

TESTIMONY OF
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BEFORE
SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS

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Thank you, Mr. Chairman, for inviting me to present views today on S. 3128, The National Uniformity for Food Act of 2006. I am William K. Hubbard, and until recently was an official of the Food and Drug Administration. I retired in 2005 after 33 years of Federal service, the last 14 of which were as an Associate Commissioner at the FDA. The issue of national uniformity for food safety laws was one in which I was involved repeatedly over the years, as successive Presidential Administrations sought FDA advice when they examined this issue.

Let me begin by observing that protecting citizens from unsafe food is a quintessential governmental function. Even before the creation of the United States, individual states (then colonies) were establishing laws protecting the public from hazards that could be intentionally or mistakenly placed in food sold in the marketplace. That role grew as commerce in food expanded, until, a century ago, in 1906, Congress determined that a Federal food safety role should be established as well, in the forms we know today as the Food and Drug Administration and the Agriculture Department's meat inspection program. With this addition of a Federal food safety structure, state and Federal food safety officials have become closely allied partners in protecting our citizens from unsafe food—sharing scientific data about potential risks to foods, cooperating on inspecting food manufacturing facilities, responding to outbreaks of foodborne illness, removing hazardous food from the market, and devising similar regulatory structures for overseeing the safety of the food supply.

Together, state and Federal health officials have developed a modern, science-based infrastructure that, along with the hard work and dedication to high standards of food producers, has given Americans a food supply of unparalleled abundance, affordability, quality, nutritional variety, and safety. There is no doubt that this system has served the nation well, and that state and Federal food safety programs have not only co-existed, but have evolved to protect our citizens using essentially the same scientific standards, regulatory mechanisms and statutory constructs. Indeed, most states, in an effort to harmonize with the judgment of Congress, have enacted food and drug laws identical or quite similar to the provisions of the Food, Drug and Cosmetic Act (the principal source of FDA's food safety authority). There have, over the years, been occasional instances in which FDA and state determination about product safety (and their concomitant public warnings) have differed. But those instances have been relatively rare, and generally have been worked out amicably among the scientists involved. There certainly has not been the sort of mass conflict and confusion that would warrant a fundamental undermining of the strong Federal/state partnership that currently exists. And the states have served the valuable function at times of being the first to identify a health risk and, through their actions to protect their own citizens, have alerted the FDA, so that it could extend such protections nationally.

The issue before the committee today, of course, is whether Congress should preempt the laws of the states, in deference to the regulatory role of the FDA. There are certainly examples where Congress has done so. For example, USDA has meat inspectors in every slaughterhouse while that facility is processing meat, and a separate state function would be redundant. When Congress required all foods to bear nutrition labeling in 1990, it

judged that a single Federal standard was appropriate, as the states had no separate nutritional labeling requirements at that time and FDA was authorized to create a strong, enforceable national standard. Most recently, Congress established standards for labeling the 8 major food allergens, and gave those preemptive effect.

However, in the case of contaminants in the food supply, Congress has never done so, and the circumstances are much different. The states' role in protecting against adulterated foods long pre-dates the creation of the FDA, and the FDA's ability to adequately oversee such potential threats to the food supply is inadequate today and growing weaker each year. So it is ironic that at this time Congress would be considering legislation that would remove a valuable food safety tool, and perhaps provide incentives to further weaken FDA. Let me explain the basis for those conclusions.

In 1972, FDA's food program constituted approximately one-half of the FDA's efforts, in terms of the agency's resource allocation. Today, it is about one-quarter, even though FDA has little more staff than it had in the 1970s. Likewise, 34 years ago, FDA conducted 35,000 inspections of food manufacturing facilities. This year, they will do perhaps 5,000. The volume of food imports from overseas is approaching 10 million per year, and the number that FDA inspectors physically examine is in the single digit thousands—making it virtually certain that any given food shipment will enter the United States with no FDA inspection. I could provide many more similar statistics, all of which paint a picture of an FDA regulatory structure that is under-resourced, under-staffed, and essentially incapable of meeting the growing demands to oversee food production, food additives, cosmetics, dietary supplements, nutrition labeling, foods produced from biotechnology, foodborne disease outbreaks, dangerous new pathogens that infect food, pesticides, and the many other responsibilities of that program. And, most recently, the President has proposed diverting traditional food safety resources toward protecting the nation against terrorism threats to the food supply—a worthy effort, but one that will force FDA to rely even more on state food safety efforts.

Yet S. 3128, in the name of “uniformity,” would remove FDA's partner in protecting against food adulteration, and throw even more responsibilities at the agency—in effect, moving problem solving from a source that has proven to be an effective complement to Federal authorities to one that cannot accept more responsibility and will thus be ineffective. Further, because the states' ability to deter adulterated foods would be weakened, and with FDA the only alternative, producers of food about which safety concerns have been raised would have incentives to maintain a weak FDA.

FDA's resource shortfalls beg for a focus on the mechanism embodied in S. 3128 to permit the states to act against adulterated food. The bill would create a petition process whereby a state wishing to maintain an existing standard, or create a new one, would petition FDA either for an exemption from preemption or to create a uniform, national standard. This provision is simply impracticable. First, FDA has shown demonstrably that resource constraints prevent it from processing the flow of citizen petitions that it currently receives. In fact, the agency slips further behind each year in its handling of citizen petitions; there is now a backlog of over 200 citizen petitions in the queue for

response in the food program alone, many dating back several years; and that program managed to respond to only 9 petitions in all of 2005. Adding yet another flood of petitions to this already-overwhelmed system would merely build in additional failure.

But I can describe an even more dismal prospect regarding FDA's ability to respond to the petitions envisioned by S. 3128. The Congressional Budget Office assumes that FDA will receive at least 200 state petitions during the first year after the bill's enactment, and that it will cost \$400,000 to review each petition. So FDA would be required to spend \$80 million to answer those petitions—for no discernible public health gain. Mr. Chairman, the entire budget for salaries and expenses of the scientists in FDA's headquarters food program is under \$100 million, so this bill, if enacted, would essentially mean that the food program would need to cease all other functions except for the review of state petitions, if it were to make a sincere effort to comply with Congress's charge. If the industry's prediction, that FDA would receive over 300 petitions from California alone, is correct, the effort to address the petitions would require more resources than the agency's food program possesses, meaning that FDA could not accomplish the goal even if ALL food headquarters staff were assigned only to petition review. Or, if FDA chose not to engage in this decimation of the agency's food safety programs, it could be forced to basically ignore the statute, thus setting the stage for great confusion, potentially endless lawsuits, and a vacuum in both state and Federal protection against food adulterants.

I would add that it is very unclear what the bill preempts. The dispute between the food industry and others—whether the state Attorneys General, state food safety officials, or the Center for Science in the Public Interest—about the number of laws preempted is a good indicator of that ambiguity. There is a very real question whether most state enforcement actions will be met with a rejoinder that the action is preempted by this bill. Resolving such disputes through the courts will add significantly to state enforcement costs and inevitably reduce the volume of enforcement the states can undertake. Obviously, FDA will not have resources to take up any slack.

The bill does not give preemptive effect only to requirements imposed by FDA by regulation. Instead, it appears to completely eliminate state safety notifications, whether the FDA has acted or not. In terms of enforcing state safety standards themselves, the bill starts at the top, broadly preempting state safety requirements unless they are identical to Federal requirements. It then allows states to enforce only those state requirements that are identical to existing FDA requirements, or even guidances, which are non-binding FDA advisories to industry. Localities, such as New York City, are apparently preempted from enforcing their own requirements. While preemption focused on circumstances when FDA has made a well-reasoned determination can make sense, it is difficult to see a problem that supports such a broad preemption. Further, the bill would not require that FDA step in (even if it had the resources) and replace state and local laws that might be a necessary, further exacerbating the vacuum in safety oversight that the bill would create.

In conclusion, Mr. Chairman, when a well resourced FDA has been able to examine a potential health risk in food, bringing to bear the best scientific data and analytical ability, and resulting in the establishment of a reasoned determination—whether to bless a substance’s safety, to require safety warnings to consumers, or to ban the substance—it would be reasonable to consider whether that determination should be dispositive for the entire nation, and whether states should second guess such a carefully reasoned disposition. However, until and unless FDA is given the resources and ability to deal with any and all questions about the safety of food constituents, I believe that the existing Federal/state cooperative relationship has passed the test of time in its effectiveness and ability to work together to protect our citizenry. Not only does the current system work well, but there is little evidence of a problem now that would justify the broad preemption envisioned by the bill, and no reason to believe that there will be a problem in the future. The vast majority of state attorneys general agree with that conclusion, as do the states’ food and drug officials, and virtually all consumer interest groups. That practical consensus of opposition to S. 3128 should be seen as a significant cautionary message about this bill. Adding in FDA’s absolute inability to implement this bill in any reasonable fashion should raise those caution flags even higher.

Thank you for giving me the opportunity to comment on this important matter.