

Written Testimony of
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The views expressed here are those of the author and do not necessarily reflect those of the Tennessee Department of Health. I am also a member of an Institute of Medicine committee that is looking at a related topic. However, none of my testimony arises from or should be taken as reflecting the confidential deliberations of the IOM committee or its eventual conclusions or recommendations.

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to be before you today.

As a public health practitioner, I appreciate the opportunity to comment on this important new bill. Recent high-profile, nationwide outbreaks running the gamut from frozen dinners and spinach to jalapenos and peanut butter demonstrate the huge challenges and opportunities for improvement in the nation's food safety infrastructure. The global distribution, intensive production, and rapidity of transport of our food supply are markedly increasing the challenges faced in ensuring its safety. That 76 million Americans experience foodborne illness each year, resulting in 325,000 hospitalizations, is unacceptable. A typical American meal includes foods from six different countries, fresh produce travels an average of 1500 miles to get to our plates, 80% of our seafood is imported, outbreaks involving several hundred victims no longer shock us... a long list of dramatic statistics demonstrate the changing environment faced by the FDA and other agencies in attempting to ensure food safety. Laws, policies, and to be frank philosophies developed decades ago no longer suffice to successfully meet these new demands. The legislation we are discussing today is therefore a critical step in reviving the food-safety capacities of the FDA and giving it the authority and resources necessary to accomplish the goal of maintaining the safest food supply in the world.

I work in a state health department as an epidemiologist, responsible for investigating foodborne diseases- in effect helping detect and "clean up the mess" left when things go awry in the food chain. I am excited to see that this proposed legislation addresses many

of the problems that I experience first-hand in my roles both investigating and helping prevent foodborne disease.

From this perspective, there are a number of important aspects of this bill which I would like to address. Improving the traceability of food, as called for in this legislation, is fundamental to successfully achieving many of the other tasks described. Appropriately, a large proportion of this bill strengthens control measures high up in the food chain at the steps of production and importation. That said, obviously those are overwhelming responsibilities, and inevitably they can't be controlled perfectly. When problems are introduced at or sneak through to later stages in the food chain, and result in contaminated food in our kitchens or on our plates, it is crucial that they can be responded to quickly and effectively and then prevented in the future. If traceback information had been more promptly available and shared faster I think that many of the problems associated with the recent tomato/jalapeno incident could have been mitigated. Likewise, tracing peanut butter from one plant to 4000 different commercial products would have been utterly impossible with many other types of foods. Ensuring that all foods are traceable efficiently and accurately is critical to maintaining food safety.

The sections of this bill that improve identification and registration of food producers and importers, and enhance the safety of imported foods will facilitate important steps toward preventing problems before they occur.

Contamination of produce and foods which are eaten uncooked are of particular concern because consumers have less control over the safety of those foods in their kitchens. Setting standards for pre-harvest food production starts to close a major current gap in the nation's food safety system. Suspected produce-associated illnesses are particularly difficult to investigate, from both the public health and regulatory perspectives. Typical produce items pass through a myriad of hands along the "farm to fork" continuum, and product tracebacks are susceptible to complete breakdown at the weakest link in the chain. Produce is generally purchased by consumers unlabeled, with no information on its origin. Produce from more than one source is often mixed at different distribution points. The challenges to performing subsequent tracebacks through such a complex food-handling chain are formidable. While large food service corporations and their suppliers often have excellent quality-control programs with impeccable records, many other companies don't. The portions of this bill requiring country-of-origin labeling, improved distribution records, and plans to regulate the safe production and harvesting of fruits and vegetables are important to help address these problems.

This bill has a number of sections addressing the nature and frequency of inspections of food facilities. I am pleased to see that the agency is being encouraged to markedly increase the scrutiny of food-handling entities. While this bill details defined inspection frequencies, I would like to emphasize the importance of basing inspections, product testing and any other interventions by the agency on sound science. The bill does have important directives to improve testing and the science-base of the agency's activities. Even with substantially increased resources the responsibilities of the FDA will be

tremendous, and it is critical that from top to bottom activities are more efficient and effective, and not just more frequent. This bill's requirement that agency activities are "risk based" is particularly critical, so that resources can be focused on issues of highest risk, and interventions that are the most effective. It is likely that as technology improves, the value of traditionally defined "inspections" will change dramatically, and I would urge that the agency retain sufficient flexibility and authority to adapt to changes rapidly and with as few barriers as possible.

The directive to expand sampling of foods for microbiologic testing is an example of a means to collect additional information to support development of "risk-based" policies. An example of this is a current project in which the state/CDC FoodNet program collaborates with FDA's Center for Veterinary Medicine to systematically collect retail meats for testing. Expanding such programs to other foods, and potentially targeting such efforts to geographic areas where there is active foodborne disease surveillance, could be an important way to identify problems before they lead to large outbreaks like those recently associated with peanut-butter, frozen foods and produce.

I think it is important in any discussion of the food safety system to emphasize the importance of interaction between FDA and CDC, along with state and local partners. In meeting the directive to enhance the science of food safety and develop risk-based approaches, data from CDC and its partners on things like outbreaks, disease surveillance, and attribution of human disease to specific foods and commodities will be critical. It is

imperative that such data are developed and shared cooperatively to meet the needs of all partners involved in the system.

In every discussion I've been in pertaining to food safety, with any permutation of agencies or stakeholders, the importance (and current inadequacy) of effective information-sharing is probably the most common single topic that is raised. I am pleased to see the issue addressed in this bill, though if anything it is understated. This legislation calls for establishing science-based performance standards, and making improvements in the surveillance systems for human illness by which success can be measured. That said, there is a tremendous amount of information already available, within CDC, USDA and other agencies as well as the FDA, which is not currently maximally utilized due to barriers in sharing among those partners. Identifying new information needs is clearly important, but it is obviously equally important to take advantage of existing resources that can help meet those needs before expending more. Improving the technological capacity to share information will be important in accomplishing this. Perhaps even more important, however, is changing the ingrained policies of not sharing information among partner agencies, far beyond any logical limit, even when failure to do so threatens public health.

To meet the mandates in this bill, FDA will have to increase interaction and coordination with state and local agencies, which will require funding and focused attention. There are many examples of situations in which state health departments have proceeded with their own product testing or limited tracebacks, and gathered important data long before

information was available from the federal agencies involved in the investigation. I don't believe that these agencies are purposely withholding critical information from public health partners, but I do think that they are required to operate under such restrictive legal constraints (or perceptions thereof) that they are unable or unwilling to share data as fully as necessary, even in urgent situations. Federal regulatory agencies are frequently prohibited from sharing proprietary information obtained during the course of their investigations. Flow of information in both directions between FDA and CDC, as well as with state health department partners, is critical. Examples of this include such things as distribution lists during recalls, information on suspected products or producers, and information on potentially exposed or ill people. The FDA, CDC and partner agencies must have both the authority and expectation to share actionable information with public health partners promptly and fully, to the extent necessary to protect the public's health.

I will conclude with a final comment about the importance of ensuring that FDA and its state and local partners have adequate resources to meet the responsibilities with which they are charged. No one would argue that the FDA is currently underfunded, overworked, and essentially overwhelmed. State and local food safety capacity must also be robust in order to maintain an effective food safety system. Adequate and consistent funding and resources must be dedicated explicitly to sustain the food safety programs of the FDA, as well as the state and local partners who work with them to keep the US food supply safe. Americans will eat a billion meals today, and I can't think of a better investment than one that will keep every one of those meals safe.

Thank you.

Summary

- This bill will facilitate important strides toward improving the nation's food safety infrastructure.
- Adequate and consistent funding and resources must be dedicated explicitly to sustain the food safety programs of the FDA, in addition to other federal, state and local partners who work with them to keep the US food supply safe.
- The FDA and partner agencies must have both the authority and expectation to share actionable information with public health partners promptly and fully, to the extent necessary to protect the public's health.
- The provisions in this bill to improve the safety of food imports, strengthen regulations to ensure the safety of foods produced domestically and in foreign countries, and improve the traceability of foods effectively through the entire farm-to-fork chain are critical.
- The importance of state and local public health partners, who perform a tremendous amount of work that supports the efforts of the FDA in protecting the US food supply, must also be recognized. Support for that critical infrastructure must also be maintained in order for FDA's activities to be successful.