

Food & Beverage

LITIGATION UPDATE

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Table of Contents

Legislation, Regulations and Standards

- [1] HHS Says Research Article Describing Potential Contamination of U.S. Milk Supply Is a “Road Map for Terrorists”; USDA Says Bioterrorists Could Target School Lunches1
- [2] FTC Settles Complaint with Tropicana over Misleading Claims in Orange Juice Ads2
- [3] CDC Director Tries to Clarify Agency’s Stance on Obesity2
- [4] Britain’s Food Standards Agency Seeks Input on Science Strategy3

Legal Literature

- [5] “A Matter of Some Weight: As Obesity Claims Increase, Experts Say the Issue Isn’t Nature or Nurture – It’s Bias,” Margaret Graham Tebo, *ABA Journal*, June 20053

Other Developments

- [6] Environmental Defense Report Provides Estimates of Antibiotics Use in Agricultural Feed3

Scientific/Technical Items

- [7] Plastics Additive Used in Food Packaging Purportedly Linked to Breast Cancer4

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Legislation, Regulations and Standards

Department of Health and Human Services (HHS)

**[1] HHS Says Research Article Describing
Potential Contamination of U.S. Milk
Supply Is a “Road Map for Terrorists”;
USDA Says Bioterrorists Could Target
School Lunches**

HHS has reportedly asked the National Academy of Sciences (NAS) not to publish a research article whose authors speculate about the ease with which bioterrorists could poison the U.S. milk supply with botulinum toxin. The article is a “road map for terrorists and publication is not in the interests of the United States,” HHS Assistant Secretary Stewart Simonson reportedly wrote in a letter to NAS President Bruce Alberts. “It seems clear on its face that publication of this manuscript could have very serious public health and national security consequences,” Simonson said. Co-authored by Stanford University Business Professor Lawrence Wein, the article was scheduled for publication in a forthcoming issue of the *Proceedings of the National Academy of Sciences*. Wein provided details of the

potential contamination scenario and recommendations to prevent such an event in a *New York Times* commentary titled “Got Toxic Milk” on May 30, 2005.

According to a news source, the contested article was approved through the normal NAS vetting process, although HHS officials had apparently expressed concerns about its content in fall 2004 when Wein provided the agency a draft. “He [Wein], at that time, indicated that he was going to work it over a bit and he’d be back to us, back to HHS, if and when he submitted it for publication,” a HHS spokesperson was quoted as saying. “That was the last we ... heard from him.” Representatives of HHS and NAS were scheduled to meet yesterday to discuss the fate of the article. *See CNN.com*, June 7, 2005.

Meanwhile, a Food Safety and Inspection Service (FSIS) administrator reportedly told a gathering of the Association of Food and Drug Officials this week that the federal school lunch program is “particularly vulnerable” to the threat of bioterrorism. Carol Maczka said FSIS has already completed evaluations of the vulnerability to tampering of milk, spaghetti sauce and egg substitutes and is currently evaluating the contamination risks posed to chicken nuggets. She noted that school lunch providers must comply



with federal food safety checklists and provide evidence of food safety plans. *See Associated Press*, June 6, 2005.

Federal Trade Commission (FTC)

[2] FTC Settles Complaint with Tropicana over Misleading Claims in Orange Juice Ads

The FTC has settled a complaint against the Tropicana Products Inc. unit of PepsiCo. Inc. for unsubstantiated health claims in advertising and promotion for the company's "Healthy Heart" orange juice. "Orange juice contains many nutrients important to a healthy diet, and advertising can be an important source of information about the health benefits of foods," the director of FTC's Bureau of Consumer Protection said. "But it is essential that such advertising be truthful. In this case, Tropicana's claims went well beyond its scientific support."

According to the FTC complaint, Tropicana falsely represented that (i) consuming three glasses of "Healthy Heart" juice daily for one month would raise HDL cholesterol by 21 percent and improve the ratio of HDL to LDL cholesterol by 16 percent; (ii) drinking 20 ounces of the product daily for one month would increase blood folate levels by 45 percent and drop homocysteine levels by 11 percent; and (iii) drinking two glasses of the orange juice daily for two months would lower blood pressure by an average of 10 points. Under the proposed consent order, Tropicana would be prohibited from making the three challenged claims or any similar claims about the effects of orange juice on various health-related endpoints absent "competent and reliable scientific evidence." The order would also prohibit any misrepresentations related to studies or tests. The only claims the

proposed order would allow Tropicana to make are those that comply with specific Food and Drug Administration food labeling regulations. *See FTC News Release*, June 2, 2005; *The Wall Street Journal*, June 3, 2005.

Centers for Disease Control and Prevention (CDC)

[3] CDC Director Tries to Clarify Agency's Stance on Obesity

Amidst growing criticism of conflicting federal research on the extent to which obesity contributes to early death, CDC Director Julie Gerberding, M.D., last week convened a press conference to clarify the agency's stance on the issue. "What we don't want is for this debate to continue to confuse people," Gerberding said. "Obesity and overweight are critically important health threats in this country. They have many adverse consequences," she said.

In April 2005, findings from CDC researchers suggested that previous government estimates of excess mortality due to obesity were inaccurate. (K. Flegal, et al., "Excess Deaths Associated with Underweight, Overweight, and Obesity," *Journal of the American Medical Association* 293(15): 1861-1867, April 20, 2005). The Flegal study's conclusion that poor diet and physical inactivity accounted for some 112,000 deaths a year sharply contrasted with the results of a revised 2004 CDC study co-authored by Gerberding that estimated obesity's death toll at 365,000. Claiming the "risk estimation process is in its infancy," Gerberding reportedly apologized for confusion over the studies' differing conclusions and reiterated the dangers of obesity-related illnesses. "A lot of people were hoping that CDC was going to come out and say it was okay



to be overweight, but we're not saying that. It is not okay to be overweight." See *CDC Telebriefing Transcript*, June 2, 2005; *Atlanta Journal-Constitution*, June 3, 2005.

United Kingdom

[4] Britain's Food Standards Agency Seeks Input on Science Strategy

Britain's Food Standards Agency has launched a [public consultation](#) seeking comment on the agency's science strategy for 2005-2010. Issues addressed in the strategy include transmissible spongiform encephalopathies, labeling, food allergies, obesity prevention, microbiological and chemical contaminant risks from imported food, and chemical and radiological risks generally. Comments are due by August 29, 2005. See *FSA News Release*, June 6, 2005.

Legal Literature

[5] "A Matter of Some Weight: As Obesity Claims Increase, Experts Say the Issue Isn't Nature or Nurture – It's Bias," Margaret Graham Tebo, *ABA Journal*, June 2005

"Lawsuits alleging discrimination based on weight are increasing," according to this *American Bar Association Journal* article. Such cases, the author says, are often based on the Americans with Disabilities Act or the few human rights ordinances in effect that include obesity. Addressing claims that being overweight increases health care costs, Paul Campos was quoted as saying, "There is no clear evidence that a person's size is the primary factor for determining overall health or longevity." The University of Colorado law professor is reportedly

one of several attorneys who lobby or litigate on behalf of overweight people and is the author of *The Obesity Myth*.

Advocates for the overweight are concerned about the consequences of characterizing obesity as either a disease or a moral failing. If obesity is considered a disease, treatments may be covered under health insurance policies and it "opens the door to more lawsuits against companies such as fast food providers," the advocates explain. Campos asserts that the moral-failing theory "would allow nearly unfettered discrimination by health providers, employers, insurers and others. ... People make a lot of assumptions based on weight that are simply morally and scientifically bankrupt. They codify their disgust with other people's appearance and allow discrimination." The solution, he says, is for lawmakers to make "body diversity" a human rights issue.

Other Developments

[6] Environmental Defense Report Provides Estimates of Antibiotics Use in Agricultural Feed

Livestock producers in North Carolina and Iowa reportedly use an estimated 3 million pounds of antibiotics as nontherapeutic feed additives each year, the same amount used for human medical treatment nationwide, according to a new [report](#) from the nonprofit organization Environmental Defense. "Feeding antibiotics to animals is not only a major cause of antibiotic-resistant bacteria in the human food supply, but also results in the presence of antibiotic-resistant bacteria in animals and in their waste," report co-author Rebecca



Goldburg was quoted as saying. "Those bacteria can in turn colonize and infect farm workers, as well as contaminate water, air and soil," she said. Environmental Defense advocates "swift" enactment of federal proposals (S. 742 and H.R. 2562) that would phase out the use of medically important antibiotics as feed additives. *See Environmental Defense Press Release*, June 1, 2005.

Scientific/Technical Items

Chemical Exposures

[7] **Plastics Additive Used in Food Packaging Purportedly Linked to Breast Cancer**

New research adds to the growing body of literature that suggests exposure to hormonally active chemicals such as bisphenol-A (BPA), a compound found in plastic food and beverage containers, could heighten the risk of breast cancer. (M. Munoz-de-Toro, et al., "Perinatal Exposure to Bisphenol-A Alters Peripubertal Mammary Gland Development in Mice," *Endocrinology*, May 27, 2005 (on-line publication: doi:10.1038)). The Boston-based research team studied the effects of perinatal exposure to low, environmentally relevant doses of BPA, which mimics the hormone estrogen, on the development of the mammary gland in female mice. Mice exposed to bisphenol-A in the womb apparently developed significantly greater breast tissue density than their control counterparts. Breast tissue density in humans is an established risk factor for breast cancer." *See Nature.com*, May 27, 2005.



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