Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

Health Advocates Seek FTC Investigation of Gatorade® Ad

The Public Health Advocacy Institute (PHAI) and several other organizations have asked the Federal Trade Commission (FTC) to "investigate PepsiCo's current 'Win from Within' commercial television advertisement and commercial website for its Gatorade sports drink product featuring Michael Jordan's performance during game 5 of the 1997 NBA Finals."

According to the letter, joined by groups such as the California Center for Public Health Advocacy, Center for Science in the Public Interest and Yale Rudd Center for Food Policy & Obesity, the ad "encourages teens to engage in dangerous behavior; sequences historical events to falsely enhance the role of Gatorade in Mr. Jordan's game-winning athletic performance; and contains deceptive product imagery." The letter claims that the ad targets teens by airing on cable networks appealing to teens, such as "Adult Swim, Teen Nick, ABC Family, and MTV."

The organizations claim that the ad promotes vigorous physical activity during illness, including a "very high fever, in Jordan's case 103 degrees." The ad copy purportedly indicates that "Jordan 'was able to persist' because he had 'the fuel to help him do it,'" an apparent reference to Gatorade®. The letter contends that game footage has been edited to lead viewers to believe that Jordan completed a three-point shot near the end of the game when he actually never returned after he was helped to the bench for the last time. Also cited as misleading is the content of the Gatorade-branded cups in the ad—evidently, in some actual game footage the liquid is clear, while the ad shows a cup filled with "vibrant orange liquid."

Calling the ad unfair and deceptive with "the tendency or capacity to influence consumers to engage in behavior which creates an unreasonable risk of harm," the letter cites FTC enforcement actions in other cases to support its call for an investigation. Before he began a sustained anti-obesity campaign in the new millennium, Richard Daynard, PHAI's president and Northeastern University law professor, focused on anti-tobacco advocacy.

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For additional information on SHB's Agribusiness & Food Safety capabilities, please contact

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

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.

Consumer Group Files FDA Complaint over NuVal Nutrition Ratings

The National Consumers League (NCL) has filed a **formal complaint** with the Food and Drug Administration (FDA), alleging that NuVal LLC's point of purchase nutrition rating system is "inconsistent with FDA guidance statements and enforcement correspondence, federal nutrition programs, and recommendations from the Institute of Medicine (IOM)." Used by more than 1,600 grocery stores in 31 states, the NuVal system apparently scores products out of 100 total points, with more nutritious options garnering a higher rating. NCL has argued, however, that NuVal relies on "a proprietary, non-public algorithm that can lead to inconsistent scores that may confuse and mislead consumers," and has asked FDA to issue a warning letter to the retail industry about its continued use.

Citing an IOM report on nutrition rating systems that criticized NuVal's formula, the NCL complaint contends that NuVal "runs afoul" of FDA Guidance on Point of Purchase Labeling, which stipulates that all such systems "be nutritionally sound, well-designed to help consumers make informed and healthy choices, and not be false or misleading." In particular, the group has charged NuVal with promoting inconsistent ratings that privilege processed foods over canned fruits and vegetables, as well as using the "proprietary" Overall Nutritional Quality Index faulted by both IOM and National Cancer Institute for its purported lack of transparency.

"The NuVal rating system is fatally flawed and should be discarded," said NCL Executive Director Sally Greenberg in a May 10, 2012, press release. "Its algorithmic formula—which is not transparent to consumers or the scientific community—results in snack chips, soft drinks, and desserts being given as high or higher nutritional scores than some canned fruits and vegetables. NuVal's so-called nutritional ratings are a travesty that confuse, rather than enlighten, consumers. We need the FDA to step in and set industry-wide standards. Moreover, the FDA should not allow NuVal or any other flawed nutritional rating system to further confuse consumers who are trying to make healthy decisions for their families."

FDA Rejects Objections and Request for Hearing on Food Irradiation Rule

The Food and Drug Administration (FDA) has determined that it will neither conduct a hearing nor make any changes to its **final rule** on the use of irradiation in processing and handling food. According to the agency, "the objections do not justify a hearing or otherwise provide a basis for revoking the regulation," issued in October 2000 in response to a petition filed by Caudill Seed Co. which sought a regulatory amendment allowing "the safe use of ionizing radiation to control microbial pathogens in seeds for sprouting." So ruling, FDA rejected Public Citizen's concerns that the agency failed to apply a 100-fold safety factor, the petitioner submitted no conventional animal

toxicity studies on sprouts from irradiated seeds, the review memorandum contained unsubstantiated statements, and the nutritional adequacy of irradiated seeds is questionable, among other matters. *See Federal Register*, May 11, 2012.

FSIS Targets Traceback Measures, Food Preservatives, Misbranded Products, HACCP Plans

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) has **proposed** new traceback measures to better control and prevent pathogens from triggering foodborne illnesses and outbreaks. Particularly concerned with meat contaminated with *Escherichia coli (E. coli)*, FSIS plans to "move quickly to identify the supplier of the product and any processors who received contaminated product from the supplier, once confirmation is received." FSIS, which has provided industry guidelines on the matter, requests comments by July 6, 2012. *See FSIS Press Release,* May 2, 2012; *Federal Register,* May 7, 2012.

FSIS has also issued a **proposed rule** that would remove the food preservatives sodium benzoate, sodium propionate and benzoic acid from a list of substances prohibited for use in meat or poultry products. Under the proposal, the Food and Drug Administration would continue to approve new safety uses of these substances in meat or poultry products while FSIS would approve them for suitability. FSIS requests comments by July 6. *See Federal Register,* May 7, 2012.

The agency has also issued a **final rule** requiring establishments to prepare and maintain recall procedures, notify the agency within 24 hours when an adulterated or misbranded meat or poultry product that could harm consumers has entered commerce, and document each reassessment of their Hazard Analysis and Critical Control Point (HACCP) system food safety plans. The provisions are part of the Food, Conservation and Energy Act of 2008. *See Federal Register,* May 8, 2012.

In addition, FSIS has **issued** guidance clarifying the necessary steps establishments should take to ensure that their HACCP food safety systems are effective in preventing foodborne illness. Called "validation," the process involves the scientific or technical support used in designing HACCP systems and the evidence demonstrating that the systems have achieved the "critical operational parameters" documented in such support. The agency requests comments by July 9. *See Federal Register,* May 9, 2012.

Former EFSA Chair Resigns over Conflict of Interest Concerns

The European Food Safety Authority (EFSA) has **announced** the resignation of Management Board Chair Diána Bánáti, describing her decision to accept a position at the International Life Sciences Institute (ILSI) as "incompatible"

with her agency duties. Bánáti apparently agreed to step down after critics raised concerns about EFSA's supposed lack of transparency "in its links with lobbyists for biotech and food companies," noted a May 9, 2012, *Parliament* article. Additional details about a Corporate European Observatory report that focused on EFSA members with ILSI ties appear in Issue **399** of this *Update*.

Although EFSA stressed that board members must consider public perception in undertaking "any activities which could raise doubts about their independence," Bánáti in her resignation speech reportedly defended the agency as "one of the most transparent organizations I know." She also reiterated that ILSI Europe, where she will serve as executive and scientific director, is not an industry lobbying group but a scientific organization that "seeks to advance understanding of issues relating to nutrition, food safety and the environment" by drawing on a wide range of expertise. "As a scientist I have nothing but respect for this unique organization where industry, academic and government scientists collaborate in an open and transparent manner to identify health and scientific issues of common concern and share ideas on how to address them," Bánáti was quoted as saying. "When decisions affecting public health and safety are made on sound science, everyone benefits."

Despite these assurances, however, the European Parliament this week voted to withhold approval for how EFSA spent its 2010 funds over its perceived lack of transparency. In particular, the Group of the European People's Party (EEP Group) has asked the European Council, Commission and member states to revise the management board appointment process for decentralized agencies and to implement robust conflict of interest policies. "The world has been changing and we must follow it," said Member of Parliament Monica Macovei in a May 10, 2012, EEP Group statement. "Transparency and proper management of the conflict of interests have become vital for governance and for our citizens. Conflicts of interest must be a criteria in the discharge procedure for all EU Institutions. If they are not correctly managed, conflict of interests can distort the allocation of financial and human resources, cause a waste of public funds and weaken the citizens' trust."

LITIGATION

Starbucks Can Limit Number of Pro-Union Buttons Worn by Employees

The Second Circuit Court of Appeals has determined that Starbucks Corp. did not violate federal labor law by adopting a dress code which limits the number of pro-union buttons its employees can wear on their uniforms. ***NLRB v. Starbucks Corp.*, Nos. 10-3511-ag, 10-3783-ag(XAP) (2d Cir., decided May 10, 2012)**.

The National Labor Relations Board (NLRB) had ruled that multiple pro-union buttons, at one-inch in diameter, "did not seriously harm Starbucks's

legitimate interest in employee image because 'the Company not only countenanced but encouraged employees to wear multiple buttons as part of that image.' These other buttons, the Board found, were not immediately recognizable by customers as company-sponsored, and the pro-union pins at issue were 'no more conspicuous than the panoply of other buttons employees displayed.'"

Reversing this part of NLRB's determination, the appeals court said that it had gone too far. "Starbucks is clearly entitled to oblige its employees to wear buttons promoting its products, and the information contained on those buttons is just as much a part of Starbucks's public image as any other aspect of its dress code," said the court. "But the company is also entitled to avoid the distraction from its messages that a number of union buttons would risk." The record apparently showed that one employee tried to display eight union pins "on her pants, shirts, hat, and apron. Wearing such a large number of union buttons would risk serious dilution of the information contained on Starbucks's buttons, and the company has a 'legitimate, recognized managerial interest[]' in preventing its employees from doing so."

New York Law on Labeling Kosher Products Deemed Constitutional

The Second Circuit Court of Appeals has determined that a New York law enacted in 2004, following the invalidation of a prior version, does not violate the Establishment or Free Exercise Clauses of the U.S. Constitution and is not unconstitutionally vague. ***Commack Self-Service Kosher Meats, Inc. v. Hooker*, No. 11-3517 (2d Cir., decided May 10, 2012)**.

The previous law, which defined "kosher" in terms of orthodox Hebrew religious requirements and required adherence to them, was found to (i) advance religion, i.e., the dietary restrictions of Orthodox Judaism, and (ii) inhibit religion "by preventing labeling of food products as kosher that did not meet the Orthodox Jewish religious requirements." The newer version simply required those marketing their food products as "kosher" to label them as kosher and to "identify the individuals certifying their kosher nature." The new law did not "define kosher or authorize state inspectors to determine the kosher nature of the products." A New York deli and butcher shop, its shareholders, officers and directors, and a Conservative Jewish rabbi, who had successfully challenged the previous version of the law, also challenged its successor.

Granting the defendants' motion to dismiss, the district court found that the new kosher law had a valid secular purpose and, unlike its predecessor, was "purely a labeling and disclosure law" that "neither endorses a particular religious viewpoint nor creates an impermissible entanglement with religion." The Second Circuit agreed.

Court Dismisses "Non-GMO" Lawsuit Against Beverage Cos. Filed by "Frequent Flyer"

A federal court in Maryland has dismissed, under the first-to-file rule, a lawsuit brought by a plaintiff characterized as a "frequent flyer in the United State judicial system," finding that five similar putative class action lawsuits against the defendants, three of which were filed before the plaintiff filed his complaint, are currently pending in a federal court in California. *Hinton v. Naked Juice Co.*, No. 8:11-cv-03740-AW (U.S. Dist. Ct., D. Md., S. Div., decided April 30, 2012).

The plaintiff, who has apparently filed at least 43 other federal civil lawsuits, all dismissed as frivolous, sought $100,000 in damages from the defendants, claiming that they label their beverages as "Non-GMO" and "natural" while using genetically modified and synthetic ingredients. He filed the complaint in state court, and it was removed to federal court. After the defendants sought to dismiss the case or transfer it to California on convenience grounds, the plaintiff filed a motion for remand. The court found that the (i) plaintiff was a member of the putative classes in the actions brought in California, (ii) theories asserted in the cases "are essentially the same," and (iii) causes of action have considerable overlap. Accordingly, the court dismissed "the action as duplicative under the first-to-file rule."

The court also would have transferred the case to California because the plaintiff could have brought his action there, despite his alleged residency in Maryland, because he has "repeatedly filed cases in out-of-state courts, including at least one in California." In a footnote, the court observes that the plaintiff has also filed actions claiming to be a Virginia resident and an Alabama resident. The court denied the plaintiff's motion to remand, determining that it was frivolous.

Animal Rights Groups Claim Foie Gras Sales Violate Federal Poultry Law

A coalition of animal rights organizations has reportedly filed a lawsuit against the U.S. Department of Agriculture (USDA) in federal court, alleging that the agency has violated the Poultry Products Inspection Act by allowing foie gras to be sold to consumers. *Animal Legal Defense Fund v. USDA*, No. n/a (U.S. Dist. Ct., C.D. Cal., filed May 9, 2012). According to the plaintiffs, "the USDA is responsible for condemning all poultry products that come from diseased birds. Foie gras consists of the pathologically diseased livers of ducks who are force-fed massive amounts of grain, inducing the disease of hepatic lipidosis, which causes their livers to swell to ten times their normal size."

The organizations have petitioned the agency in the past to require warning labels that would state "NOTICE: Foie gras products are derived from diseased birds." And they now cite a recent study that purportedly linked the consumption of foie gras to secondary amyloidosis, a potentially fatal human disease of

particular danger to those with chronic inflammatory disease. *See Huffington Post* and *Farm Sanctuary* and *Animal Legal Defense Fund Press Releases*, May 9, 2012.

Meanwhile, some 100 California chefs have apparently petitioned the state assembly seeking to overturn a foie gras production ban enacted in 2004 that takes effect July 1. Some of the chefs apparently believe the prohibition will trigger a black market in the state; they also oppose government mandates of this nature. Chicago tried to prohibit the sale of foie gras, according to a news source, but city chefs were able to defeat it by giving away free foie gras. Additional information about the Chicago ban appears in **Issue 182** of this *Update*. California's legislative leaders have reportedly indicated that they do not intend to repeal the law. Democratic Party Chair John Burton, who supported the legislation, was apparently surprised about the protest, wondering what had taken the chefs so long to take action. *See The Washington Post,* May 3, 2012; *UPI.com*, May 6, 2012.

Class Claims Kefir Products Are Falsely Advertised

New York and New Jersey residents have filed a putative class action in an Illinois federal court against the company that makes a line of kefir dairy products, alleging that they are falsely promoted as providing "clinically proven therapeutic benefits for various health conditions." *Keatley v. Lifeway Foods, Inc.*, No. 12CV3521 (U.S. Dist. Ct., N.D. Ill., E. Div., filed May 8, 2012).

According to the complaint, Lifeway claims, without adequate proof, that its kefir products containing ProBoost, "an exclusive blend of live and active probiotic cultures," can support immunity, enhance digestion, boost well-being, alleviate diarrhea, and otherwise address autoimmune disorders, bad breath, celiac disease, Crohn's and colitis, high cholesterol, immune deficiency, infantile colic, irritable bowel syndrome, lactose intolerance, seasonal allergies, and yeast infections. The plaintiffs contend that they would not have purchased the products if they had known that ProBoost products "did not have the quality, health benefits or value as promised."

Seeking to certify a nationwide class and two state subclasses of consumers, the plaintiffs allege violation of the Magnuson-Moss Act; unjust enrichment; breach of express warranty; intentional misrepresentation; fraudulent concealment/nondisclosure; and violations of Illinois, New Jersey and New York consumer protection laws. They seek declaratory and injunctive relief; compensatory, treble and punitive damages exceeding $5 million; interest; restitution; attorney's fees; and costs.

Red Wax Seal Is Protected Trademark for Maker's Mark

The Sixth Circuit Court of Appeals has determined that the red dripping wax seal that Maker's Mark Distillery has registered as a trade dress element used on its Kentucky bourbon bottles is protected under trademark law due to its strength and distinctiveness in the marketplace, thus upholding a lower court ruling that Jose Cuervo infringed the mark by using a similar element on its tequila bottles. ***Maker's Mark Distillery, Inc. v. Diageo N. Am., Inc.*, Nos. 10-5508/5586/5819 (6th Cir., decided May 9, 2012)**. With the apparent care of a connoisseur, the opinion's author opens with a detailed history, part legend, of the birth of bourbon and explains how Maker's Mark came to use the red dripping wax seal on its bottles. According to the court, the evidence fully supported the district court's evaluation of the strength of the mark and its balancing of the factors regarding consumer confusion over Jose Cuervo's similar mark. The court also upheld the lower court's award of partial costs and fees to the plaintiff.

Patent/Trademark Infringement Suit Takes Aim at Grape Tomatoes

A Texas-based tomato producer has sued a Canadian company in federal court alleging that its packaging and label for grape tomatoes infringes the Nature Sweet Cherubs™ patents, issued in 2010 and 2011, and trademarks, in use since 2007. *NatureSweet, Ltd. v. Mastonardi Produce Ltd.*, No. 3:12-cv-01424-G (U.S. Dist. Ct., N.D. Tex., Dallas Div., filed May 8, 2012). According to the complaint, the defendant's "Angel Sweet" label copies the Sweet Cherubs™ label by using similar colors and a "winged tomato design mark." Claiming that its mark, in which the company has made a considerable investment, is famous and distinctive, the plaintiff alleges a likelihood of confusion among consumers by defendant's use of similar marks and packaging. The plaintiff also claims that the defendant's grape tomatoes, in contrast to its own, "do not have the same consistent great taste throughout the year."

Alleging federal trademark infringement, dilution and unfair competition; unjust enrichment; and design patent infringement, the plaintiff seeks injunctive relief, recall and destruction of all infringing packaging and promotional material, an accounting, actual and treble damages, attorney's fees, costs, and interest.

EU Court of Justice Finds Certain Dutch Eco-Contracting Requirements Unlawful

The Court of Justice of the European Union (EU) has agreed, in part, with the European Commission's challenge to requirements imposed by the Dutch government on contractors providing organic and fair trade products in its automatic coffee machines. **Case C-368/10 EC v. *Kingdom of the Netherlands* (E.C.J., decided May 10, 2012)**. According to the Court, government requirements for the award of contracts may be based on environmental or social criteria, but the criteria must be clear and the government must allow proof "that a product satisfies those criteria by all appropriate means." The Court also held that "all the conditions and detailed rules of the award procedure must be drawn up in a

clear, precise and unequivocal manner in the notice or contract documents." To the extent that the Dutch requirements fell short of these standards, the Court found that the government failed to fulfill its obligations under the award of public contracts directive.

Grocers Sued Under Prop. 65 for Purportedly Selling Lead-Tainted Honey

The Center for Environmental Health has reportedly sued several grocery chains in California alleging that independent testing has shown that the honey they were selling contains high levels of lead in violation of Proposition 65 (Prop. 65). Some of the honey purchased and tested allegedly contained lead levels more than double the legal limit. According to the center, honey suppliers sometimes use metal barrels with lead solder that can leach into the honey. It is seeking agreements that would bind the companies to use non-leaded containers for their honey and to test their supplies for lead content. *See Center for Environmental Health News Release*, May 2, 2012.

OTHER DEVELOPMENTS

IOM Issues Weight of the Nation™ Strategy Report

The Institute of Medicine (IOM) has published a May 8, 2012, **consensus report** assessing more than 800 obesity prevention strategies and identifying those "with the greatest potential to accelerate success." Released at the Centers for Disease Control and Prevention's Weight of the Nation™ conference and funded by the National Academies of Sciences, Robert Wood Johnson Foundation and Michael & Susan Dell Foundation, the report evidently focuses on five goals for preventing obesity: (i) "integrating physical activity into people's daily lives"; (ii) "making healthy food and beverage options available everywhere"; (iii) "transforming marketing and messages about nutrition and activity"; (iv) "making schools a gateway to healthy weights"; and (v) "galvanizing employers and health care professionals to support healthy lifestyles." Included in these goals are specific recommendations that address, among other things, sugar-sweetened beverage consumption, the availability of lower-calorie children's meals in restaurants, nutritional labeling, and food and beverage marketing to children.

In particular, IOM's Committee on Accelerating Progress in Obesity Prevention urges both the public and private sectors to incentivize nutritious diets and physical activity while discouraging the consumption of sugar-sweetened beverages and other foods not in alignment with the federal government's dietary guidelines. The report thus recommends "substantial and specific excise taxes on sugar-sweetened beverages…, with the revenues being dedicated to obesity prevention programs," as well as requiring restaurants to ensure "that at least half of all children's meals are consistent with the food and calories guidelines of the *Dietary Guidelines for Americans* for moderately active 4- to 8-year-olds and

are competitively priced." It also calls on the Food and Drug Administration and U.S Department of Agriculture to develop "consistent nutrition labeling for the front of packages [FOPs], retail store shelves, and menus and menu boards that encourages healthier food choices" and to implement a mandatory FOP system that would help consumers "compare products on a standard nutritional profile."

In addition, the report authors have asked the food, beverage and media industries to consider adopting "common standards for marketing foods and beverages to children and adolescents." These standards would require that all products advertised to this age group conform to the *Dietary Guidelines for Americans,* with the Federal Trade Commission, Children's Food and Beverage Advertising Initiative and National Restaurant Association Initiative ensuring compliance among member companies. "If such marketing standards have not been adopted within two years by a substantial majority of food, beverage, restaurant, and media companies that market foods and beverages to children and adolescents, policy makers at the local, state and federal levels should consider setting mandatory nutritional standards for marketing to this age group to ensure that such standards are implemented," concludes the report.

"As the trends show, people have a very tough time achieving healthy weights when inactive lifestyles are the norm and inexpensive, high-calorie foods and drinks are readily available 24 hours a day," said IOM Committee Chair Dan Glickman. "Individuals and groups can't solve this complex problem alone, and that's why we recommend changes that can work together at the societal level and reinforce one another's impact to speed our progress." *See National Academies Press Release,* May 8, 2012.

When Gruyère Cheese Is Not Made in Gruyère, Is It Still Gruyère Cheese?

A Wisconsin-based cheese maker has reportedly agreed, under pressure from its Swiss parent and the Swiss gruyère industry, to cease using the word "gruyère" in labeling and promoting its Grand Cru Gruyère cheese. The change, effective in May 2013, was agreed to despite a recent decision by the U.S. Patent and Trademark Office (USPTO) refusing the "le gruyère" trademark because "[t]he existence of seven U.S. cheese manufacturers of gruyère cheese and the widespread generic internet and dictionary usage . . . clearly demonstrate that gruyère has lost its geographical significance and is now viewed as a genus of cheese."

Geographical food and beverage designations are significant in Europe where many EU countries give them legal protection; a French reporter apparently visited Wisconsin to cover the negotiations leading to the agreement. She indicated her wish that American cheese makers adopt the European approach and name their cheeses after the area of origin, saying "It's not a question of name. The soil is different, so the taste of the cheese will be different. It's something that is obvious in Europe." Gruyère production in a particular Swiss region reportedly dates to the 13th century and could be even older given the legend

that a Roman emperor died of indigestion in 161 CE after consuming too much cheese from the Gruyère region.

According to a news source, the Virginia-based Consortium for Common Food Names issued a statement this week praising USPTO for taking "a common-sense approach to generic names that protects both consumers and producers." A spokesperson reportedly said, "What we're against are efforts to monopolize." *See The Monroe Times*, May 9, 2012.

MEDIA COVERAGE

Iowa Kosher Meatpacking Plant Manager Seeks U.S. Supreme Court Consideration

Asking "Wouldn't it be better, as a general rule, if judges who meet regularly with prosecutors in advance of a cascade of high-profile indictments didn't hear the cases that follow?," *Slate* court-watcher Emily Bazelon recently discussed the petition for *certiorari* currently pending before the U.S. Supreme Court in the case of the kosher meatpacking facility manager convicted of bank fraud and sentenced to 27 years, essentially a life term for the 50-year-old defendant from Iowa. ***Rubashkin v. United States*, No. 11-1203 (U.S., petition for cert. filed April 2, 2012)**.

Mostly on procedural grounds, a federal appeals court rejected the defendant's claims that the judge should have recused herself because she participated extensively with prosecutors in activities that led to an immigration raid on the facility, the detention and deportation of hundreds of workers, and charges of harboring illegal immigrants, child labor law violations and bank fraud. Bazelon suggests that the Court will not review the matter given that the jurors who convicted the defendant "sat for 18 days and reviewed more than 9,000 exhibits," a thicket the justices are not likely to want to wade into. Still, writes Bazelon, "even if you can't bring yourself to care much about the fate of Sholom Rubashkin, the oddities of this case don't sit well. Judges shouldn't be able to make up their own rules for policing themselves." Additional information about the case appears in **Issue 410** of this *Update*.

SCIENTIFIC/TECHNICAL ITEMS

Rhesus Monkey Study Allegedly Reveals Link Between BPA and Breast Cancer

A recent study has reportedly claimed that bisphenol A (BPA) alters mammary gland development in rhesus monkeys, raising concerns about the chemical's alleged link to breast cancer in humans. Andrew Tharp, et al., "Bisphenol A alters the development of the rhesus monkey mammary gland," *PNAS*, May 2012. According to the study, researchers fed fruit containing 400 µg of BPA per kilogram of body weight to pregnant rhesus monkeys to achieve BPA serum

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levels "comparable to [those] found in humans." The authors then examined the mammary glands of female offspring after birth, noting that "the density of mammary glands was significantly increased in BPA-exposed monkeys, and the overall development of their mammary gland was more advanced compared with unexposed monkeys."

Based on these results, one study author told media sources that the sum of scientific evidence suggests that BPA is also "a breast carcinogen in humans" and that its use should be reduced. "Previous studies in mice have demonstrated that low doses of BPA alter the developing mammary gland and that these subtle changes increase the risk of cancer in the adult," explained another study author in a May 7, 2012, *ScienceDaily* article. "Some have questioned the relevance of these findings in mice to humans. But finding the same thing in a primate model really hits uncomfortably close to home."

Meanwhile, the American Chemistry Council (ACC) has reportedly drawn attention to the study's limited scope. "It's hard to see the study's relevance to humans, as only four or five animals were tested and the dose used was 10,000 times higher than typical human exposure to BPA, as documented by the Centers for Disease Control and Prevention's large-scale biomonitoring studies," an ACC spokesperson said. *See McClatchy Newspapers,* May 7, 2012.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400