STATE OF CALIFORNIA

OFFICE OF THE ATTORNEY GENERAL

BILL LOCKYER
ATTORNEY GENERAL

MEMORANDUM

Date : February 10, 2006

To : Honorable Members of the California Congressional Delegation

From : California Attorney General, Bill Lockyer

Re : Opposition to H.R. 4167, the National Uniformity for Foods Act of 2005

H.R. 4167, the National Uniformity for Foods Act of 2005, endangers important public health protections California law provides its citizens. As the measure moves toward a possible vote on the floor of the House of Representatives, I wanted to make sure members of the California delegation fully understand this threat, and urge you to oppose the bill. Perhaps the proponents did not make clear the extent to which H.R. 4167-would deprive Californians of the particular benefits of Proposition 65. This landmark law was passed by 63% of the voters, and it has reduced Californian's exposure to toxic chemicals in food.

1. Scope of the Bill

The dramatic sweep of this bill may not have been made apparent:

- It apparently would forbid any state from requiring any form of health disclosure for a food, even where the FDA has no requirement in place for a given food, and is not even considering a requirement. This prohibition would even bar warnings posted in stores within a single state, and which therefore have no effect on interstate commerce, other states or a manufacturer's nationwide product label. (Proposed § 2(b)(2).)

- It would bar states from limiting toxic chemicals in a food simply because the FDA has a general rule barring foods that are "injurious to health," even where the FDA has not set any exposure standard for specific toxic chemical states may want to regulate. (Proposed § 2(a)(3).)

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- It would remove the incentive that currently exists for food companies to reduce toxic chemicals in food products to below the level that requires a warning under Proposition 65.

2. Examples of Benefits of State Regulation

There are many examples of how Proposition 65 has benefitted Californians. An excellent case in point is the recent effort by my office, the Legislature and Governor Schwarzenegger to address the issue of lead in imported Mexican candies. These candies are extremely popular with millions of Californians, especially our large Latino population. But they have garnered little attention from federal regulators in Washington, D.C. For years, FDA has set an allowable lead level in these candies of 0.5 parts per million. That standard, uniformly recognized by public health officials as too lax, allows approximately 20 times more lead in a piece of candy than Proposition 65 permits. Lead damages the developing fetus, and impairs nervous system development in young children. A 2003 article in the New England Journal of Medicine concluded that levels of lead previously considered safe, actually caused a significant reduction of children's IQ.[1] Thus, what may in the past have been considered a "trace amount" posing no real risk now is known to damage health.

Despite numerous press stories showing these candies' adverse health effects on children in the local Latino population, FDA took only limited action to enforce its own alarmingly lax standard. As a result, in June 2004, my office filed an action under Proposition 65 which will force Mexican style candy manufacturers to reduce to safe levels the lead in their candies. In addition, last year the Legislature passed and the Governor signed Assembly Bill 121, which prohibits the sale of adulterated candy containing lead, imposes fines for the sale of such candy and directs the state Office of Environmental Health Hazard Assessment to set a regulatory level allowing only "naturally occurring" lead to be present in candy.

H.R. 4167 would preempt Assembly Bill 121, simply because FDA has a more lax, and largely unenforced, lead standard. Additionally, H.R. 4167 would preempt Proposition 65's warning requirement because it is a non-uniform disclosure.

The bill would preempt another important use of Proposition 65-my vigorous efforts to assure that parents and women of childbearing age are aware of the risks to unborn babies and their small children from consuming too much fish with high levels of mercury. This effort is largely consistent with the FDA's own policies. The FDA website warns that women who are pregnant or may become pregnant should not consume certain types of fish (such as swordfish and shark), and should limit

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[1] "Exposure to Lead in Children–How Low is Low Enough?" *New England Journal of Medicine* (April 17, 2003).

consumption of all types of fish, because of their mercury content. California has given life to this requirement by requiring that similar information be posted in grocery stores that sell fresh fish and restaurants that serve fish. At least six other states have instituted similar public disclosure requirements concerning mercury in fish. We recently completed the evidence phase of a trial concerning warnings for canned tuna. We believe such warnings can be provided in a manner that will not conflict with FDA's advice, but will ensure the advice is seen by more consumers of fish than FDA's website. H.R. 4167 would preempt this disclosure requirement.

In addition, even well established and successful uses of Proposition 65 could no longer be enforced, unless approved by the FDA. For example:

Lead in ceramic tableware: Based on a 1991 action by then Attorney General Dan Lungren, industry agreed to substantially reduce lead that leaches from ceramic tableware into food and beverages. Manufacturers took that step because of the marketplace incentive created by the duty to post conspicuous point-of-sale warnings. While warnings initially were common, most companies have reduced lead levels to substantially below FDA requirements.

Lead in calcium supplements: In June of 1997, California reached agreement with makers of calcium supplements to reduce levels of lead contamination in their products below the level at which a warning would be required under Proposition 65. Because of the importance of encouraging women to increase their intake of calcium, this agreement was negotiated without ever providing a consumer warning. Meanwhile, FDA issued advisories concerning some sources of calcium as early as 1982, and requested additional data in 1994. But it never has taken regulatory action.

Arsenic in Bottled Water: Arsenic in bottled water has been reduced to less than 5 parts per billion under the settlement of a Proposition 65 action reached in 2000. FDA, in contrast, still applies a standard of 50 parts per billion.

Leaded crystal: Based on science showing that substantial quantities of lead leach from fully-leaded crystal (defined as 24% lead) into beverages, California took action to require visible warnings at the point of sale in California, as early as September of 1991. Leaded crystal – as distinguished from other types of glassware – now carries prominent warnings in California stores. Since 1991, FDA never has publicized its advisory addressing this hazard in a manner likely to be seen or read by consumers.

In other instances, quiet compliance with Proposition 65 has produced public health benefits without litigation. Lead soldered cans leach substantial amounts of lead into foods stored in the cans. As soon as Proposition 65 took effect in early 1988, our investigations found that food processors were switching to cans that do not use lead, before enforcement action was even necessary. In 1993, years after Proposition 65 took effect, FDA issued "emergency" action levels.

Similarly, potassium bromate is a listed carcinogen under Proposition 65. Informal surveys in 2002 of stores in California found no bread containing potassium bromate for sale. And the 2002 surveys found stores in other states sold bread containing potassium bromate. Meanwhile, FDA remains engaged in a multi-year process to encourage bakers to stop using this additive.

I recognize many have expressed concern about certain enforcement activities of Proposition 65 by private parties. That is why my office and the California Legislature have taken vigorous action to ensure that private lawsuits brought under Proposition 65 are pursued only in the public interest. In 1999, the Legislature amended the statute to require that private plaintiffs report to the Attorney General concerning their enforcement activities. In 2001, I sponsored additional legislation that requires all persons who want to bring private Proposition 65 cases seeking consumer warnings to first provide my office with appropriate scientific documentation. That statute also requires that all settlements of those cases be reviewed by my office and approved by courts in a public proceeding under specific legal standards. These actions by the state have curbed questionable lawsuits filed by private litigants, and reduced the number of settlements that are not in the public interest.

I am aware that many in the food industry have expressed great concern over the chemical acrylamide, its presence in many foods, and the potential application of Proposition 65 to those foods. The FDA has been considering this issue since 2002, and currently has no schedule for when, or whether, it will take any action concerning the matter. In the meantime, a single serving of french fries contains 80 times the amount of acrylamide EPA allows in drinking water. Accordingly, I have filed suit under Proposition 65 to require warnings for acrylamide in french fries and potato chips, so that people in California can make their own choices about their exposure to this chemical. This suit would not ban any products or require that warnings be provided in any other state. It would, however, provide Californians the health information they demanded in passing Proposition 65.

3. Petition Process

While H.R. 4167 would allow states to petition FDA for authority to impose additional requirements, it is inappropriate to require a state to seek the federal government's permission to protect the health of its citizens. Moreover, our past experience suggests the FDA would deny any such petition.

Further, the specific provisions of the petition process raise concerns. Initially, states would have six months to petition FDA for approval of existing requirements applicable to specific foods, during which time those requirements would remain in effect until disapproved by the FDA. (Proposed § 403B(b).) While the bill provides for judicial review of FDA's decision, it does

not establish the standard by which any denial of a petition would be judged. The lack of a review standard would leave FDA potentially unlimited discretion to arbitrarily strike down state requirements. (Proposed § 403B(b)(3)(C)(ii)(I).)

Any general requirement -such as Proposition 65 itself- and any new requirement, could be adopted only after approval by FDA. The FDA could delay that process indefinitely through extension of the "public comment period." (Proposed New § 403B(c)(1), (3)(B).) Thus, it appears that any time a state official sought to apply an existing law to a food product where no specific requirement for that food had been set, enforcement of the law would be barred until and unless the FDA granted its permission.

Indeed, H.R. 4167's petitioning scheme brings to mind one of the grievances against distant British authority recorded in the Declaration of Independence. "He has forbidden his governors to pass laws of immediate and pressing importance, unless suspended in their operation till his assent should be obtained; and when so suspended, he has utterly neglected to attend to them." (Declaration of Independence, 4th paragraph.)

4. Need for National Uniformity

In a few instances, legitimate reasons exist for national uniformity in food labeling and standards. These circumstances, however, already are addressed under current federal law, which also prohibits states from adopting requirements that conflict with properly adopted and necessary federal labeling requirements.

Existing section 403A of the Federal Food, Drug, and Cosmetic Act expressly precludes state laws mandating label requirements for a wide variety of matters on which the FDA has acted and uniformity is necessary. This preemption covers standards of identity, use of the term "imitation," identification of the weight of the product and its manufacturer, the presence of food allergens, and whether the product is pasteurized.

Other federal regulatory statutes that govern nationwide industries, such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), adopt a much more limited approach. FIFRA, for example, preempts only state warning requirements that would appear on the nationwide label of the product. It also allows each state to adopt more restrictive requirements for use of pesticides within that state.

Even where Congress has not expressly preempted state law, courts uniformly have held that state law must give way to federal requirements where the two are in "actual and irreconcilable conflict." The California Supreme Court applied that requirement in *Dowhall v. SmithKlineBeecham*

(2004) 32 Cal.4th 910.) This doctrine sufficiently ensures state regulations do not interfere with properly adopted federal requirements.

In fact, FDA officials have demonstrated a disturbing tendency to manufacture "conflicts" in their desire to preclude states from enforcing their own laws to protect public health. FDA officials arbitrarily declare "misbranded" products for which additional warnings would be given, without even consulting state authorities. For example, last August, the FDA, at the behest of a Washington, D.C. law firm, sent me a letter asserting that state warning requirements concerning mercury in canned tuna conflicted with federal law. The FDA sent this letter without any advance notice to my office. Further, the letter was based on inaccurate information provided the FDA by the industry law firm, and was sent without awareness that we proposed only that California stores provide warnings completely consistent with FDA's own published "mercury in fish advisory." In light of such incidents, it's arguable that if there is any need for legislation, it is to amend federal law to protect the states against arbitrary and informal action by federal officials who take it upon themselves to declare California law in "conflict" with federal law, without providing state authorities advance notice or any opportunity to be heard.

H.R. 4167 would greatly impede our ability to protect the health of Californians, both under Proposition 65 and under other laws that could be adopted by the voters or our Legislature. I thank those of you who are opposing this measure. For those of you still considering the bill, I strongly urge you to oppose it. And for those of you who have agreed to co-sponsor the measure, I hope you will reconsider your position in light of the important consumer protections H.R. 4167 will impede.

[End of Memo]