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# COURT SHOULD DISMISS JUNK SCIENCE-BASED PROPOSITION 65 SUIT

by  
Andrea D. Tiglio

The Physician's Committee for Responsible Medicine (PCRM)<sup>1</sup> is suing fast food chains that include Burger King Holdings, McDonald's Corporation, Chick-fil-A, Chili's, Applebee's, Outback Steakhouse and TGI Friday's for serving, without warning consumers, "carcinogenic" grilled chicken.

PCRM has recently filed the lawsuits in the United States District Court in Los Angeles under California's Proposition 65 to compel the restaurants to warn consumers. Proposition 65<sup>2</sup>, California's "toxics right to know" law, requires the executive branch to maintain a list of "chemicals known to the state to cause cancer or reproductive harm" and requires companies to warn consumers about exposure to the ever growing list of toxins, even in harmless quantities.

PCRM has alleged that an independent laboratory analysis of every sample of grilled chicken products served at each of the defendants' national chains tested positive for the carcinogen, 2-amino-1-methyl-6-phenylimidazo[4,5-b]pyridine (PhIP). PhIP is one of a group of carcinogenic compounds called heterocyclic amines (HCAs). In 2005, the federal government officially added HCAs to its list of carcinogens, and PhIP has been on the California's Proposition 65 list of known carcinogens for more than 10 years.

HCAs are a fact of life. HCAs are formed by the condensation of creatinine with amino acids when meat is cooked. Specifically, HCAs are found in muscle meats (beef, pork, chicken and fish) cooked at home, in fast food restaurants, and in non-fast food

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<sup>1</sup>PCRM is a non-profit organization based in Washington, DC, founded in 1985 by psychiatrist Neal D. Barnard, and advocates for a vegetarian diet.

<sup>2</sup>See California health and Safety Code § 25249.5 *et seq.*

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**Andrea D. Tiglio** is an associate in the Tyson's Corner, Virginia office of the law firm McGuire Woods LLP. She holds a Ph.D. in Molecular Biology and Biochemistry, and is the co-author of a 2006 FOOD AND DRUG LAW JOURNAL article *Not the Next Tobacco: Defenses to Obesity Claims*.

restaurants.<sup>3</sup> Formation and concentration of HCAs are dependent upon the type of food, cooking method, temperature, and time. Of these, temperature is the most important. Frying, broiling, and barbecuing produce the largest amounts of HCAs because these methods require the highest temperatures.

The Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 301, *et seq.*, prohibits the introduction of food that is adulterated or misbranded within the meaning of the statute. Pursuant to the FFDCA, the United States Food and Drug Administration (FDA) is authorized to regulate food labeling<sup>4</sup> and is charged with protecting food. The FDA has indicated that Proposition 65 warning labels may be preempted by federal law if the warnings are without scientific basis or are silent respecting the amounts of such foods required to cause harm.

For example, in a similar case, the so-called “French-fry lawsuits,” former California Attorney General Bill Lockyer’s office used Proposition 65 to warn consumers about acrylamide, which occurs naturally when starchy foods are heated at high temperatures. Studies published in the *British Journal of Cancer* and *JAMA*, however, show no added risk of cancer from acrylamide at the levels commonly found in food. Data from the U.S. Environmental Protection Agency demonstrate that a person of average weight would have to eat over 182 pounds of French fries, every day, for his entire life, in order to have the weight-adjusted cancer risk found in laboratory rats.

At present, the maximum daily intake of HCAs in food has not been established, and no Federal agency monitors the HCA content of cooked meats. There is simply no good measure of how much HCAs would have to be eaten to increase cancer risk,<sup>5</sup> and there are no guidelines concerning consumption of foods with HCAs.

In sum, PCRMA is attempting to compel fast food companies to issue warnings about PhIP that are without scientific basis and that would be silent respecting the quantities of food required to cause harm. The PCRMA lawsuits, therefore, should be dismissed because the Proposition 65 warnings would be legally insufficient and legally insufficient warnings should be preempted by the FFDCA.

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<sup>3</sup> “One study has suggested that greater exposure to HCAs stems from home cooking and cooking in non-fast-food restaurants where food may be cooked to order and where a larger amount of meat is consumed.” See <http://www.cancer.gov/cancertopics/factsheet/Risk/heterocyclic-amines> (last visited Oct. 14, 2006).

<sup>4</sup> See 21 U.S.C. § 343, *et seq.*

<sup>5</sup> A report by the NTP Executive Committee Working Group for the Report on Carcinogens has stated that it was “difficult to draw any conclusions from the human epidemiology studies on the carcinogenicity of PhIP, MeIQ, and MeIQx in humans. The human epidemiology studies were inconsistent in their findings and were potentially influenced by other carcinogenic substances found in meats.” See [http://ntp-server.niehs.nih.gov/ntp/newhomeroc/roc11/HCA\\_RG2Summary-final.pdf](http://ntp-server.niehs.nih.gov/ntp/newhomeroc/roc11/HCA_RG2Summary-final.pdf) (Last visited Oct. 14, 2006).