

Food & Beverage

LITIGATION UPDATE

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LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Launches Nanotechnology Task Force, Solicits Public Comment on the Use of Nanotechnology Materials in FDA-Regulated Products

FDA yesterday announced formation of a nanotechnology task force charged with identifying knowledge and policy gaps that could prevent the agency from effectively evaluating possible adverse health effects from FDA-regulated products that contain nano-engineered components. Among other things, task force responsibilities include (i) assessing the value of current regulatory approaches with respect to “unique” challenges that nanotechnology might present in FDA-regulated products; (ii) building collaborative relationships with other federal agencies taking part in the National Nanotechnology Initiative; and (iii) hosting an October 10, 2006, public meeting for the purpose of helping the agency learn about “the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices.” The meeting will be held on the campus of the National Institutes of Health in Bethesda,

Maryland; details will appear in a notice slated for publication in the *Federal Register* on August 11. Written or electronic comments must be submitted by November 10. See *FDA News Release*, August 9, 2006.

Litigation

Warnings

[2] Class Action Claims Based on Lactose Intolerance Dismissed

Finding that a 1990 amendment to the Federal Food, Drug, and Cosmetic Act preempts the imposition of labeling duties on dairy producers and retailers by means of state court action, a federal district court has dismissed a putative class action filed in October 2005 by 10 lactose intolerant individuals in the District of Columbia. [*Milton Mills, M.D. v. Giant of Md., LLC, No. 05-02211 \(U.S. District Court, District of Columbia\) \(decided August 2, 2006\).*](#)

The named plaintiffs alleged that they had unwittingly been subjected to gastrointestinal pain and discomfort by purchasing and consuming milk sold by the defendants. They sought monetary damages and a permanent injunction requiring defendants to provide product labeling that would describe the purported risks of lactose intolerance. Additional information about the lawsuit can be found in issue 146 of this Report.



U.S. District Court Judge Henry Kennedy, Jr. states, “there is little doubt that the common law duties plaintiffs seek to impose constitute ‘requirements for a food which is the subject of a standard identity.’” The plaintiffs, who claim that 75 percent of the world’s population is lactose-intolerant, had suggested that appropriate milk product labels could state: (i) “Warning – if you experience diarrhea or stomach cramps after consuming milk, you may be lactose intolerant. Check with your physician”; or (ii) “Warning – Lactose intolerant individuals may experience bloating, diarrhea, or other gastrointestinal discomfort from consuming milk. Check with your physician.”

The court notes that such warning labels would “far exceed” federal requirements mandated by the “standard of identify,” which applies to milk and cream, set forth in 21 C.F.R. § 131. The court further observes that deviations from federal requirements are allowed under the law, “but only following a formal application to [the Food and Drug Administration].” Plaintiffs apparently sought to bring their warning under a safety exception to the federal rules, but the court was not convinced that flatulence, bloating, cramps, and diarrhea rose to the level of a safety concern. The court also found that the plaintiffs’ claims did not state a cause of action under District of Columbia law, because under the Restatement (Second) of Torts § 402A, sellers, who may reasonably assume that those with common allergies are aware of them, are not required to warn about allergies to common food items.

Legal Literature

- [3] “Low-Fat Foods or Big Fat Lies?: The Role of Deceptive Marketing in Obesity Lawsuits,” Matthew Walker, *Ga. St. U. L. Rev.*, Spring 2006

This student-authored note examines deceptive food marketing and its potential to support obesity-related lawsuits “in light of the fact that such claims could soon be one of the only theories by which consumers could hold a food industry defendant liable for obesity and related health problems.” The note discusses litigation already undertaken, including *Pelman v. McDonald’s Corp.*, 396 F.3d 508 (2d Cir. 2005), the legal theories that anti-tobacco attorneys Richard Daynard and John Banzhaf have espoused to impose obesity-related liability on the food industry, and the difficulties faced by those attempting to hold food manufacturers accountable under negligence theories.

The author recognizes that individuals must take responsibility for their eating choices and that some lawyers are bringing obesity-related litigation “purely for personal financial gain.” Nevertheless, he concludes that a continuing threat of litigation based on deceptive marketing theories will encourage “the industry to take responsibility for its role in this problem.” The author contends that the hurdles facing plaintiffs bringing such claims limit any potential for serious economic harm the food industry could experience.



[4] National Ag Law Center Updates Bibliography

The University of Arkansas National Agricultural Law Center recently published an updated [agricultural law bibliography](#). The document contains references to law review and journal articles focusing on issues ranging from biotechnology, the environment and food and drug law to farm policy, pesticides and torts and insurance, among other matters.

Other Developments

[5] International Organization Issues Framework for Food Corporations to Address Obesity

Declaring that “the world’s food companies are ‘not yet fully engaged with the seriousness and urgency’” of the global obesity problem, the International Business Leaders Forum (IBLF) and Insight Investment have issued “A Proposed Framework for the Corporate Response to Addressing Consumer Health and Obesity.” The framework assumes that the food industry can play a key role in promoting healthier lifestyles and suggests how businesses can take action in the workplace, the marketplace and the community to do so.

The IBLF is a non-profit organization “that aims to promote responsible business leadership.” According to the director of IBLF’s Healthy Eating & Active Living Global Partnership, “Consumer health and obesity are crucial public health issues which

demand further attention and resources.” Insight Investment is described as one of the United Kingdom’s largest investment managers. Its investment responsibility director stated, “While companies are increasingly recognizing the importance and value of acting responsibly, many in the food sector appear blind to how critical consumer health issues are likely to be their future business successes.”

The product of these organizations’ collaboration on obesity urges food companies to fully understand the issues, formulate strategies, establish governance mechanisms, and roll out an action plan. The framework identifies companies that demonstrate good practices because they appear to understand the risks and opportunities presented by the “obesity epidemic,” including changing consumer preferences and increased government regulation. Specific recommendations include the development of “healthier product portfolios,” a range of portion-size options, informative package labeling, nutrition education, and physical activity promotion.

The framework includes a section on marketing to children, noting that many companies are already addressing youth marketing issues, some by eliminating in-school sales and advertising that targets children younger than age 8. IBLF and Insight Investment are hoping to “inform and inspire food companies to commit to playing a full role in responding to the crisis and to develop long-term, workable solutions.” The framework cites World Health Organization statistics showing that 1 billion adults are overweight with 300 million clinically obese and at risk for a variety of chronic diseases.



Media Coverage

[6] **“Is It the Drunk or the Drink Doing the Talking?”** John Schwartz, *The New York Times*, August 6, 2006

Seeking an explanation for actor Mel Gibson’s anti-Semitic outbursts during a recent drunk driving arrest, a *New York Times* reporter questioned experts about the effects of alcohol on the brain. Because alcohol suppresses the prefrontal cortex and the cerebellum regions of the brain, inhibitions are reduced and it is more difficult to suppress inappropriate behavior, according to experts who study addictions. “Alcohol brings you back into adolescence and childhood,” said the director of the National Institute on Drug Abuse, and after a couple of drinks, it is more difficult to suppress desires and urges that may otherwise be inappropriate. Nevertheless, anecdotal evidence shows that some individuals under the influence will do completely uncharacteristic things, leaving unanswered, “where, exactly did those words come from?”

Scientific/Technical Items

Diabetes

[7] **Vegan Diet Allegedly Linked to Reversal of Diabetes Symptoms**

Type 2 diabetics who adhere to a low-fat vegan diet, a regimen that removes all meat, fish and dairy products and is also low in added fat and sugar, have lower blood sugar and lose more weight than individuals on the standard American Diabetes Association diet. (N. Barnard, et al., “A Low-Fat Vegan Diet Improves Glycemic Control and Cardiovascular Risk Factors in a Randomized

Clinical Trial in Individuals With Type 2 Diabetes,” *Diabetes Care* 29: 1777-1783, 2006). Researchers studied 99 individuals with Type 2 diabetes and assigned them randomly to either a low-fat, low-sugar vegan diet or to the standard American Diabetes Association diet. The vegan diet excludes any animal-derived foods, but does not limit carbohydrates, portion sizes or calories. After five months of observation, the research team found that individuals on the vegan diet showed improvements in blood sugar control, cholesterol reduction, weight control and kidney function. In addition, 43 percent of those following the vegan diet were reportedly able to reduce their use of diabetes medications, compared to 25 percent in the group on the American Diabetes Association diet. The study’s lead author was quoted as saying that he hopes the study’s conclusions will “rekindle interest in using diet changes first, rather than prescription drugs.” See *Reuters*, July 27, 2006.



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LITIGATION UPDATE

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