

Food & Beverage

LITIGATION UPDATE

Issue 60 • December 10, 2003

Table of Contents

Legislation, Regulations and Standards

- [1] FDA Enhances Bioterrorism Safeguards1
- [2] FDA Requests Public Comments on Qualified Health Claim1
- [3] WHO Issues Draft Strategy on Diet, Physical Activity and Health.....1
- [4] EU Remains Undecided on Allowing Sale of GM Corn2

Legal Literature

- [5] "The Power of Positive Drinking: Are Alcoholic Beverage Health Claims Constitutionally Protected?" Ben Lieberman, 58 *Food and Drug Law Journal* 511 (2003)2

Other Developments

- [6] "Back Door to Prohibition: The New War on Social Drinking," Radley Balko, *Cato Institute Policy Analysis* #501, December 5, 20033
- [7] Brian Young, "Does food advertising influence children's food choices? A critical review of come of the recent literature," *International Journal of Advertising*, Vol. 22, No. 4, 20033
- [8] Lieberman Calls for FTC Investigation into Food Ads3

Media Coverage

- [9] Robert Levy, "Liquor and Beer Ads Are Not the Problem," *The Chicago Tribune*, December 8, 20033
- [10] "Who's to Blame? Obesity in America: How to Get Fat Without Really Trying," An ABC News Special with Peter Jennings, December 8, 20034

Scientific/Technical Items

- [11] Johns Hopkins' Researchers Allege Link Between Drinking and Brain Atrophy4

Shook,
Hardy &
Bacon L.L.P.

Food & Beverage

LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA and CBP Agreement to Enhance Bioterrorism Safeguards; Agency Delays Final Recordkeeping and Detention Rules

To help ensure the safety of imported foods, FDA and the office of U.S. Customs and Border Protection (CBP) have signed a memorandum of understanding that allows FDA to commission CBP officers to conduct any necessary investigations or examinations of food shipments in accordance with FDA's new rule requiring prior notice of food products imported or offered for import to the United States.

FDA has also announced a delay in finalizing two bioterrorism regulations related to the establishment and maintenance of records related to food and the administrative detention of food shipments that might pose a threat of serious adverse health effects or death to humans or animals. Initially expected in mid-December 2003, the final rules are now expected during March 2004. See *FDA News Release*, December 3, 2003.

[2] FDA Requests Public Comments on Qualified Health Claims

In an advanced notice of proposed rulemaking, FDA has requested public comment on qualified health claims -- those not supported by significant scientific agreement (SSA) -- and "other potential initiatives to help consumers choose a healthy diet." The three broad areas of FDA inquiry include

(i) alternatives for regulating health claims not meeting the SSA standard, (ii) data and research on a substance/disease relationship, (iii) the use of phrases such as "FDA authorized" in qualified and unqualified health claims, (iv) consumer education about qualified health claims, and (v) dietary guidance statements on conventional food and supplement labels. Interested parties must submit comments by January 26, 2004. See *Federal Register*, November 25, 2003.

World Health Organization (WHO)

[3] WHO Issues Draft Strategy on Diet, Physical Activity and Health

After consultations with all concerned stakeholders, WHO has issued its [*Draft Global Strategy on Diet, Physical Activity and Health*](#) for review by WHO's executive board in preparation for the World Health Assembly in May 2004. The strategy aims to provide a framework by which regional and national authorities can establish action plans to reduce the growing rates of chronic diseases related to "unhealthy" diets and physical inactivity in collaboration with the private sector.

With respect to food manufacturers, the draft strategy encourages "cooperative rather than adversarial relationships with industry" and acknowledges recent industry efforts to modify the salt, sugar and fat content of processed foods. Specific recommendations for food companies in the report include (i) limiting saturated fats, *trans*-fatty acids, sugar, and salt in existing products, (ii) following "responsible" marketing practices that



support the strategy, especially in regard to children, (iii) implementing consistent labeling practices and evidence-based health claims to help consumers make informed choices, and (iv) providing information on food composition to national authorities.

European Union (EU)

[4] EU Remains Undecided on Allowing Sale of GM Corn

The EU Standing Committee of the Food Chain and Animal Health has again failed to endorse a European Commission proposal to allow the sale of imported canned corn grown from genetically modified seeds (BT-11) in the EU's 15 member states. BT-11 corn is produced by Sygenta and grown primarily in the United States and Canada. News reports indicate that the proposal will now be forwarded to EU farm ministers who will have three months to consider it before the commission takes other action. If approved, the decision to allow importation of the GM corn will mark the end of a five-year ban the EU has maintained against GM foods.

Meanwhile, in what observers say will contribute to rising pressure on member states to lift the moratorium on GM foods, the European Food Safety Authority has reportedly determined that Monsanto's Roundup Ready corn is as safe as conventional corn and "unlikely" to cause adverse health effects. See *Associated Press*, December 5 and 8, 2003; *EU Observer*, December 8, 2003.

Legal Literature

- [5] "The Power of Positive Drinking: Are Alcoholic Beverage Health Claims Constitutionally Protected?" Ben Lieberman, 58 *Food and Drug Law Journal* 511 (2003)

Makers of alcoholic beverages have a First Amendment right to include on their labels and advertisements accurate, succinct references to the health benefits of moderate alcohol consumption, an analyst at the Competitive Enterprise Institute argues in this article. Based on that premise, the article criticizes the current stance of the Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB), which has decided that promotional references to moderate drinking and health are misleading unless they detail the risks of heavier drinking and explain every category of individual unlikely to benefit.

The agency's "*de facto* ban on substantive health information absent prohibitively lengthy qualifications does not pass constitutional muster," the article states. "TTB has not demonstrated any misleading effect necessitating such disclaimers." The author ultimately concludes that "the agency's action apparently rests on the paternalistic assumption that the public needs to be protected from this information."

The article includes a review of the medical evidence on moderate drinking and health as well as a description of proposed health statements that the federal government has rejected.



Other Developments

- [6] **“Back Door to Prohibition: The New War on Social Drinking,” Radley Balko, Cato Institute Policy Analysis #501, December 5, 2003**

This white paper asserts that policymakers at all levels of government are using taxation, censorship, zoning restrictions, and police powers to make alcohol less available. According to Balko, however, these initiatives are based on insufficient evidence and are unlikely to achieve their goals. “Such policies place the external costs attributable to a small number of alcohol abusers on the larger percentage of people who consume alcohol responsibly,” he states.

“Although we may never again see alcohol formally prohibited at the federal level, it isn’t difficult to imagine the day when alcohol is prohibited in all but a few public places and private residences,” the author concludes. “It is vitally important to recall that the disastrous era of Prohibition that ended 70 years ago began with incremental steps. Policymakers and citizens ignore that history at our peril.”

- [7] **Brian Young, “Does food advertising influence children’s food choices? A critical review of some of the recent literature,” *International Journal of Advertising*, Vol. 22, No. 4, 2003**

Young, an economic psychologist at Great Britain’s University of Exeter, reviews studies that attempt to identify the age at which children understand advertising and concludes that kids have an adequate understanding of its commercial and persuasive intent by about age 8. He then looks at the types of foods targeted to children and finds no evidence that such advertising directly influences their diets.

The author explores how families make food choices and finds that, although children do play a role in those choices, family and friends constitute the most significant influences, with advertising playing a smaller, much weaker role. With respect to studies alleging a direct relationship between advertising to children and their subsequent food choices, Young says such “studies are methodologically unsound as they do not use longitudinal or experimental designs,” both of which are required to claim a causal relationship.

- [8] **Lieberman Calls for FTC Investigation into Food Advertising Aimed at Kids**

Democratic presidential hopeful Joseph Lieberman reportedly advocates a Federal Trade Commission (FTC) investigation into the purported effect of advertising for low-nutrition “junk” food on the rising rates of obesity in U.S. youth. If elected president, Lieberman would evidently support (i) mandated food warnings in advertising similar to the ratings required in film advertising, (ii) nutritional disclosure by restaurant chains and (iii) Department of Agriculture jurisdiction over offerings in school vending machines. *See Associated Press*, December 4, 2003.

Media Coverage

- [9] **Robert Levy, “Liquor and Beer Ads Are Not the Problem,” *The Chicago Tribune*, December 8, 2003**

This guest editorial asserts that the recently filed purported class action accusing alcohol makers of advertising to minors is an unwarranted attempt by plaintiffs’ counsel “to add one more notch to their expanding tobacco belt.” *See* issue 59 of this Update, December 3, 2003.



Levy, a senior fellow at the Cato Institute, argues that the lawsuit not only interferes with defendants' commercial speech rights, but also ignores the results of the Federal Trade Commission's 2003 Report on Alcohol Marketing and Advertising, which "found no evidence of targeting underage consumers" in the market for flavored malt beverages. The message of plaintiffs' counsel is that "the doctrine of personal accountability is out the window," Levy concludes. "In its place is the insidious notion that you can engage in risky behavior, then force someone else to pay for your mistakes. That message is far more pernicious than any beer or liquor commercial."

[10] "Who's to Blame? Obesity in America: How to Get Fat Without Really Trying," An ABC News Special with Peter Jennings, December 8, 2003

Noting that federal statistics indicate that almost one in three Americans is obese, this program ostensibly explored the various aspects of the U.S. obesity epidemic, asking "Is it bad eating habits or poorly executed exercise regimes? Could the government and the food industry also be to blame?" Public health advocates Marion Nestle and Michael Jacobson weighed in heavily on the purported link between agricultural subsidies and health, e.g., corn sweeteners, as well as the effects of food advertising on children and their diets. See *ABC News.com*, December 8, 2003.

Scientific/Technical Items

Alcohol

[11] Johns Hopkins' Researchers Allege Link Between Drinking and Brain Atrophy

Light to moderate drinking might result in the loss of brain tissue in middle-age adults, according to a new study from Johns Hopkins University researchers. J. Ding, et al., "Alcohol Intake and Cerebral Abnormalities on Magnetic Resonance Imaging in a Community-Based Population of Middle-Aged Adults. The Atherosclerosis Risk in Communities (ARIC) Study," *Stroke* online 4 December 2003, doi: 10.1161/01.STR.0000105929.88691.8E. Their conclusions further assert that such alcohol consumption might not lower the risk of stroke, contradicting previous findings. The study involved an analysis of nearly 2,000 adults and the influence of lifestyle on neurocognitive decline and cerebral infarction, or stroke. Using cerebral magnetic resonance imaging, the researchers identified subclinical abnormalities in the brain often associated with these conditions, finding corresponding increases in tissue atrophy as patients consumed more alcohol. The researchers did not, however, find any association, negative or positive, between alcohol consumption and stroke.

Food & Beverage

LITIGATION UPDATE

Food & Beverage Litigation Update is distributed by Mark Cowing and Mary Boyd in the Kansas City office of SHB. If you have questions about the Update or would like to receive back-up materials, please contact us by e-mail at mcowing@shb.com or mboyd@shb.com. You can also reach us at 816-474-6550. We welcome any leads on new developments in this emerging area of litigation.

Shook,
Hardy &
Bacon_{L.L.P.}TM

Geneva, Switzerland

Houston, Texas

Kansas City, Missouri

London, United Kingdom

Miami, Florida

New Orleans, Louisiana

Orange County, California

Overland Park, Kansas

San Francisco, California

Tampa, Florida

Washington, D.C.

