



**Written Testimony of  
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**Before the Subcommittee on Agriculture, Rural Development, FDA and  
Related Agencies  
House Committee on Appropriations  
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Chairwoman DeLauro, Ranking Member Kingston and members of the Subcommittee, thank you for the opportunity to testify before you today regarding appropriations for food safety activities at FDA and USDA. I am Dr. Jeffrey Levi, Executive Director of Trust for America's Health (TFAH). TFAH is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority. We applaud the Committee for continuing its examination of the food safety functions at the federal level.

Earlier this year, TFAH released a report entitled *Fixing Food Safety: Protecting America's Food Supply from Farm-to-Fork*. Our report finds that food safety represents a significant public health threat. The food safety system is fragmented, dependent on archaic laws, and chronically underfunded. The current system is reactive, not preventive, meaning we are wasting millions of dollars on responding to threats rather than building proper controls into the production system. The recent salmonella crisis provided an all too real demonstration of the dangers of a reactive system, as over 1,400

people in 43 states were sickened, and took nearly three months to discover the true source of the outbreak. The economic repercussions from the delayed response are still being felt in the agricultural, restaurant, retail and food production industries, and the health and trust of the American people has been shaken by this failure in prevention and traceability. Our report finds that Congress has not provided the Food and Drug Administration with a modern, public health mandate to prevent foodborne illness; has not updated the agency's legal tools to meet the challenges of a high-tech, globalized food supply; nor has it provided the funding stream necessary to carry out research and inspection. At the same time, the agency has not adequately expressed its resource needs as it moves forward with its Food Protection Plan.

Food safety represents a significant public health threat. One in four Americans is sickened by foodborne disease each year, and an estimated \$44 billion is lost each year in medical and lost productivity costs. According to FDA's website, since May of this year alone, FDA has issued over 30 recalls, alerts, withdrawals and warnings of unsafe or mislabeled food, including several alerts related to the salmonella crisis. This figure does not even take into account similar alerts related to USDA-inspected foods. These numbers are far too high, and major gaps in our nation's food safety system are to blame. Indeed, if we had a modernized food safety system focused on prevention, we would not need to be issuing this number of alerts and recalls. That said, given the disjointed and underfunded nature of our food safety surveillance system, we cannot be sure that the alerts and recalls issued by FDA truly even reflect the extent of the problem today.

The public is deeply concerned about this issue. A 2008 public opinion poll conducted on behalf of TFAH found that 78 percent of Americans thought that protecting the food supply was a very important issue for the government to focus on, and 65 percent thought another foodborne outbreak was likely to occur in upcoming years. These numbers illustrate how personal the issue is to people, as it has such a direct impact on the health and wellbeing of their families. The food supply is vulnerable to a variety of pathogens, toxic metals and other pollutants, product tampering, and emerging diseases. The current food safety system is reactive, not preventive, meaning we are wasting millions of dollars on responding to such threats rather than building proper controls into the production system.

I want to turn now to two critical issues related to assuring a modernized food safety system: the FDA's Food Protection Plan and funding levels needed by the FDA for food safety.

The Food Protection Plan issued in November 2007 sets broad goals for improving food safety in the United States. However, while it provides an agenda for Congress, it lacks specificity about goals and objectives and implementation strategies that would allow the Congress and the public to determine what resources are needed to implement the plan and what milestones could be used to measure the progress of the FDA in making our food safety system safer.

TFAH has always advocated for a stronger investment in the public health system. But we also expect accountability and transparency with respect to that investment. During a hearing before the Energy & Commerce Committee in June , at which TFAH testified, the FDA Associate Commissioner for Foods, David Acheson, was unable to tell members of the Subcommittee exactly how much money FDA actually needs to implement the Food Protection Plan. Whether constrained by political realities of his position or the fact that the Agency had simply not made such a determination, we strongly urge the FDA to begin making those strategic calculations. When the FDA released its Food Protection Plan Progress Report in July, it demonstrated that the Agency is committed to implementation of a modernization strategy by explicitly stating action steps it had taken, and we hope they continue to make this a transparent process. However, I fail to see how FDA can go from an ‘agency in crisis,’ as experts and Members on both sides of the aisle have referred to it, to a modern, capable preventive body without resource requests attached to the Food Protection Plan.

Indeed, if the Administration is serious about modernizing the food safety system, each step of the implementation plan would carry with it a professional judgment budget number describing the appropriations necessary to achieve the goal, not just the legislative authority needed. FDA should then regularly report to Congress and the public with measurable benchmarks of its progress in implementing the plan and the funding levels necessary to move it forward. Just as the federal government has begun incorporating program evaluation for state and local entities into its grantmaking process, Congress could explore the possibility of integrating reporting and strategic planning

disclosure requirements into the appropriations process. We recommend that in the upcoming appropriation for the FDA, the Committee deny FDA the authority to obligate some of the increased funding until it receives a detailed and acceptable multi-year budget for implementing the Food Protection Plan. Or, in the event of a continuing resolution (CR), the Committee could indicate its intention to make additional funds in the final appropriation conditional on FDA leadership sharing its plans for expenditures *before the expiration of the CR*. This way, both the Committee and the Agency could adequately prepare for steady funding when the regular appropriations process resumes next year.

We make these recommendations not simply for the sake of transparency, but to strengthen FDA's argument for additional funding. There are precedents for such an approach. For example, the Administration released a National Strategy for Pandemic Influenza along with a request for \$7 billion to carry out the strategy. The initial strategy articulated broad concepts and principles for pandemic preparedness, just as the Food Protection Plan does. But as Congress moved forward and provided the necessary funding for pandemic influenza preparedness, the strategy was accompanied by an Implementation Plan, which contained actionable steps for multiple federal departments, including interim milestones against which Congress and the public could measure progress.

In addition, several agencies within HHS are legislatively mandated to provide, directly to Congress, so-called bypass budgets that reflect their professional judgment of funding

that is needed without having to receive OMB clearance. Dr. von Eschenbach had experience with this process during his tenure with National Cancer Institute. Each year, both the National Cancer Institute and the Office of AIDS Research provide Congress bypass budgets, which include the resources necessary to maintain existing research and the money required to achieve specific expanded or new initiatives. The recent “dance” we saw leading to the formal request for an additional \$125 million for the FDA’s food safety work was an ad hoc version of this approach. The Subcommittee may want to work with the authorizing committees to enact a regular bypass budget for the FDA as it embarks on this important process of modernization.

Let me also address the issue of specific funding levels. Others with far more expertise than we have identified a series of shortfalls within the FDA’s budget – overall, and for food safety. We strongly endorse the recommendations of the FDA Science Board and recommend that Congress provide the requested funding levels in two ways:

- Congress should provide “no-year” funding to allow FDA to develop a long-term plan for infrastructure transformation. The kind of rebuilding that FDA must undertake requires a capital investment. The Science Board recommends increasing FDA’s base by \$450 million over the next 5 years for information technology modernization alone. Knowing that full funding for a multi-year endeavor is guaranteed will facilitate this kind of investment. The subcommittee could consider a second stimulus/supplemental bill as a vehicle for additional FDA and/or food safety funding. That said, Congress can and should expect definition of milestones and regular progress reports.

- Absent specific budgetary goals associated with the Food Protection Plan, the Committee can provide targeted funding in FY 2009 for specific policy initiatives such as those identified by the Science Board and by Professor Taylor in his testimony today.
- Congress must also assure that increases are provided in the FDA's base appropriation to sustain the investment that was made as part of the supplemental funding recently approved. We are pleased that the Administration asked for and Congress approved supplemental funding for FDA's food safety function. But increased funding must be sustained over time to allow for effective strategic planning. Given the uncertainty of food safety funding, it is exceedingly difficult for the federal food agencies to implement modernization plans. Although FDA recently announced plans to hire 1,300 science and medical staff, including 600 new positions, it is unclear if the resources to fund those positions will be stable from year to year. The supplemental money also does not solve the problem of out-year planning. FDA is an agency in transition, so its appropriations parameters should allow for such transformation. Instead of budget requests that allow for only incremental changes from previous fiscal years, we recommend the Committee look into the possibility of multiyear or no-year funding streams for FDA's food safety function, at least until the agency can be modernized and fully staffed. At the same time, FDA should develop multiyear plans to correspond to its budget requests. This kind of strategy would allow FDA to more easily link its Food Protection Plan with specific funding requests and facilitate recruiting and retention of quality staff. And it must be stated, although supplemental funding for FDA this year is important, appropriators should bear in

mind that increased funding should be rolled into baseline appropriations in FY 2010, rather than returning to previous funding levels. Fluctuations in financing levels in response to public catastrophes such as the Heparin and Salmonella crises do not allow for effective planning.

Increased funding for food safety is a start. But our report notes that the federal government is spending existing funds on outdated, inefficient practices. The federal food safety system is an example of misallocation of funds due to adherence to an archaic framework. For example, the FDA oversees foods responsible for 85 percent of foodborne illnesses, yet receives just over half the appropriations that USDA receives for its food safety activities. According to Center for Science in the Public Interest, FDA inspects most American food facilities an average of once each decade. The USDA's FSIS spends most of its resources visually inspecting every beef, pork, and poultry carcass in ways not too different from practices used 100 years ago, although the health of animals has greatly improved and most foodborne illnesses cannot be detected visually. Likewise, FDA's food safety statutes date back to 1906 and 1938. These statutes resulted in a system that is built to be reactive to problems prevalent in early 20<sup>th</sup> Century food system, such as adulteration and misbranding. It empowers FDA primarily to act only after food safety problems occur, yet modernization continues to happen in a piecemeal, incremental way.

Our federal food safety system is broken. While Congress blames the FDA for implementing the plan too slowly, FDA claims Congress has not provided the Agency

with the authorities it has requested. The time for finger-pointing is past, and we should instead focus on the steps both Congress and the FDA can take to provide the Agency with the legal and financial resources it needs to implement the strategy. While your colleagues in the authorizing Committees clearly have significant work ahead of them, there are opportunities for this Committee to help ensure FDA has the tools it needs to modernize and unify the fragmented system. As you know, the problem cannot simply be fixed with additional funding, but with aligning appropriations with the Agency's modernization plans. If this Committee is successful in requiring the FDA to cross-walk its strategic vision with specific budget requests, it could set a precedent for a more transparent, responsive, and agile federal government.

Thank you for including me in this important discussion. I look forward to your questions.