



**Written Testimony of
Jeffrey Levi, PhD
Executive Director
Trust for America's Health**

**Before the Subcommittee on Oversight & Investigations
House Committee on Energy & Commerce
"American Lives Still at Risk: When Will FDA's Food Protection Plan Be Fully Funded
and Implemented?"
June 12, 2008**

Chairman Stupak, Ranking Member Shimkus and members of the Subcommittee: Thank you for the opportunity to testify before you today regarding modernizing the food safety functions at the Food and Drug Administration. I am Dr. Jeffrey Levi, Executive Director of Trust for America's Health (TFAH). Trust for America's Health 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 thorough examination of the food safety functions at the Food and Drug Administration (FDA).

At the end of April, TFAH released a report entitled *Fixing Food Safety: Protecting America's Food Supply from Farm-to-Fork*. As we know, recent tragedies have shed a light on glaring gaps in the nation's federal food safety system, but we now have the opportunity to build a better system for the future. My comments today will discuss the report's findings as well as additional concerns we have with the current food safety system. The report can be found in its entirety at www.healthyamericans.org.

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 January of this year alone, FDA has issued over 80 recalls, alerts, withdrawals and warnings of unsafe or mislabeled food. 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 disjointedness 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 2007 public opinion poll conducted on behalf of TFAH found that 67 percent of Americans are worried about food safety. This number ranked above the threat of pandemic flu or natural disasters, illustrating just how strongly food safety truly touches every American. 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.

TFAH's report identifies several problems with the government's food safety system: inadequate federal leadership, coordination and resources; outdated laws and policies; and inadequate federal, state and local collaboration.

Inadequate Federal Leadership, Coordination and Resources

The Federal food safety system is fragmented. According to the 2007 GAO report, there are 15 agencies collectively administering over 30 laws. Even among lead agencies, the government's ability to prevent illness is undermined by the segmented responsibilities among many agencies, which often use differing regulatory approaches. No agency has statutory authority to forge an integrated strategy, and no agency or person has final authority over food safety. This results in overlapping inspections by FDA and USDA's Food Safety and Inspection Service (FSIS) and food companies having to follow different regulations from each agency within the same plant. Clearly, FDA could use its resources better through increased collaboration and coordination with USDA.

The current system is not just fragmented, but also experiences misaligned priorities and resources. FDA regulates 80 percent of the U.S. food supply, and an estimated 85 percent of known foodborne outbreaks are associated with FDA-regulated food. However, FDA receives less than 40 percent of the overall federal dollars devoted to food safety programs. In addition, funding for food safety programs at FDA and FSIS has barely kept pace with inflation. Even as these agencies must take on new challenges, such as those laid out in the FDA Food Protection Plan, they are barely able to pay for their existing food safety system.

Furthermore, within both FDA and USDA, food safety is not the top priority. At FDA, pharmaceuticals and medical devices -- the "drug" part of the Food and Drug Administration -- receive priority attention. At USDA the focus is on promoting U.S. farm commodities abroad and helping farmers and agribusiness at home.

We agree with the Science Board's assessment that weaknesses in the FDA's food safety function are directly related to its inadequate resources. Trust for America's Health recommends at least doubling FDA's food budget in real terms over the next five years. The need for additional appropriations has been echoed by the National Academy of Sciences Institute of Medicine, the Government Accountability Office, and the Health and Human Services Inspector General. TFAH believes FDA needs a consistent source of funding to keep up with its mandate. We were pleased to see additional food safety money in the Senate's supplemental, but appropriators should bear in mind that increased funding should be rolled into baseline appropriations in FY 2010, rather than returning to previous funding levels. It is nearly impossible for the Agency to adequately plan and hire full-time staff if it is unclear whether money will be stable from year to year.

In addition to funding, FDA needs to ramp up its personnel levels. According to former FDA Commissioner Mark McClellan, the President's FY 2009 budget "does little to make up for the steady loss of staffing that the Agency has endured for the past decade." We were pleased that FDA recently announced plans to hire 1,300 science and medical staff, including 600 new positions, and we are eager to see how they are used to implement the FDA's Food Protection Plan. However, given the broad consensus among experts who doubt the FDA's ability to fulfill even its existing food safety mandate given current funding levels, we are reluctant to view this announcement as an end to the Agency's problems.

Outdated Laws and Policies

Increased funding for food safety is a start. But our report notes that the federal government is spending existing funds on outdated, inefficient practices. TFAH has long been an advocate for accountability within the public health system, and the federal food safety system is an example of misallocated funds due to adherence to an archaic framework. 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 to 1906 and 1938. FDA's law developed a system that is reactive to problems prevalent in early 20th Century food system, such as adulteration and misbranding. It empowers FDA primarily to act only after food safety problems occur.

Our report finds that Congress has not provided the agency 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.

America's food supply faces new threats, and the safety system needs to reflect changes in the market. A 21st Century production and distribution system means that instead of a single contaminated head of lettuce affecting one family, that lettuce may be divided among a dozen prepackaged bags of salad shipped across the country. The centralization of agribusiness means there is significant contact between livestock and crops, which can lead to a single infected product causing pervasive damage.

Deliberate contamination of the food supply for economic or terroristic reasons could also have a widespread, devastating impact on the nation before the federal government even has time to react. We saw this in 2007 when imported pet food killed thousands of cats and dogs in the United States after being deliberately contaminated with melamine for economic profits. It is not science fiction to believe such action could occur again, with malicious intent. The Administration's Homeland Security Presidential Directive 9 called for a coordinated national approach to deliberate threats to the food supply. HSPD-9 tasked the Department of Homeland Security to work with USDA, HHS, and EPA to coordinate a national response, but FDA has not received additional funding and USDA has received only additional \$150 million. FDA needs more authority to implement measures against agroterrorism, including increased surveillance.

Inadequate Federal, State, and Local Collaboration

The existing governmental food safety system is decentralized, so state and local departments have authority that extends beyond federal jurisdiction. State and local health departments are the frontlines in the fight against unsafe food, as they investigate outbreaks, inspect restaurants, and coordinate communication up the chain. The vast majority of foodborne diseases are detected and investigated at the local level. Yet, the capacity of states to conduct appropriate safety surveillance and communicate that back to the federal government varies dramatically. Federal support (through the CDC) for such critical state activities is minimal. In a 21st Century food economy, outbreaks are not limited to one state; early detection of what

could become a national problem is dependent on the capacity of the state with the weakest surveillance system.

The relationship between federal and state regulators is also not well defined, so jurisdiction and communication may be hindered. In addition to a lack of resources to quickly respond to outbreaks, there are no mandatory national standards for state and local governments to adopt in their communities. Instead, most states adhere to voluntary standards such as the FDA's Food Code, a model to assist governments in regulating the retail and food service industry. Although these standards are updated every other year, the vast majority of states have not adopted the most recent guidelines. The Voluntary National Retail Food Regulatory Program is another voluntary guideline for states to develop science-based measures of performance that will lead to more effective and uniform regulation of the food industry. Only 12 states have fully enrolled and achieved verification by external evaluators of the program. TFAH recommends creating uniform standards and practices across the federal, state, and local levels. States should be encouraged and incentivized to adopt and comply with uniform standards of the most recent FDA Food Code and the National Retail Food Regulatory Program.

The systems used to monitor food disease outbreaks are also a patchwork of various government agencies at the federal, state, and local level working largely independently with limited coordination. Government surveillance, or detection of foodborne diseases, exists alongside food safety practitioners from the private sector, public interest groups, and academia. As Michael Taylor, former FDA Deputy Commissioner for Policy, addressed in his recent report on the Food Safety Information Infrastructure, these data sources remain isolated, without the legal, logistical, or cultural means to share information. At a recent congressional briefing hosted by TFAH, Dr. Tim Jones, state epidemiologist for Tennessee, noted that communication of hazards is highly variable among states, which often lack the personnel, technology, and data sharing systems to react quickly to detected outbreaks. TFAH contends that a person's protection from disease should not depend on where he or she lives, and the fragmented food surveillance system is an example of such disparity.

Opportunities for Modernization

TFAH believes that we need a comprehensive approach to update and strengthen the federal food safety system. The institution of Hazard Analysis and Critical Control Points (HACCP) is a good example of a promising approach to modernization within FDA and FSIS. Such a system first requires companies to identify potential hazards and critical control points throughout the production process, and then establish preventive procedures to monitor and ensure those hazards are avoided. However, FDA has not implemented HACCP across the food production chain, and where it exists in many cases it is only on a voluntary basis. Widespread implementation of HACCP and other preventive systems could save money in the long-run by identifying potential problems before they occur.

Imported food presents a new, troubling frontier for food safety. Fifteen percent of the food we eat is imported, including 60 percent of produce and 75 percent of seafood. Yet, only 1 percent of shipments are inspected by the FDA each year. The Administration released the *Import Safety Action Plan* and the *Food Protection Plan* in November. These plans called for working with foreign governments to ensure compliance with U.S. safety standards, but as Mr.

Taylor notes in our report, the FDA does not have the resources to ensure the safety of imports without harnessing the expertise and resources of the private sector. In addition to providing resources for implementing the Import Safety Action Plan and the Food Protection Plan, Congress should require food importers to be legally accountable for assuring that foreign producers are shipping goods to the U.S. that meet U.S. food safety standards.

As mentioned earlier, surveillance is a key component to identifying foodborne outbreaks. Congress can support this mission through removing legal restrictions on data sharing, mandating coordinated data collection among government agencies, and improving the collection of and accessibility to data. Data collection and improving networks among all actors, including private sector and academia, is critical to mitigate the effects of unsafe food. TFAH recommends government food safety officials and food companies should be given the tools to keep track of information about disease outbreaks in humans, plants, and animals and results of food inspections so they can quickly detect and contain problems. CDC's surveillance program should also be able to function in a way that not only monitors outbreaks and investigates preventive strategies, but also provides accountability to gauge how well U.S. food safety systems are working.

In order to develop a dynamic, evolving food safety system, greater investment in research is a prerequisite. Ongoing research is needed to identify emerging threats and up-to-date ways to contain them, as well as to rank relative risks and the health impacts of those hazards. The FDA *Food Protection Plan* echoes the need to strengthen the Agency's research capacity, but the document does not clarify how it will implement the mission or how it will work with other federal agencies to coordinate a research agenda. As the Science Board report tells us, FDA does not have the funding to conduct its existing research requirements and lacks a clear vision of new areas of research needed. Funding and planning are vital to carrying out a modern research program, which should serve as a basis for FDA's regulatory framework.

Planning and Resources

Clearly, a profound investment is necessary to prepare FDA's food safety function for the 21st Century marketplace. However, Congress should not provide significant additional appropriations without a clear strategy of how that money will be spent. We agree that the *Food Protection Plan* is a good start. The Plan represents a consensus document, outlining broad concepts for modernizing the food safety system. However, it lacks the specificity necessary to fund or to implement such a plan. TFAH has long been a watchdog for responsible government spending. While we advocate for a stronger investment in the public health system, all of our reports insist on accountability and transparency with respect to that investment. FDA's food safety system should be no different. Before Congress appropriates significant funds to modernize the food regulatory system, FDA must demonstrate exactly how it intends to spend those funds. Instead of broad principles, we urge FDA to articulate the steps it will take to achieve each element of the plan, including the personnel, laboratory capacity, information technology, and research necessary to carry out each concept in the document. FDA should regularly report to Congress and the public with measurable benchmarks, data sharing, and the resources necessary to move forward with its plan.

In addition to lacking detail, the *Food Protection Plan* remains abstract because there is no budget request associated with it. If the Administration is serious about modernizing the food safety system, each step of the implementation plan should carry with it a professional judgment

number describing the appropriations necessary to achieve the goal. We make this recommendation not simply for the sake of transparency, but to strengthen FDA's argument for additional funding. As an 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 with appropriating funding for pandemic influenza preparedness, the strategy was followed by an *Implementation Plan*, which contains actionable steps for multiple federal departments to take to achieve an adequate level of preparedness, including interim milestones against which Congress and the public could measure progress. The implementation plan gave credence to the President's funding request.

Developing a comprehensive strategic plan with a corresponding budget request is not a novel concept. Several agencies within HHS are legislatively mandated to provide Congress with so-called by-pass budgets that reflect their professional judgment of funding that is needed without having to receive OMB clearance. In fact, 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 and the President with their annual budgets, which include the resources necessary to maintain existing research and the money required to achieve specific expanded or new initiatives. The Subcommittee may want to consider enacting a similar mandate for the FDA as it embarks on this important process of modernization.

Conclusion

Just as policymakers are attempting to transform America's healthcare system from a sick-care system to a well-care system, we must convert our food safety policies from a reactive to a preventive system. The federal government can save money and lives by investing in technology, information networks, and research. This effort will require leadership from Congress and the Administration to assure that both financial and human resources are devoted to this critical public health problem. The end result should be a safer food supply from farm to fork.