

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Issues Revised Bioterrorism Preparedness Compliance Guides

FDA has issued two revised guides for enforcement of specific provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The compliance guide dealing with [prior notice of imported foods](#) provides additional guidance to FDA and Customs and Border Protection staff about prior notices that fail to “provide the identity of the manufacturing facility of food no longer in its natural state, articles of food imported or offered for import by express courier, prior notice time frames, and lastly, gift packs purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes.” The [other guide](#) provides additional information for FDA staff charged with oversight of the registration of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. See *Federal Register*, November 9, 2004.

Federal Trade Commission (FTC)

[2] Public Interest Group Asks FTC to Enjoin SUBWAY Restaurant Ads

The National Legal and Policy Center (NLPC) has [petitioned](#) the FTC to order SUBWAY Restaurants to discontinue a television advertising campaign that the public interest group deems “misleading and possibly dangerous to health.” The ads in question compare eating a McDonald’s Big Mac with a 12-inch SUBWAY Sweet Onion Chicken Teriyaki sandwich and say that the sub contains 10 grams of fat while the Big Mac contains 33 grams of fat. SUBWAY spokesperson Jared Fogle goes on to say that the fat content comparison “means you can eat another and another [chicken subs] over the course of three meals and still not equal the fat content of one Big Mac.” A voiceover later adds: “Who else but SUBWAY really cares that you live a long and healthy life?”

In announcing the FTC complaint, NLPC Chair Ken Boehm was quoted as saying that SUBWAY bases its claim “on the fact that the fat content in the three chicken teriyaki subs is slightly less than the fat content of a Big Mac, but they conveniently ignore the fact that those three sandwiches have 3.5 times the calories in a Big Mac, and they are loaded with much more cholesterol, sodium, carbohydrates, and sugar.” A spokesperson for the sandwich chain reportedly disputed NLPC’s allegations, asserting the



commercials compare only the fat content of the two products. “That’s the claim Jared makes, and it is absolutely correct,” he said. “We are not encouraging anybody to eat three foot-long Sweet Onion Chicken Teriyaki subs in one sitting.” See *The Boston Herald*, November 5, 2004.

European Union (EU)

[3] Hormone Controversy Leads EU to File WTO Complaint Against United States and Canada

The European Union initiated a World Trade Organization case against the United States and Canada this week over the two nations’ boosting of tariffs on European textiles, meat and other food exports in retaliation for the EU’s continuing ban on imported beef treated with growth hormones. Despite a 1998 WTO ruling that the EU’s contentions about the purported danger of hormone-treated beef were scientifically unfounded, the EU imposed a permanent ban on imports of beef products treated with estradiol and a provisional ban on beef treated with five other hormones in October 2003, citing European research that linked residues of the hormones to cancer in humans. A spokesperson for U.S. Trade Representative Robert Zoellick was quoted as saying the EU is worried about hormone levels that are about “50 times less than the acceptable daily intake and represent a tiny fraction of what occurs naturally in an egg or one glass of milk.” If negotiations among the parties fail to resolve the trade dispute within 60 days, the EU can ask the WTO to issue a binding ruling on the legality of the U.S. and Canadian tariffs. See *EU Press Release, Bloomberg* and *Associated Press*, November 8, 2004.

State/Local Initiatives

[4] California Voters Decide GM Crop Proposals

Voters in Marin County, California, last week approved a ballot measure calling for a ban on the growing of genetically modified crops in the area, while voters in Butte, San Luis Obispo and Humboldt counties rejected similar initiatives. News sources indicate that observers expected the measure in Humboldt County to be defeated because it called for the jailing of farmers who use GM seeds. Voters in Mendocino and Trinity counties approved biotech crop bans earlier this year. See *Associated Press* and *The Sacramento Bee*, November 3, 2004.

Litigation

Atkins Diet

[5] Florida Judge Allows Suit Against Atkins Nutritionals to Proceed

Palm Beach County Judge Susan Lubitz has denied Atkins Nutritionals’ motion to dismiss a Florida businessman’s lawsuit which alleges that following the high-protein diet plan resulted in his “life-threatening” heart disease. *Gorran v. Atkins Nutritionals, Inc.*, Case No. Unknown (County Court for Palm Beach County, Florida) (filed May 27, 2004). See *Reuters* and *Physicians Committee for Responsible Medicine News Release*, November 4, 2004.

Fifty-three-year-old Jody Gorran seeks damages “of less than \$15,000” under Florida’s Deceptive and Unfair Trade Practices Act as



well as common-law claims of negligent misrepresentation and product liability. He also requests “a permanent injunction preventing [defendants] from promoting and marketing their diet and products unless each such product and all marketing materials used have warnings deemed adequate by the Court to advise consumers of the risks of the Atkins diet.”

Legal Literature

[6] Safety and Security of U.S. Food Supply Focus of *Food and Drug Law Journal*

Nine articles in *Food and Drug Law Journal* explore the question of whether the multi-agency system the United States now employs to regulate food-related issues should be consolidated under the umbrella of a single food agency to eliminate overlapping responsibilities and better meet such emerging challenges as biotechnology and bioterrorism. Most of the authors, including Senator Richard Durbin (D-Ill.), Caroline Smith DeWaal of the Center for Science in the Public Interest, and Sir John Krebs, chair of Britain’s Food Safety Agency, advocate establishment of a single agency, claiming that agencies making up the current food safety infrastructure are largely ineffective due to insufficient or overlapping authority, fragmented resources and perceived conflicts of interest. Other authors believe establishment of a single agency would endanger food security because “the extensive amount of time required to merge such large, multifaceted regulatory agencies and resolve long-standing jurisdictional and other issues would jeopardize existing safeguards and potentially compromise the food supply.” See 59 *Food and Drug Law Journal* 383-458 (2004).

Other Developments

[7] Reducing Food Industry’s Exposure to Obesity Claims Is Theme of January 2005 Conference

Longtime antitobacco lawyer Richard Daynard will reportedly kick off the [2nd National Forum on Preventing and Defending Obesity Claims](#) by explaining reasons why plaintiffs’ groups plan to target the food industry with consumer fraud allegations. The event is slated for January 24-25, 2005, at the St. Regis Hotel in Washington, D.C. Other sessions at the conference will include discussions of (i) complying with federal agency programs that address diet and obesity; (ii) understanding “addiction” allegations; (iii) refuting scientific studies; (iv) establishing “best practices” with respect to advertising, labels and nutritional content; (v) defeating consumer fraud allegations; (vi) dealing effectively with insurance coverage issues; and (vii) establishing consistent document retention policies. [Victor Schwartz](#), chair of Shook, Hardy & Bacon’s Public Policy Group, will participate in a panel discussion of state and federal obesity litigation reform initiatives.

Scientific/Technical Items

Cardiovascular Disease

[8] Fruits and Vegetables Reduce Risk of Cardiovascular Disease but Not Cancer, Say Harvard Researchers

Increased consumption of fruits and vegetables is associated with a decreased risk of cardiovascular disease but not cancer, according to Harvard School of Public Health researchers. (H.-C. Hung, et al.,



“Fruit and Vegetable Intake and Risk of Major Chronic Disease,” *Journal of the National Cancer Institute* 96: 1577-1584, 2004). The research team analyzed data from more than 100,000 participants in two large studies, the Nurses’ Health Study and the Health Professionals’ Follow-Up Study, and reported an inverse or negative association between total fruit and vegetable consumption and the risk of cardiovascular disease, but no relationship with cancer incidence. Consumption of green leafy vegetables showed the strongest inverse association with both cardiovascular disease and cancer. Even though the American Heart Association recommends five or more servings of fruits and vegetables daily, the researchers noted that a protective effect for fruit and vegetable intake against cancer may be overstated.

In an accompanying editorial, National Cancer Institute researchers opine that substantial errors in measuring dietary intake may distort true associations between fruit and vegetable consumption and cancer. (A. Schatzkin and V. Kipnis, “Could Exposure Assessment Problems Give Us Wrong Answers to Nutrition and Cancer Questions?” *Journal of the National Cancer Institute*: 96, 1564-1565, 2004). They conclude that “the evidence is simply inadequate at this time to determine whether fruit and vegetable intake confers moderate protection against cancer.”

Obesity

[9] **Obese and Overweight Men Spend More on Prescription Drugs**

A study conducted at the Mayo Clinic involving 328 male corporate executives has found that prescription-drug costs are higher for obese and overweight men than for those of normal weight. Presented this week at the American Heart Association’s annual meeting in New Orleans, the study reportedly indicated that normal-weight men spend an average of nearly \$23 on prescription drugs every month, while overweight men spend about \$39 and obese men, about \$80 per month. Overweight and obese men used blood-pressure lowering drugs more frequently and also experienced higher rates of low-back pain, degenerative joint disease, sleep apnea, gastroesophageal reflux disease, depression, and gout. *See The Wall Street Journal*, November 8, 2004.



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