

Food & Beverage

LITIGATION UPDATE

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Shook,
Hardy &
Bacon LLP

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LITIGATION UPDATE

Legislation, Regulations and Standards

Food and Drug Administration (FDA)

[1] FDA to Convene Public Meeting on Animal Feed Safety System

FDA will hold a [public meeting](#) to discuss progress on development of its risk-based Animal Feed Safety System (AFSS) on April 5-6, 2005, in Omaha, Nebraska. AFSS is a regulatory program aimed at covering the labeling, production and distribution of all feed ingredients and mixed feeds at all stages of manufacture, distribution and use. FDA is especially interested in stakeholders' views on (i) applying Hazard Analysis and Critical Control Point to any or all segments of the industry, (ii) development of risk standards for contaminants, (iii) revising good manufacturing practices, and (iv) the role of state and first-party inspections. See *Federal Register*, February 7, 2005.

Litigation

Bivens Actions

[2] Nebraska Meat Packer Cannot Sue USDA Inspectors, Says Eighth Circuit

The Eighth Circuit of Appeals has ruled that a meat packing and processing plant in Omaha, Nebraska, could not bring a *Bivens* suit against U.S. Department of Agriculture (USDA) food safety inspectors for allegedly damaging its reputation and business. [Nebraska Beef, Ltd., v. Dennis Greening, et. al., No. 04-1918, \(8th Cir. 2/28/05\)](#). *Bivens* allows direct tort actions under the U.S. Constitution against federal officials and employees. *Bivens v. Six Unknown Named Agents of the Federal Bureau of Narcotics*, 403 U.S. 388 (1971).

Nebraska Beef and USDA entered into a mutual consent agreement to resolve alleged violations of the Federal Meat Inspection Act that were issued when USDA inspectors visited the Omaha facility in September 2002. According to Nebraska Beef, however, the inspectors later contravened the consent agreement by maliciously issuing 58 additional notices of alleged violations. The meat packer filed a *Bivens* suit against the inspectors in district court, and the court rejected the



inspectors' motion to dismiss, which asserted qualified immunity and the nonavailability to Nebraska Beef of a *Bivens* remedy. The inspectors appealed.

In reversing the district court's denial of the inspectors' motion to dismiss and remanding with an order to dismiss the complaint for failure to state a claim, the Eighth Circuit decided that a *Bivens* remedy was not available to Nebraska Beef. "The Supreme Court has been wary of extending *Bivens* remedies into new contexts" because existing procedures can address alleged constitutional violations, the court said. "Parties may not avoid administrative review simply by fashioning their attack on an agency decision as a constitutional tort claim against individual agency officers."

Discrimination

[3] California-Based Group of Physicians Alleges Discriminatory FDA Policies Cause Vitamin D Deficiency in African-Americans

A small group of doctors incorporated as the Vitamin D Council, Inc. last week petitioned the U.S. attorney general seeking declaratory and mandatory injunctive relief against the Food and Drug Administration (FDA) for food fortification policies the group claims discriminate against African-Americans. In its [petition](#) setting forth both Fifth Amendment and Humans Rights violations, the council claims that (i) vitamin D deficiency is associated with many health problems; (ii) "vitamin D deficiency disparately afflicts African-Americans"; (iii) FDA relies primarily on milk to deliver vitamin D to consumers; and (iv) African-Americans drink little milk. As a result of those alleged circum-

stances, the group contends "the FDA's policies, vitamin D deficiency, and the diseases associated with that deficiency, disparately afflict African-Americans." The council asserts that FDA has done nothing to correct its fortification policies even though an FDA employee cautioned two years ago that vitamin D deficiency was "an alarming two to eight times higher among blacks."

To remedy the alleged discrimination, the Vitamin D Council asks the attorney general to compel FDA to treat African-Americans equally under the law by taking various actions such as revising the agency's food fortification policies "to ensure that African-Americans are receiving adequate amounts of vitamin D and calcium" and undertaking "a public education effort to warn all Americans about vitamin D deficiency and advise them to supplement with adequate doses of vitamin D if sun exposure is curtailed." See *The New York Times*, February 25, 2005.

Legal Literature

[4] Adam Benforado, Jon Hanson and David Yosifon, "Broken Scales: Obesity and Justice in America," 53 *Emory L.J.* 1645 (2004)

Food choices are not necessarily a matter of personal volition, according to these authors (a recent Harvard Law School graduate, a Harvard Law School professor and a visiting professor at Rutgers School of Law, respectively). In their opinion, food choices are driven by situational influences (e.g., the availability of high-fat, sugary foods) and manipulation. They disagree with the presumption that individuals know what is best



for them and act in their own interests, asserting that a “free market/dispositionist” worldview has protected the food industry from significant administrative regulation.

The authors fall short of accusing lawmakers of being “in the kitchen with the food industry,” but fault policymakers for failing to appreciate the situational sources of obesity in sponsoring legislation such as the “Personal Responsibility in Food Consumption Act.” They view the Bush Administration’s refrain of personal responsibility as “marching in lockstep with the [food] industry” and further claim the administration is making two claims that were “central to the success of the tobacco industry in avoiding ‘responsibility’ for the costs caused by smoking: first, that there is no causal connection between industry practices and the harms (in this case, obesity and its attendant effects on physical and mental health); and second, that consumers need to take personal responsibility for their choices.”

The authors fail to offer a solution for what they perceive as a broken system that relies on the “chimera” of free choice. Instead, their stated aim is convincing “policy analysts and policymakers to begin thinking about problems and solutions from a different, counterintuitive perspective.” They contend that dispositionism “has had and continues to have an immense effect on both the framing and resolution of virtually every major social policy debate, from affirmative action to standardized testing, from gun control to school ‘choice,’ and from gay rights to the war on terrorism.”

Other Developments

[5] CAMY Issues New Report on Underage Drinking

Georgetown University’s Center on Alcohol Marketing and Youth (CAMY) has released a [report](#) that concludes the United States has made little progress in reducing the rate of drinking among underage consumers. “We have a huge public health crisis in this country with our kids drinking, and as a nation we are in denial,” CAMY’s research director was quoted as saying. Among the report’s conclusions: (i) some 7,000 youth younger than age 16 “take up” drinking every day and (ii) about 4,500 people younger than age 21 die every year because of “excessive” alcohol use. *See CAMY Press Release*, February 23, 2005.

Scientific/Technical Items

Cardiovascular Disease

[6] Consumption of Red Meat and Dairy Products Purportedly Linked to Heart Disease in Women

A 15-year study of 29,000 postmenopausal Iowa women has concluded that those who often substituted red meat and dairy products for carbohydrates were more likely to die from heart disease, while those who often opted for vegetable protein in place of carbohydrates appeared to be protected from cardiovascular ailments. (L. Kelemen, et al., “Associations of Dietary Protein with Disease and Mortality in a Prospective Study of Postmenopausal Women,” *American Journal of Epidemiology* 161(3): 239-249, 2005.) “Protein from different sources seems



to have different health effects,” co-author Linda Kelemen, M.D., of the Mayo Clinic College of Medicine, was quoted as saying. The investigators reported that women who ate vegetable protein in place of carbohydrates or animal protein were nearly 30 percent less likely to die of heart disease. Although they reported no association overall with any adverse disease outcome when animal protein was substituted for carbohydrates in the diet, they found that coronary heart disease mortality was associated with increased consumption of red meat (risk ratio = 1.44, 95% CI: 1.06, 1.94) and dairy products (risk ratio = 1.41, 95% CI: 1.07, 1.86). Kelemen recommended that people on high-protein diets stick with vegetable protein sources such as tofu, nuts and peanut butter, or “healthier” meats like chicken or fish. See *Reuters*, February 23, 2005.

Cancer

[7] Studies Examine Effects of Coffee Consumption on the Incidence of Liver and Colorectal Cancers

Drinking coffee may be associated with a decreased risk of hepatocellular carcinoma – a type of liver cancer – and no increased risk of colorectal cancer, say two recently published studies. One

study examined the effects of coffee consumption in a large cohort of middle-aged and elderly Japanese subjects. (M. Inoue, et al., “Influence of Coffee Drinking on Subsequent Risk of Hepatocellular Carcinoma: A Prospective Study in Japan,” *Journal of the National Cancer Institute* 97(4): 293-300, February 16, 2005.) The authors found that individuals who drank coffee on a daily basis had roughly one-half the risk of hepatocellular carcinoma compared with those who never drank coffee.

A study conducted by researchers with various Harvard University affiliations examined data from the Nurses’ Health Study (women) and the Health Professionals’ Follow-up Study (men) and found no association between the consumption of caffeinated coffee or tea and the incidence of colon or rectal cancer for either of the groups. (K. Michels, et al., “Coffee, Tea, and Caffeine Consumption and Incidence of Colon and Rectal Cancer,” *Journal of the National Cancer Institute* 97(4): 282-292, February 11, 2005.) Drinkers of decaffeinated coffee were observed to have about one-half the incidence of rectal cancer compared with those who never drank decaffeinated coffee.



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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,
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