

Food & Beverage

LITIGATION UPDATE

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Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA Changes Package Labeling for Fat Substitute

Concluding that warnings about possible gastrointestinal effects are no longer warranted on products containing the fat-substitute olestra, FDA has announced that it has changed the labeling requirement in effect for the last seven years. FDA will, however, continue to require that foods with olestra, most commonly snack foods, contain added Vitamins A, D, E, and K to compensate for olestra's effects on these nutrients. The change is apparently based on post-market studies conducted by Procter & Gamble Co., which developed olestra, and adverse event reports showing that any gastrointestinal effects were mild and infrequent among those consuming the substance. According to a news source, more than 20,000 people have complained about diarrhea and cramping from consuming olestra since it went on the market. Products containing olestra have reportedly not reached their marketplace potential because many consumers were wary of potential digestive consequences.

In conjunction with making the labeling change, FDA also issued a notice indicating that it was denying the requests for hearing it received from the Center for Science in the Public Interest (CSPI) regarding the olestra labeling rule promulgated

in 1996. According to the agency, CSPI had not established that the agency overlooked significant information in the record in reaching its conclusion that olestra is safe. *See Reuters and FDA Talk Paper*, August 1, 2003; *Federal Register* and *The Wall Street Journal*, August 5, 2003.

108th Congress

[2] Bill to Establish Fruit and Vegetable Pilot Program Introduced

Representative Richard Hastings (R-Wash.) has introduced the "[Healthy Nutrition for America's Children Act](#)" that would amend existing school-lunch legislation by requiring the Agriculture Secretary to establish a pilot program that would make fresh and dried fruits and fresh vegetables available at no charge to elementary and secondary school students throughout the country. The bill (H.R. 2832), which contains findings about the benefits of fruit and vegetable consumption, notes that "Among needy students, school nutrition programs often provide the primary opportunity for consumption of nutritionally valuable foods."

Department of Health and Human Services (HHS)

[3] New Federal Institute Suggested as Part of Obesity Strategy

HHS Secretary Tommy Thompson reportedly met July 30, 2003, with federal agency directors, food industry representatives, nutrition professionals, and



other stakeholders to discuss components of a departmentwide obesity action plan. Those attending the meeting included Food and Drug Administration Commissioner Mark McClellan, Surgeon General Richard Carmona, Centers for Disease Control and Prevention Director Julie Gerberding, and National Institutes of Health (NIH) Director Elias Zerhouni. News sources indicate that the group discussed the possibility of a national walking program, an improved food labeling system and the establishment of an NIH obesity institute as ways of addressing the obesity issue. See *CNN.com*, July 30, 2003; *The Washington Times*, July 31, 2003.

State/Local Initiatives

[4] California Agency Issues Proposed Acrylamide Work Plan

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment has issued a proposed [acrylamide work plan](#) targeting Safe Drinking Water and Toxic Enforcement Act (Prop. 65) regulatory options for the byproduct of high-temperature cooking processes. "In California, we firmly believe the consumer should know what is in the products they purchase so they can make informed decisions," OEHHA Deputy Director Val Siebal was quoted as saying. Acrylamide is currently listed as a carcinogen "known to the state to cause cancer" under Prop. 65; a No Significant Risk Level (NSRL) of 0.2 micrograms/day was established for the chemical in 1990.

Under OEHHA's four-pronged proposal, the agency would (i) update the NSRL for acrylamide and evaluate data on foods containing less than the updated NSRL, seeking particular input from the Carcinogen Identification Committee; (ii) identify levels of acrylamide in foods that fall below the limit of detection; (iii) "identify alternative acrylamide

exposure levels for certain foods based on public health considerations"; and (iv) devise the form and content of Prop. 65 warning labels for those foods deemed to require them. OEHHA is accepting public comment on the proposed work plan until September 26, 2003.

Citing potential difficulty in putting warning labels on products sold only in California, the proposal reportedly has food manufacturers in an "uproar." *The Wall Street Journal* also reported that the industry is worried that the "public health consideration" exemption for certain foods would "lead to snack foods being singled out for potentially alarming cancer warnings while healthier fare such as whole grains or toasted nuts that also contain acrylamide would be spared." See *The Wall Street Journal*, August 1, 2003.

Other Developments

[5] Pediatricians Call for Action on Childhood Obesity

The American Academy of Pediatricians has issued a call to arms among its members to monitor their patients throughout childhood and adolescence to detect early signs of overweight and obesity, educate families about obesity prevention and become advocates in their communities to support a healthful lifestyle for all children. In an [article](#) appearing in the August 2003 issue of *Pediatrics*, the organization's Committee on Nutrition recommends that physicians calculate and plot BMI [Body Mass Index] once a year and use changes in BMI "to identify rate of excessive weight gain relative to linear growth."

The article discusses the risk factors for childhood overweight and obesity, including specific genetic conditions, dietary factors, family and parental dynamics, decreasing levels of physical activity, and,



in the case of low-income families, lack of safe places for physical activity and lack of consistent access to healthful food choices. The academy also calls for doctors to become advocates for (i) regulating or curtailing ads that promote energy-dense, nutrient-poor foods to children, (ii) decreasing the availability of foods and beverages of little nutritional value in schools, and (iii) increasing physical education programs.

Meanwhile, those who contend that the obesity issue has been overblown claim that BMI, a mathematical formula developed 150 years ago by a Belgian statistician, is a crude tool for making overweight and obesity determinations. BMI does not apparently distinguish between men and women, between teens and octogenarians, or between people with different bone structures or musculature types. BMI critics note that Hollywood stars such as Richard Gere, Pierce Brosnan and Kevin Costner are all considered “overweight” with BMIs ranging between 26 and 29. *See JunkScience.com*, July 23, 2003.

In a related development, an advice columnist recently advised the father of a 9-year-old girl who is gaining weight to consult her physician as a means of convincing his ex-wife to make changes in the child’s diet. Reminiscent of advice to divorced parents regarding their children’s exposure to environmental tobacco smoke, Jeanne Phillips writing as Abigail Van Buren, advises the father to “talk to his lawyer,” if the mother is not receptive to a doctor’s recommendation that she supervise her daughter’s diet. *See The Kansas City Star*, August 4, 2003.

[6] **Welsh Physicians Advocate Warning Labels on Alcoholic Beverages**

Members of the British Medical Association (BMA) Cymru are reportedly advocating alcoholic beverage labels that disclose a product’s alcohol content and provide information on the maximum

recommended daily intake of alcohol. “We are concerned about the marketing of alcopops with a high alcohol content to young people. The appeal of designer drinks is greatest between the ages of 13 and 16,” BMA’s Welsh secretary Richard Lewis was quoted as saying. According to a news source, more than one-half of all Welsh 15- and 16-year olds drink alcoholic beverages daily. The physicians’ group also reportedly seeks restrictions on television advertising for liquor and educational campaigns sponsored by the Welsh Assembly Government. *See The Western Mail*, August 4, 2003.

Media Coverage

[7] **Meg Green, “Food Fright,” *Best’s Review*, August 2003**

A publication devoted to insurance issues and analysis has designated as its August 2003 cover story an article that focuses on current and potential litigation involving obesity-related claims against the food industry. According to the article, “insurers are keeping a wary eye on the food cases, which, if successful, may trigger not only general or product liability claims, but additional lawsuits.” Some insurance companies are apparently tracking the obesity issue as one of a number of emerging trends that “could blossom into either an adversity or an opportunity” for them. The insurers are tracking not only litigation, but also changes in government regulation and self-imposed responses in the food industry. Large and small carriers are monitoring the issues because some of the smaller carriers specialize in property and casualty insurance for “Main Street” restaurants across the nation. Generally, the liabilities covered address premises (slip-and-fall) and operations (food spoilage, food poisoning and damage from spilled food).



Article sidebars detail the most recent litigation in this arena, including the Oreo cookie lawsuit and the lawsuit filed against McDonald's on behalf of overweight youth, and information about the *trans* fat controversy and research purportedly finding addictive qualities in dairy products. Lawyers interviewed for the article opined that as documents proved damaging to cigarette manufacturers, there could be documents that show companies have lied about or misrepresented food ingredients. Legal experts predict that it may take several years before an obesity-related lawsuit is successful.

[8] David Barboza, "If You Pitch It, They Will Eat," *The New York Times*, August 3, 2003

In an environment where food companies tie their products to popular children's cartoon characters and toys, schools have contracts to sell fast food and sugary beverages, and advertising is ubiquitous, food-industry critics are reportedly claiming that the scope and intensity of marketing fast food, snacks and beverages to children have increased dramatically in the last decade. According to this article, the increase has "closely tracked their increase in weight." Most large food companies, claims the article, deny they are to blame for the epidemic of excess weight and point, instead, to sedentary lifestyles and poor supervision and eating habits. The article details the ways companies sell to children, particularly via television, and quotes a Harvard professor who says, "The programs have become advertising for the food, and the food has become advertising for the programs." Marketing experts have apparently determined that the campaigns are effective and that children are targeted because they are where the money is, i.e., they influence their parents to spend \$600 billion annually.

Scientific/Technical Items

Alcohol

[9] Moderate Drinking Might Affect Incidence of Periodontal Disease

New research from Harvard University claims that even moderate alcohol consumption is a risk factor for gum disease. W. Pitiphat, et al., "Alcohol Consumption Increases Periodontitis Risk," *Journal of Dental Research* 82(7): 509-513, 2003. In an investigation of nearly 40,000 men, Harvard School of Dental Medicine researchers found that those subjects who consumed alcoholic beverages were at an 18 to 27 percent higher risk of developing periodontitis than those who did not. To make this determination, the Harvard team followed male health professionals ages 40 to 75 over an eight-year period, examining alcohol intake and monitoring for the development of gum disease. During that time, 2,125 of the initially disease-free men developed periodontitis. Low to moderate drinking allegedly increased the risk of developing the disease by as much as 24 percent; heavier drinking increased the risk by 27 percent. While previous studies have purportedly shown a link between alcohol consumption and unhealthy gums, most involved heavy drinkers or alcoholics.

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Food & Beverage Litigation Update is distributed by Dale Walker 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 dwalker@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.

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