



Vol. 20 No. 63

December 16, 2005

STATE LAW AS HEALTH HAZARD: HOW PROP 65 UNDERMINES NATIONAL FOOD LABELING

By

Gene Livingston and Lisa L. Halko

California's Proposition 65 requires warnings on "consumer products" that contain traces of chemicals suspected of causing cancer or birth defects. No risk-benefit analysis is required; if the substance is present then Prop 65 compels a warning. When this law is applied to food, it endangers the public health by proliferating warnings where there is no actual risk. This undermines important public health protections developed over many years by the Food and Drug Administration (FDA) and other federal agencies.

In 1989, Dr. Louis Sullivan was appointed Secretary of Health and Human Services. Among the many accomplishments of his four-year tenure, Dr. Sullivan reformed food labeling in the United States, mandating uniform, scientifically-supported nutritional information in a meaningful form. In 1990, Congress enacted the Nutrition Labeling and Education Act of 1990¹ (NLEA) to support his regulatory proposals. FDA used its enhanced authority to expand consistent and intelligible nutritional labeling to nearly all packaged food, to standardize the meanings of "light," "low sodium," and "high fiber," and to permit specific, scientifically-supported health claims. On December 2, 1992, Dr. Sullivan announced, "The Tower of Babel in food labels has come down, and American consumers are the winners."² Since then, FDA has continued to evaluate requests for health claims on food labels. FDA also evaluates the need for warnings, based on whether there is clear evidence that the food poses an actual risk to consumers. FDA has carefully considered requests for warning language, and has adopted food warnings only in extraordinary circumstances.

¹Pub. L. 101-535, Nov. 8, 1990, 104 Stat. 2353.

²FDA Press Release, archived on line at <http://www.hhs.gov/news/press/pre1995press/921202.txt>.

Gene Livingston is a Shareholder with the law firm Greenberg Traurig, LLP in its Sacramento office. He was the first director of California's Office of Administrative Law. **Lisa L. Halko** is an associate with the firm, also in its Sacramento office. *The views expressed here are those of the authors and do not necessarily reflect the views of the Washington Legal Foundation. This publication should not be construed as an attempt to aid or hinder the passage of legislation.*

Meanwhile, in California, the Safe Drinking Water and Toxics Enforcement Act of 1986 (Proposition 65) was gathering the building blocks to construct a new Tower of Babel. When Proposition 65 was on the ballot in 1986, its supporters argued: “Certain chemicals are scientifically known — not merely suspected, but known — to cause cancer and birth defects. Proposition 65 would keep these chemicals out of our drinking water [and] warn us before we’re exposed to any of these dangerous chemicals.”³ Codified in California’s Health and Safety Code,⁴ Proposition 65 requires the state to keep a list of chemicals “known to the State of California to cause cancer or reproductive toxicity,” and makes it illegal to “expose” anyone to a listed chemical without “first giving clear and reasonable warning.” Violators are subject to civil penalties of \$2500 per violation per day, which may be collected either by public prosecutors or by private plaintiffs, who receive a quarter of the penalties plus their attorneys’ fees.

California has now listed more than 750 chemicals “known” to cause cancer or reproductive harm. In addition to the dangerous drinking-water contaminants mentioned in the ballot arguments, the current list includes common products such as unleaded gasoline and alcoholic beverages, ubiquitous elements such as arsenic, lead, mercury, nickel and silica (sand), and essential nutrients such as Vitamin A. Any product containing traces of any chemical on the list is at risk for enforcement litigation, even when the product meets all state and federal safety requirements and poses no actual risk of human harm.

California law provides some exceptions to Proposition 65’s warning requirement. Three examples: (1) No warning is required when the exposure is less than 1/1000th of the amount that causes reproductive harm, or would not increase cancer risk assuming lifetime exposure at the level in the product;⁵ (2) No warning is required when the listed chemical occurs naturally in a food product;⁶ and (3) No warning is required when federal warning law preempts state law.⁷

Unfortunately, California courts have construed these exceptions as affirmative defenses for which the regulated industry bears the burden of proof. Plaintiffs often bring meritless cases and settle for nuisance value, knowing that the cost of proving affirmative defenses is usually prohibitive. Warnings proliferate on safe products because their producers cannot sensibly pay for independent scientific research to show a 1000-fold margin of safety or the natural presence of constituents in their products.

These California warnings undermine national nutrition policy by habituating consumers to food warnings, making it more difficult to communicate true threats to human safety. When applied to products like canned tuna, the warnings undermine national health much more directly, by misleading consumers to believe that a safe, affordable, and nutritious food is harmful. Under Proposition 65, the new Tower of Babel will be posted with signs warning people away from some things they have always known to pose risks (cigarettes, alcohol abuse) and other things that are perfectly safe (fresh fish, graham crackers). Earlier this year, for example, under threat of Proposition 65 penalties, a number of seafood restaurants agreed to post dramatic signs with “WARNING!” in large, bright-red print over a fish silhouette. While the text mentions in a much smaller type size that fish and seafood contain

³See *California Ballot Pamphlet*: General Election, Nov. 4, 1986 at 54.

⁴CALIFORNIA HEALTH AND SAFETY CODE § 25249.5 *et seq.*

⁵See CALIFORNIA HEALTH AND SAFETY CODE § 25249.10(c).

⁶See Title 22, CALIFORNIA CODE OF REGULATIONS, § 12501.

⁷See CALIFORNIA HEALTH AND SAFETY CODE § 25249.10(a).

“essential nutrients” and are part of “a healthy diet,” the sign focuses on limiting consumption and does not mention fish’s FDA-recognized health benefits such as low fat, high protein, and abundant omega-three fatty acids.⁸ The posted sign was the negotiated alternative to the “safe-harbor” sign permitted by regulation,⁹ stating “Warning: this product contains a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.” Since 1997, three private plaintiffs have served the nation’s major tuna canners with “notices” alleging that Proposition 65 requires a similar warning on canned and packaged tuna fish. In 2004, California’s attorney general joined the canned tuna litigation,¹⁰ and a deputy attorney general appeared on national television to display the restaurant warning sign and to attack the canners for not displaying it “in the tuna aisle.”¹¹

In contrast, the FDA has worked for years to develop informative, meaningful information about mercury in fish and seafood. In 2001, after extensive research, FDA created an advisory for pregnant women and young children. FDA’s studies continued, and revised seafood information was developed jointly with EPA in 2004.¹² FDA encourages “women and young children in particular” to eat fish, because of the many benefits of foods high in protein and omega-three fatty acids, and low fat. FDA also encourages children and women who are pregnant or may become pregnant to eat fish with lower mercury content, such as canned light tuna and salmon. Brochures detailing these recommendations are provided to medical practices so that pediatricians, obstetricians, and other health professionals can give balanced advice to the appropriate people. FDA has specifically rejected requests to require a mercury warning label on canned fish, because the warning would not be directed to the appropriate population, cannot convey complex and nuanced information, causes confusion, and lacks appropriate detail.¹³ FDA’s decisions were recently vindicated by a series of five articles published in the November 2005 special edition of the *American Journal of Preventive Medicine*.¹⁴ The articles detail findings of a panel convened by the Harvard Center for Risk Analysis. The panel compared the risk of mercury exposure with the benefits of omega-three fatty acid, as they affect stroke,^{14(a)} coronary heart disease,^{14(b)} and

⁸See consent judgment entered February 4, 2005, in *People v. Benihana*, San Francisco Superior Court No. BC 293749, Exhibit B.

⁹See Title 22, CALIFORNIA CODE OF REGULATIONS, § 12601(b).

¹⁰*People v. Tri-Union Seafoods, et al.*, San Francisco Superior Court No. CGC-04-432394.

¹¹See transcript of “NOW,” aired on PBS Jan. 21, 2005, available on line at http://www.pbs.org/now/transcript/transcriptNOW103_full.html.

¹²U.S. Department of Health and Human Services and U.S. Environmental Protection Agency, “What You Need to Know About Mercury in Fish and Shellfish, 2004 EPA and FDA Advice For: Women Who Might Become Pregnant, Women Who are Pregnant, Nursing Mothers, Young Children,” Mar. 2004.

¹³Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401), n. 71.

¹⁴(a) “A Quantitative Analysis of Fish Consumption and Stroke Risk” by Colleen Bouzan, MS, Joshua T. Cohen, PhD, William E. Connor, MD, Penny M. Kris-Etherton, PhD, George M. Gray, PhD, Ariane König, PhD, Robert S. Lawrence, MD, David A. Savitz, PhD, and Steven M. Teutsch, MD; (b) “A Quantitative Analysis of Fish Consumption and Coronary Heart Disease Mortality” by Ariane König, PhD, Colleen Bouzan, MS, Joshua T. Cohen, PhD, William E. Connor, MD, Penny M. Kris-Etherton, PhD, George M. Gray, PhD, Robert S. Lawrence, MD, David A. Savitz, PhD, and Steven M. Teutsch, MD;” (c) “A Quantitative Analysis of Prenatal Methyl Mercury Exposure and Cognitive Development” by Joshua T. Cohen, PhD, David C. Bellinger, PhD, and Bennett A. Shaywitz, MD;” (d) “A Quantitative Analysis of Prenatal Intake of n-3 Polyunsaturated Fatty Acids and Cognitive Development” by Joshua T. Cohen, PhD, David C. Bellinger, PhD, William E. Connor, MD, and Bennett A. Shaywitz, MD;” (e) “A Quantitative RiskBenefit Analysis of Changes in Population Fish Consumption” by Joshua T. Cohen, PhD, David C. Bellinger, PhD, William E. Connor, MD, Penny M. Kris-Etherton, PhD, Robert S. Lawrence, MD, David A. Savitz, PhD, Bennett A. Shaywitz, MD, Steven M. Teutsch, MD, and George M. Gray, PhD.

prenatal cognitive development.^{14(c),(d)} The panel found that the risk of harm from reducing fish intake is greater than the risk of mercury exposure from eating fish.^{14(e)} FDA's public health decisions are based on science and careful case-by-case deliberation. They do not promote catchy headlines or fit the "scare-of-the-week" format for television news. FDA's considered decisions quietly protect the public health from true risks as well as from irrational fears.

In 2005, FDA reiterated its reasoning, in a letter from its Commissioner to California's Attorney General about California's lawsuit against the tuna canners.¹⁵ Despite the director's letter explaining how California's actions undermine FDA policy, the trial began on October 18, 2005. It is expected to conclude in early December. The canners produced evidence from illustrious scientific experts that the average tuna consumer eats less than 1/1000th the amount of mercury shown to have no adverse effect, and that the mercury in tuna occurs naturally in deep-sea ocean vents. The U.S. Tuna Foundation, funded by the canners, has developed independent scientific research into the marine geochemistry of deep-sea vents and the incidence of mercury in tuna over many years. The canners also argued, based on FDA's long-standing food-warning policy as well as the Commissioner's recent letter, that federal law preempts Proposition 65 as applied to tuna warnings. On November 8, 2005, Dr. Sullivan himself testified that tuna fish is an important source of omega-three fatty acids, that omega-three fatty acids are associated with full-term births, fetal brain development, and other health benefits, and that low-fat sources of high-quality protein are important in reducing obesity. He also testified about the reasoning behind FDA's long-standing policies for food warnings: allow them only where there is clear evidence of actual hazard; provide meaningful information that allows consumers to make healthy choices; direct information to the appropriate audience; and avoid unintended harm to the public health from false alarms.

Very few consumer product companies have such well-founded defenses to Proposition 65 as the tuna canners. Even fewer companies have the will to produce those defenses at trial, at the risk of draconian civil penalties and alarmist publicity. It is unreasonable to expect private businesses to defend FDA's complex and nuanced food-labeling policies against state prosecutors. If a letter from the FDA's Commissioner to the state's Attorney General is insufficient to protect the national public health, then prosecutorial discretion does not work. It shouldn't take an act of Congress to support federal nutrition policy — but it seems this is what may be needed.

One idea that has been examined recently is national review and adoption of state requirements for food warnings. States could petition FDA to adopt a state regulation as the national food-warning standard. FDA would have authority to review and adopt state regulations, providing uniformity and consistency. Where state regulations conflict with FDA's practices, FDA could determine whether a change in national policy would improve or endanger the public health. This idea respects federalist principles as well as science-based national policy. As Justice Brandeis wrote, state experiments in legislation are "one of the happy incidents of the federalist system," and should not be casually discouraged.¹⁶ On the other hand, Justice Brandeis assumed that such experiments were "without risk to the rest of the country,"¹⁷ and not every experiment is a success. It is reasonable that FDA be authorized to decide whether experiments like Proposition 65 are providing useful information, or endangering public health.

¹⁵Aug. 12, 2005, letter from Dr. Lester Crawford to Bill Lockyer, available on-line at the FDA website: <http://www.cfsan.fda.gov/~dms/fl-ltr65.html>

¹⁶*See New State Ice Co. v. Liebmann*, 285 U.S. 262, 311, 52 S. Ct. 371, 387 (1932) (Brandeis, J., dissenting).

¹⁷*Id.*