free" claims with calorie counts, could not mislead consumers because "the number of calories that come from fat is clearly disclosed in the nutrition panel on Kraft's labels."

The plaintiff also alleged that the defendants' use of their "percent fat free" claims on labels and websites and in advertising is misleading and constitutes a violation of every state's "Little FTC Act." According to the court, application of Florida's Deceptive and Unfair Trade Practices Act (or Little FTC Act) is preempted as to label claims, but not as to those claims implicating the defendants' Websites and non-label advertising. Because the plaintiff did not "describe the context of the misrepresentations," the court dismissed this remaining claim, but without prejudice, giving the plaintiff leave to amend the complaint.

Class Cert. Sought in *Trans* Fat Lawsuit Against Smuckers

A California woman who alleges that certain J.M. Smucker's products contain partially hydrogenated vegetable oil (PHVO), or *trans* fat, while the company falsely promotes them as healthy for consumers, has requested an October

10, 2011, hearing on her motion to certify a nationwide class. *Henderson v. The J.M. Smucker Co.*, No. 10-04525 (U.S. Dist. Ct., C.D. Cal., first amended complaint filed August 12, 2010).

According to the complaint, the plaintiff purchased the company's Crisco Original Shortening®, Crisco Butter Flavor Shortening® and Smucker's Uncrustables Sandwiches® relying on representations that the shortening had "50% Less Saturated Fat Than Butter" and was "All Vegetable," and that the Uncrustables were "Wholesome," made from "whole wheat" and "homemade goodness." Characterizing PHVO as an "unwholesome manufactured additive," most of the complaint focuses on the purported health effects of consuming *trans* fat.

The plaintiff alleges violations of various consumer fraud laws and seeks injunctive relief, corrective advertising, disgorgement, the destruction of "all misleading and deceptive advertising materials and products," restitution, actual and punitive damages, attorney's fees, and costs.

Coffee Drinker Claims That Safeway Misled Purchasers of "Kona Blend"

After Kona coffee growers called for Safeway, Inc. to comply with Hawaiian regulations on labeling Kona coffee, a California resident filed a putative class action against the company in federal court, alleging that its Safeway Select™ "Kona Blend" coffee contains "very little Kona coffee bean content." *Thurston v. Safeway, Inc.*, No. 11-04285 (U.S. Dist. Ct., N.D. Cal., filed August 30, 2011). Seeking to certify nationwide or statewide classes, the plaintiff calls the company's labeling false and misleading and contends that she "did not receive the 'Kona Blend' she bargained for when she purchased Safeway's Kona Blend Coffee, and has lost money as a result in the form of paying a premium for Kona Blend coffee" instead of paying less for a non-Kona or low-Kona coffee alternative.

The plaintiff alleges common law fraud, violations of various consumer fraud statutes and restitution based on quasi contract or unjust enrichment. She requests restitution, compensatory and punitive damages, an injunction to stop Safeway from "advertising its products misleadingly, in violation of California's Sherman Food, Drug and Cosmetic Law and other applicable laws and regulations," attorney's fees and costs. According to a news source, the Safeway product costs $8.99 a pound, while pure Kona coffee can sell for $25 for 8 ounces. Hawaii requires Kona coffee labels to specify what percentage comes from the Kona bean and whether it was grown in the state. *See West Hawaii Today*, August 6, 2011.

Brandeis University Sues Cookie and Biscuit Makers for Patent Infringement

Brandeis University has filed suit against a number of cookie and biscuit manufacturers, including Keebler Co., Famous Amos Chocolate Chip and

The Pillsbury Co., alleging that they have infringed patents that adjust the LDL/HDL ratio in human serum by balancing saturated and polyunsaturated dietary fatty acids. *Brandeis Univ. v. East Side Ovens, Inc.*, No. 11-619 (U.S. Dist. Ct., W.D. Wis., filed September 7, 2011). According to the complaint, the patents ('497 and '192) were issued in 1998 and 2003 and "are directed to fats and fat blends that decrease low-density lipoprotein cholesterol (LDL) and increase high-density lipoprotein cholesterol (HDL) in human serum," resulting "in significant health benefits." The university alleges that the defendants' cookie, cookie dough, and reduced fat biscuit and crescent roll products infringe its patents. The plaintiff seeks injunctive relief, damages, costs, and a "declaration that this is an exceptional case and an award of attorneys' fees."

Consumer Claims Skinnygirl™ Margarita Is Not "All Natural" as Advertised

A putative class action has been filed in a federal court in California against Beam Global Spirits & Wine, Inc., alleging that the company's Skinnygirl™ Margarita beverage, purportedly created by a natural foods chef, contains sodium benzoate and other preservatives and should not be advertised and sold as a "natural" product. *Bonar v. Beam Global Spirits & Wine, Inc.*, No. n/a (U.S. Dist. Ct., S.D. Cal., filed September 6, 2011). Alleging purely economic damages, the plaintiff seeks to certify a nationwide class of purchasers and claims that the company has violated California's Consumers Legal Remedies Act and Business & Professions Code Section 17200 *et seq.*, and breached express warranties. She requests compensatory and punitive damages, restitution, disgorgement, corrective advertising, injunctive relief, attorney's fees, and costs.

White Castle Devotee Sues Company, Alleging Injury from Small Booth

According to news sources, a man who weighs nearly 300 pounds has filed an Americans with Disabilities Act lawsuit against White Castle in a federal court in New York, claiming that the stationary booth seating in a Nanuet restaurant is made for smaller people and that he hurt a knee trying to wedge into one in 2009. When he complained in writing, he purportedly received three "very condescending letters," with offers for free hamburgers, although added cheese would have cost extra. He has since used take-out to purchase his food from White Castle or asked his wife to go into the facility to pick up his meals, while waiting almost three years for promised renovations that would have enlarged the seating spaces. Stockbroker and plaintiff Martin Kessman reportedly said, "I just want to sit down like a normal person." *See New York Post*, September 11, 2011; *The Wall Street Journal*, September 13, 2011; *USA Today*, September 14, 2011.

California Court Reverses $12-Million Verdict , Rules Spinach Contamination Not Insured

A California court of appeal has determined that a trial court erred in allowing a spinach seller to recover $12 million under the accidental contamination portion of its insurance policy. *Fresh Express Inc. v. Beazley Syndicate 2623/623 at Lloyd's*, No. H035246 (Cal. Ct. App., decided September 8, 2011) (unpublished). According to the court, the produce company's product was not the source of the *E. coli* outbreak linked to spinach in 2006 and led to a nationwide recall, although when it filed its insurance claim, the company had made several sourcing errors that led it to believe it could have been implicated in the outbreak. Those errors would have brought it under the terms of the insurance agreement, if the company had been the source of the *E. coli* contamination. Because it was not, the appeals court concluded that "the policy's plain language refutes the trial court's finding that 'the E. coli outbreak' was an 'Insured Event' under the policy."

Popcorn Lung Alleged Against Diacetyl Makers and Sellers

A number of former employees of an animal-food flavoring maker have sued companies that make or sell the butter-flavoring chemical diacetyl, alleging that occupational exposure caused them to contract a debilitating lung disease known as bronchiolitis obliterans (or popcorn lung). *Huerta v. Aldrich Chem. Co., Inc.*, No. 11-009461 (Ill. Cir. Ct., Cook County, filed September 9, 2011). The 112-count complaint alleges negligence, strict liability design defect and failure to warn, conspiracy, and loss of consortium. The plaintiffs seek unspecified compensatory damages. According to the complaint, "Defendants knew or should have known of the hazardous nature of their diacetyl and diacetyl-containing flavors both at the time of sale and when plaintiffs were exposed to such products while working at the Feed Flavors facility. [Yet], defendants failed to warn of the defective nature of their flavoring chemicals and failed to give instructions on safe use of the flavoring chemicals."

OTHER DEVELOPMENTS

Law Profs Contend Nutrition Guidelines for Food Marketed to Children Pass 1st Amendment Muster

A number of law professors, including anti-tobacco activist and Public Health Advocacy Institute President Richard Daynard, have written to the heads of four federal agencies, in their role as the Interagency Working Group on Food Marketed to Children, to support the group's proposed nutrition principles for food marketed directly to children ages 2-17. Details about the proposed principles appear in **Issue 392** of this *Update*.

According to the September 6, 2011, letter, the principles "embody a constitutionally permissible set of government recommendations." Written to counter a trade association letter that urged the group to withdraw the principles on constitutional grounds, the professors' letter notes that the "recommended nutrition principles contain no mandates" and thus "do not violate the First Amendment."

Observing that the group "is better characterized as a routine governmental advisory body than an oppressive censorship panel," the professors note, "no federal agency can impose legal repercussions on a company for following the [Interagency Working Group] principles in only a piecemeal fashion, for ignoring them entirely, or—for that matter—mounting a wide-ranging public relations campaign disparaging them, as the food and beverage industry has done."

According to the letter, the group made "suggestions regarding the content of food marketed to children in the same way the National Institutes of Health has called for a reduction in youth exposure to smoking in movies; the Surgeon General has attempted to promote breastfeeding by encouraging hospitals to refuse infant formula advertisements; and Congress has called on the entertainment industry to reduce the exposure of underage audiences to 'programs with unsuitable alcohol content.'"

In a related development, the Environmental Working Group (EWG), a public health advocacy organization, has called on supporters to demand that the CEOs of major food and beverage manufacturers "use their resources to market healthier food to our children, not to lobby to protect the unhealthy *status quo*." In a call to action undertaken with the Center for Science in the Public Interest, EWG discusses the objections the food industry has filed to the proposed nutrition guidelines for food marketed to children, referring to the government's guidelines as "commonsense recommendations" that "would encourage children to adopt healthy eating habits." Claiming that the companies need to hear from their customers, EWG urges action "to stop childhood obesity." *See EWG Take Action Initiative*, September 15, 2011.

CAMY Releases Study on Radio Alcohol Ads

The Center on Alcohol Marketing and Youth (CAMY) has issued a **report** claiming that "almost 1 out of 11 radio ads for alcoholic beverages in 75 markets across the nation in 2009 failed to comply with the alcohol industry's voluntary standard for the placement of advertising." According to CAMY, "Approximately 9 percent of all alcohol product advertisements aired on programming with underage audiences in violation of the industry's 30 percent standard," thus accounting for 18 percent of youth exposure to alcohol advertising. The report also alleges that (i) 32 percent of advertising placements "occurred when proportionately more youth were listening than

adults age 21 and above"; (ii) "these overexposing ads generated more than half of youth exposure to radio advertising for alcohol in 2009"; and (iii) "in 2009, girls ages 12 to 20 were more likely than boys in the same age group to be exposed to alcohol advertising for alcopops, distilled spirits, and wine."

The center faults the industry's current standard as too lenient, noting that "more than two-thirds of underage exposure to alcohol advertising on the radio went to young people between the ages of 12 and 20." As a result, CAMY has joined the National Research Council, Institute of Medicine and 24 state attorneys general in calling for a new standard that limits alcohol advertising to programming where this age group comprises less than 15 percent of the audience.

MEDIA COVERAGE

Thomas Watkins, "'Corn sugar' is false advertising, FDA warns," *AP*, September 15, 2011

According to documents obtained by *Associated Press* reporter Thomas Watkins, the Food and Drug Administration (FDA), which is currently considering a Corn Refiners Association petition to allow high-fructose corn syrup (HFCS) to be called "corn sugar," has written to the association indicating concern with the trade group using the terms interchangeably. In the July 12, 2011, letter, an FDA director reportedly stated, "We request that you re-examine your websites and modify statements that use the term 'corn sugar' as a synonym for (high fructose corn syrup)."

On behalf of the association, Audrae Erickson reportedly stated, "We do not believe that anyone could be confused or believe that the statements regarding 'corn sugar' on the websites refer to anything other than high fructose corn syrup." Watkins notes that FDA has no regulatory authority over the association's advertising because it promotes an industry and not a product. The FDA letter apparently indicated that the agency may bring enforcement actions against food companies that begin listing HFCS as "corn sugar." Referring to internal FDA documents, Watkins suggests that the agency is skeptical of a name change, although, when asked to comment, an agency spokesperson said nothing should be inferred from them about a ruling on the petition.

SCIENTIFIC/TECHNICAL ITEMS

Studies Investigate Significance of BPA Health Effects

A recent study funded by the U.S. Environmental Protection Agency (EPA) has reportedly measured internal exposure to bisphenol A (BPA) from dietary

sources, with results suggesting that the substance is, for the most part, metabolized and excreted by the body. Justin Teeguarden, et al., "Twenty-Four Hour Human Urine and Serum Profiles of Bisphenol A during High-Dietary Exposure," *Toxicological Sciences,* September 2011. Scientists with the Centers for Disease Control and Prevention, Food and Drug Administration, and Northwest Pacific National Laboratory apparently profiled the urine and blood serum of 20 healthy adults for 24 hours (24-h) after "high-dietary" BPA exposure via meals enriched with canned foods.

"From a safety perspective, the most pressing fundamental question regarding BPA is whether human blood/tissue concentrations of BPA following typical daily exposures are similar to, above, or below blood/tissue concentrations causing demonstrably adverse effects in animal models," wrote the authors. "The main objective of this study was to characterize internal exposure to $_{TOT}$BPA and BPA by concurrently determining the 24-h urinary elimination profile of $_{TOT}$BPA and the serum time course of $_{TOT}$BPA and BPA in a group of healthy human adults on a controlled diet enriched in canned food items likely to be significant dietary sources of BPA."

The results evidently indicated that, "during these high dietary exposures," the subjects' average BPA consumption, "estimated from the urinary excretion of total BPA ($_{TOT}$BPA = conjugated BPA + BPA), was 0.27 µg/kg body weight (range 0.03-0.86), 21% greater than the 95th percentile of aggregate exposure in the adult U.S. adult population." At the same time, however, "$_{TOT}$BPA concentrations in serum were undetectable in 83% of the 320 samples collected and BPA concentrations were determined to be less than or equal to LOD [limit of detection] in all samples."

The researchers concluded that "attributions of high blood BPA concentrations from oral exposure seem implausible," with peak BPA serum concentrations "1-3 orders of magnitude below levels recently associated with histological changes in a sensitive experimental model of rat prostate intraepithelial neoplasia." Recommending that future studies rule out dermal exposure or leaching from the plastic tubing used in field collection, the authors also urged a "continued focus on concurrent collection of internal exposure data for experimental models of toxicity," as well as "additional refinements in the ability to collect and interpret human BPA biomonitoring data through improved survey data and use of pharmacokinetic and reverse dosimetry models to calculate internal exposures where experimental measures are not feasible."

Meanwhile, a second study has suggested that BPA and other xenoestrogens could inhibit the effectiveness of new breast cancer drugs, as well as cause healthy breast cells to behave like cancerous ones. William Goodson, et al., "Activation of the mTOR Pathway by Low Levels of Xenoestrogens in Breast Epithelial Cells from High-Risk Women," *Carcinogenesis,* September

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2011. Conducted by California Pacific Medical Center researchers, the study allegedly found that exposing "renewable, human, high-risk donor, breast epithelial cells (HRBECs)" to BPA and the beauty product ingredient methylparaben activated "mammalian target of rapamycin (mTOR) pathway genesets," thereby triggering "prosurvival changes" in healthy cells.

According to a September 12, 2011, medical center press release, this study "breaks new ground" by examining BPA's effect on cells before they turned cancerous, while also raising questions about the impact on cancer drugs such as Tamoxifen and Rapamycin. "Not every cell exposed to BPA or methylparaben will become cancer, but anything—any chemical exposure—that 'flips the switch' and causes healthy cells to act like cancer is cause for concern," the lead author was quoted as saying. "Healthy breast cells exposed to cancer preventing and cancer treating drug Tamoxifen should undergo 'programmed cell death' or apoptosis, but after BPA exposure they don't. Having two breast cancer drugs rendered ineffective by BPA exposure is very concerning for women who are battling breast cancer."

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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.