Legal Backgrounder

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THE JUNGLE VS. PROP 65: FEDERAL LAW PREEMPTS CALIFORNIA HEALTH WARNINGS

by

Gene Livingston and Lisa L. Halko

The beef industry is suing a private bounty-hunter for a declaratory judgment that federal law preempts California's Safe Drinking Water and Toxics Enforcement Act of 1986 (Proposition 65).[1] The action[2] filed by the American Meat Institute and the National Meat Association, follows a dispute between the United States Department of Agriculture (USDA) and California's Attorney General over the pre-emption issue, almost twenty years after USDA first announced that its statutes and regulations are controlling. In response, the Attorney General filed an *amicus* brief asserting a right to require beef labels despite USDA's claim of preemption. On August 26, the court allowed the action to go forward, overruling the bounty-hunter's motion to dismiss. The court declined to consider the Attorney General's brief at that hearing, but indicated that it would do so in the context of future motions by the parties. On the same day, the Attorney General filed another Proposition 65 action seeking warnings on French fries and potato chips for containing traces of acrylamide.

Meanwhile, in another Proposition 65 action filed by the Attorney General last summer,[3] tuna canners have moved to dismiss, arguing that the Food and Drug Administration's nuanced and comprehensive consumer-information program preempts Proposition 65 as applied to canned tuna. The Attorney General of California has continued to prosecute that action despite urging from the federal Food and Drug Administration that Proposition 65 warnings on canned tuna are likely to harm Californians by needlessly scaring them away from a nutritious, safe, and healthy food. *See* Letter from Commissioner

[1]Proposition 65 is codified at California Health and Safety Code section 25249.6 *et seq.*

[2]*American Meat Institute et al v. Leeman*, San Diego Superior Court case number GIN-04-4220.

[3]*People v. Tri-Union Seafoods et al.*, San Francisco Superior Court case number GCG-04-432394/01-402975.

Gene Livingston and **Lisa L. Halko** are members of Livingston & Mattesich Law Corporation located in Sacramento.

Lester M. Crawford, Commissioner of Food and Drugs to California Attorney General Bill Lockyer, Aug. 12, 2005. The tuna canners' motion will be heard on September 30, 2005. While preemption is not a novel issue in Proposition 65 law, the beef case is unusual because the targeted business interest initiated litigation themselves, rather than raising preemption as a defense.

USDA enforces the Federal Meat Inspection Act (FMIA),[4] enacted in 1906 after Upton Sinclair published *The Jungle*, an exposé of Chicago's unsanitary stockyards and meat-packing plants. The FMIA's stated purpose is not only to ensure a safe food supply, but also to prevent harm to the market for safe meat. The FMIA requires humane slaughter, authorizes government inspection, and prohibits the sale of meat that is adulterated, unwholesome, or misbranded. Under the FMIA, Congress gave USDA broad power to assure wholesome meat by regulating the hoof-to-shelf process of selecting, preparing, and packing meat products. USDA also received power to regulate product "labeling," that is, all written or graphic material on the package or that "accompanies" the products. False or misleading labeling makes the meat "misbranded."

Eighty years later, in 1986, California voters passed Proposition 65, which requires businesses to give a "reasonable warning" before exposing consumers to a chemical "known to the State of California to cause cancer, birth defects, or other reproductive harm." The state maintains a list of more than 750 chemicals for which warnings may be required. The list includes chemicals that have never been found to cause harm to humans. Proposition 65's lead agency, the Office of Environmental Health Hazard Assessment (OEHHA), promulgated safe-harbor regulations specifying the warning language for consumer products: "WARNING: This product contains chemicals known to the State of California to cause cancer," and "WARNING: This product contains chemicals known to the State of California to cause birth defects or other reproductive harm." In addition to the obvious marketing problems, especially for foods, such labels may imply — falsely — that the products are unsafe. This creates a conundrum for food producers, pharmaceutical manufacturers, and other industries with strict legal obligations to label their products accurately and in accord with federal laws such as the Food, Drug and Cosmetics Act[5] or the FMIA. The beef industry and USDA have long maintained that compliance with both FMIA and Proposition 65 is impossible.

In 1987, then-Secretary of Agriculture Richard Lyng wrote to California's governor expressing USDA's view that the FMIA preempts Proposition 65. In 1988, USDA rejected a meat producer's request to add Proposition 65 warning language to a product label because it would imply that the product is unwholesome when, in fact, all U.S. meat is strictly regulated for potential carcinogens and reproductive toxins. The misleading label would render the product "misbranded," so the producer could not sell it.

In the late 1980s and early 1990s, OEHHA appeared willing to leave most foods alone. Although early OEHHA regulations required warnings for alcoholic beverages, the agency also promulgated the naturally-occurring exemption,[6] intended to allow producers to sell foods without warnings so long as other federal and state regulations are followed and no listed chemicals are added. Until recently, most enforcement actions attacked consumer products other than foods. Since 2000, however, both public enforcers and private plaintiffs have begun to target foods including candy, fried potatoes, snack chips, fish, and ketchup — and now, beef.

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[4]Title 21 United States Code section 601 *et seq.*

[5]Title 21 United States Code section 301 *et seq.*

[6]Title 22 California Code of Regulations section 12501.

In November 2004, private plaintiff Whitney Leeman claimed that beef products, including ground beef, contain dioxin and PCB in amounts requiring warnings under Proposition 65. Her claim was in the form of a notice of violation, which Proposition 65 requires a private plaintiff to serve at least 60 days before filing a lawsuit.[7] In February 2005, USDA General Counsel Nancy S. Bryson reiterated USDA's position in a letter to California Attorney General Bill Lockyer. The Attorney General's chief Proposition 65 deputy, Edward G. Weil, responded that the FMIA does not preempt Proposition 65, and that the meat industry could comply with both Proposition 65 and the FMIA by posting warnings on shelf signs in stores. The beef industry then filed its lawsuit, seeking a declaratory judgment to resolve the issue with a complaint apparently tailored to Weil's specific points. On August 8, 2005, the Attorney General filed an *amicus* brief presenting the arguments to the court, in support of the defendant's motion to strike the complaint as a strategic lawsuit against public participation. The brief says that the Attorney General decided not to pursue allegations against the beef industry itself, but argues that federal law does not preempt Proposition 65.

The Attorney General first argues that the FMIA's express preemption language does not apply to Proposition 65. This argument rests on a distinction between labels attached to products, like the one USDA rejected in 1988, and labels attached to shelves or walls at the grocery store, which the Attorney General has requested in other Proposition 65 cases.[8] The Attorney General argues that FMIA's express preemption language prohibits only state regulation of labeling that "accompanies" the product in interstate commerce, and that preemption clauses are construed narrowly, especially as applied to state health laws. Since shelf signs in California stores do not move through interstate commerce, the Attorney General concludes they are not prohibited by USDA and therefore not preempted. In making this point, the Attorney General cites an *amicus* brief filed by USDA in a Michigan case,[9] asserting that FMIA did not preempt Michigan's requirement for signs in stores and restaurants with information on compliance with state standards. However, as the beef industry's complaint explains, USDA has changed its practices and now regulates signs and brochures that are posted in stores as well as on product packaging. Indeed, the letter from Nancy Bryson included copies of enforcement letters from USDA to packagers requiring that signs and brochures in stores comply with FMIA labeling requirements.

In arguing against express preemption the Attorney General also cites *Chemical Specialties Mfrs. Assn. v. Allenby*,[10] the U.S. Court of Appeals for the Ninth Circuit's 1992 case holding that the nearly-identical definition of "labeling" in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) excludes point-of-sale signs, and that pesticide manufacturers may therefore comply with Proposition 65 by posting signs in stores. *Allenby* was a facial challenge to Proposition 65, in which the court could find Proposition 65 preempted only if "no set of circumstances exists" under which it would be valid. When pesticide manufacturers argued that their products would be misbranded under FIFRA if they posted Proposition 65 warnings, the court dismissed the concern: "It seems implausible that the EPA would prosecute a company for, in essence, complying with Proposition 65."[11]

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[7] *See* California Health and Safety Code section 25249.7(d).

[8] For example, in *Dowhal v. Smithkline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (2004), the nicotine-patch case discussed below.

[9] *American Meat Institute v. Ball* 424 F.Supp. 758, 763 (W.D. Mich. 1976).

[10] 958 F.2d 941 (9th Cir. 1992).

[11] *CSMA v. Allenby*, *supra*, at 958 F.2d 947.

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Unlike *Allenby*, the meat industry's complaint presents more than a facial challenge to Proposition 65. The complaint alleges an actual conflict between the FMIA, as applied to beef by USDA, and Proposition 65. Therefore, the court may instead follow *Dowhal v. Smithkline Beecham Consumer Healthcare*, 32 Cal.4th 910 (2004), in which the California Supreme Court found that Proposition 65 was preempted by the federal Food Drug and Cosmetics Act, despite the savings clause expressly inserted during 1997 amendments to prevent preemption of Proposition 65. In *Smithkline*, the federal Food and Drug Administration (FDA) refused to approve a Proposition 65 label on nicotine patches used to stop smoking, for fear that the warning might discourage pregnant women from quitting. It was impossible for the manufacturers to comply with Proposition 65 without rendering their products "misbranded" under the FDA's rulings. Therefore, the California Supreme Court found a direct preemption of Proposition 65 by the FDA as applied to nicotine-patch labeling. Although the plaintiffs in that case argued that the industry could meet Proposition 65's requirements without changing their FDA-approved labels by posting point-of-sale signs in stores, the court rejected that argument: "Warnings through point-of-sale posters or public advertising could have the same effect of frustrating the purpose of the federal policy.[12]" As the complaint alleges, USDA's stated concern about Proposition 65 warnings is to prevent the misleading conclusion that the products are unwholesome. The complaint alleges that in addition to product packaging, USDA has exercised regulatory power over point-of-sale signs relating to meat. USDA's regulation of point-of-sale materials shows the difficulty of complying with FMIA as well as with Proposition 65, and illustrates that the purposes of the FMIA, as administered by USDA, are frustrated by Proposition 65 warning requirements.

The Attorney General in his *amicus* brief attempts to distinguish *Smithkline*, arguing that the conflict there was the result of FDA's more "specific" consideration of the "specific" nicotine products and their "specific" risks and benefits. Since USDA has no specific standards for PCB and dioxin, he argues, there is no conflict preemption. Finally, the Attorney General's brief attempts to dismiss USDA's communications as irrelevant, describing them as a mere "exchange of differing views" that cannot "create a conflict between Proposition 65 and the FMIA."

These arguments will be scrutinized by several Californian trial courts in the next few months, as the Attorney General continues to prosecute Proposition 65 in defiance of federal agencies authorized to develop and enforce careful and comprehensive programs for consumer safety and information. In addition to the beef complaint and the tuna canners' pending motion, the issue will undoubtedly be raised in the Attorney General's recently-filed lawsuit alleging that fried potatoes require Proposition 65 warnings, again despite FDA's urging that it is still studying this complex issue. FDA has not taken a public position on the Attorney General's acrylamide lawsuit, but did send representatives to meetings convened by OEHHA, to discourage the agency from promulgating acrylamide regulations while FDA is trying to determine whether acrylamide in food poses any risk to humans. The FDA carefully considers any proposal for warnings on food, balancing both risks and benefits, to avoid frightening consumers away from healthy foods or immunizing consumers to meaningless warnings. The FDA has determined that warnings are appropriate only when there is an actual risk to the public.

Should these cases reach California's appellate courts, will they follow the California Supreme Court's *Dowhal* ruling and find preemption, or will they follow the Ninth Circuit's *Allenby* ruling and allow Proposition 65 point-of-sale signs over the objections of federal agencies authorized to regulate consumer safety and information? Almost one hundred years after publication, *The Jungle*'s influence in comprehensive national food regulation is at issue once again.

[12] *Dowhal v. Smithkline Beecham, supra,* at 32 Cal.4th 929.