Testimony of

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Committee on Energy and Commerce
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Hearing On

"The Recent Salmonella Outbreak:
Lessons Learned and Consequences to Industry and Public Health"

July 31, 2008

Mister Chairman, Ranking Member Shimkus, members of the subcommittee, thank you for the opportunity to testify at today's hearing.

Introduction

This hearing has been convened as the country enters the fourth month of an outbreak of illness associated with *Salmonella saintpaul*. This outbreak has sickened more than 1,250 people in 43 states, the District of Columbia and Canada and has had a devastating impact on the U.S. tomato industry, even as the food vehicle or vehicles responsible for the illnesses remain uncertain.

As the outbreak has continued, the inability of public officials to identify definitively the food vehicle and ultimate source of the contamination has become a matter of great

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public concern, and well it should. There is also an understandable tendency to find fault for the perceived failure of the food safety system in this case. And I agree that the management of this outbreak should be carefully examined, both to see if any breakdowns occurred and to learn lessons for the future.

I cannot speak to the details of the ongoing *Salmonella saintpaul* investigation, Mister Chairman, and whether particular agencies or individuals made mistakes. I can, however, speak to the system within which they work, and my message today is this: regardless of whether we find that this outbreak could have been managed better, the fundamental problem is with the system itself, not with how it operated in this case. The sad truth is that we have no system for managing multi-state foodborne illness outbreaks that deserves to be called a system. Many capable people work hard and do the best they can, but they work within a set of institutional arrangements and with tools that are not up to the task.

We are not in this situation for lack of knowing that a system is needed or because we don't know what its basic elements should be. Rather, we simply have yet to make the decision – and the sustained commitment – to have such a system. For reasons I will outline in this testimony, Congress must act to solve this problem.

Before discussing possible solutions, let me share some perspectives on why prompt and accurate outbreak investigations can be very difficult, but also why they are essential to protecting food safety and to achieving the more preventive food safety system to which

we all aspire. I will also describe how the current "system" is simply not designed for success in conducting such investigations.

The Difficulty and Importance of Multi-State Outbreak Investigations

Any outbreak of foodborne illness – defined as two or more cases linked to a common source – is a noteworthy event. It means people have gotten sick and it suggests the existence of a breakdown that could result in making others sick and that could be on-going. Thus, the most immediate need is for prompt response and identification of the common source to prevent further illnesses from that source.

Most outbreaks are relatively small-scale and inherently local in nature. They might involve such breakdowns as poor food handling or employee hygiene practices in a restaurant, cross-contamination during food preparation at home, or the problematic dish at a church picnic. Investigating local outbreaks is a core public health responsibility of local and state health departments. If the root cause is local, local investigators are frequently able to discover it by carefully interviewing people who got sick, analyzing food samples, and gathering other relevant information.

In the past two decades, however, we have seen an increasing number of outbreaks that involve illnesses in multiple states. These have affected most major sectors of the food supply, including meat and poultry, seafood, dairy and produce; and some have been essentially nationwide in scope, such as the current Salmonella outbreak.

This increase in multi-state outbreaks is a result of many factors, including changes in the food system that make it more likely that a problem at one point in the system will radiate out across the system to affect many consumers. These changes include centralized production and nationwide distribution of both fresh and processed foods, convenience-oriented packaging and eating practices, and the increasing volume of imports.

The increase in reported outbreaks of all kinds, including multi-state outbreaks, is also a direct result of investments and improvements in foodborne disease surveillance made over the last decade that have improved our ability to detect outbreaks. These include moving to electronic reporting systems and communications platforms that serve to better connect public health officials in local, state, and federal agencies.

The innovation that deserves specific mention in this context is PulseNet, a collaborative effort of the Centers for Disease Control and Prevention (CDC) and state and local public health laboratories. PulseNet has played a major role in identifying numerous recent outbreaks, including the outbreak due to *E. coli* O157:H7 in spinach in 2006, the Salmonella outbreak associated with frozen pot pies in 2007, and this year's Salmonella outbreak.

Essentially, PulseNet is a shared database of genetic "fingerprints" of bacteria. Public health laboratories throughout the country perform tests to fingerprint bacteria obtained from people sickened by food poisoning in their city, county, or state and then submit these fingerprints to the central database. By analyzing these fingerprints and

discovering matches, individual cases or clusters from multiple locations and states can then be recognized as part of an outbreak rather than isolated local events. PulseNet's success in detecting outbreaks is due to two factors. First, the participating state laboratories use a standardized methodology for fingerprinting the bacteria, which makes data from diverse sources comparable. Second, the system uses modern information technologies for storing, analyzing and sharing data.

While major outbreaks present huge challenges to government and industry alike, it is always better to detect an outbreak than not detect it, for the containment and prevention reasons noted earlier. And this is especially true for large, multi-state outbreaks. Not only are more people at risk, especially if the outbreak is due to a breakdown that is on-going, but multi-state outbreaks also provide the opportunity to draw lessons to help shape preventive interventions of possible system-wide application. It is thus essential not only to detect the outbreak but investigate it promptly and accurately so that the outbreak can be contained and lessons learned.

As evidenced by the impact of the current Salmonella outbreak on the tomato industry, such investigations are important for economic reasons as well.

Unfortunately, our recent advances and growing sophistication in detecting outbreaks has not been matched by corresponding advances and sophistication in investigating them. PulseNet only detects the fact that multiple illnesses are linked to a common pathogen; it does not reveal the common food vehicle(s) responsible for the illnesses or the root cause

of the contamination that led to illness. This requires marshalling the efforts of multiple agencies at federal, state, and local levels of government to conduct case-control studies, traceback investigations, and targeted microbial sampling of food and food environments, and to analyze and act on the information they glean from these efforts.

This is where the difficulty begins, in part because outbreak investigations are inherently difficult and in part because we lack an effective system for conducting them. As outbreaks grow larger and cross state lines, their investigation only becomes more difficult due to the number of parties involved. Moreover, outbreaks associated with fresh produce are particularly difficult to investigate for other reasons.

It typically takes 2-3 weeks for lab results to confirm that a person's illness is part of an outbreak. The short shelf life of fresh produce generally means that, by the time an investigator arrives on the scene, there is no product left to test to see if it is contaminated with the pathogen that made the person sick.

Investigators thus must rely on the indirect, essentially inferential, tools of epidemiology to form hypotheses about what food carried the pathogen that caused illness. This commonly means conducting a case-control study in which investigators use interviews to elicit and compare the recent food consumption of people who got sick with people who did not. In the Salmonella outbreak, CDC reported that 80% of the people who got sick ate tomatoes, while only 50% of those who were not sick ate tomatoes, and

concluded this created a statistically significant association between tomatoes and the *Salmonella saintpaul* illness.

Such an association is not proof of a causal link. However, absent other evidence disproving the link, it is generally considered a sufficient basis for providing public health advice to consumers, notwithstanding recognized methodological uncertainties in case-control studies. The central, inherent uncertainty stems from the fact that the quality of the data on which the studies rely depends on the quality of the subjects' recall of what they ate, perhaps weeks ago – recall that researchers have shown to be of limited reliability. In addition, in large or multi-state outbreak investigations, persons conducting interviews typically come from different state and local health departments, and may or may not conduct interviews and report data consistently due to the lack of nationally standardized food category definitions and interview templates and differences in training and experience.

While a well-conducted case-control study can provide sufficient information about the possible food vehicle to support public health action and advice to consumers, it is not the end of the outbreak investigation. Based on the leads provided by the study, investigators from federal, state and local food regulatory agencies then become involved, often with health department staff, to try to trace the suspect food or foods back to their source in order to find a potential common source of contamination, such as a processing plant or farm. This can be a daunting and labor-intensive task when the suspect food has been found all across the country and passed through many hundreds of processing plants,

wholesalers and retailers. Investigators also collect and test food and environmental samples to see if they can link the pathogen that caused illness directly to the particular food and to possible places where it was produced, processed, or stored.

Such traceback and product testing evidence, coupled with the epidemiological findings, can provide persuasive proof of the casual connection between a particular pathogen-food combination and the reported illnesses, but even that does not, ideally, complete a full outbreak investigation. Once the illness, pathogen, food vehicle, and locations where the food has been have been conclusively linked, multi-disciplinary teams of investigators from federal, state and local agencies can search for the "root cause" of the outbreak by examining what might have gone wrong to result in the pathogen entering the food in the first place and/or not being processed sufficiently to eliminate the pathogen or reduce it to acceptable limits. Information derived from this final "root cause" phase of the investigation can be crucial for both the food industry and food safety regulators in devising future prevention strategies and interventions.

As this brief background illustrates, multi-state outbreaks are inherently complicated affairs that are difficult to investigate – as a function of both technical and scientific complexity and the many different government agencies involved – but they provide absolutely indispensable information for a food safety system that seeks to be preventive, both in the context of the particular outbreak and prospectively. It should thus be a high priority goal of the food safety system to perform prompt, accurate and complete outbreak investigations.

How the "System" for Outbreak Investigations Fails as a System

The very nature of multi-state outbreaks means that high quality response and investigation requires a high level of preparedness and planning. Time is of the essence. Many agencies are involved from all levels of government, with varying degrees of expertise and resources. Data from multiple sources must be compiled and analyzed. And decisions with potentially great public health and economic impact must be made and communicated in the face of unavoidable uncertainty and unrelenting scrutiny.

To perform well under these circumstances, a system for responding to and investigating and multi-state outbreaks should include at least these seven elements:

- **Federal Leadership and Accountability** – Clearly defined responsibility and accountability at the federal level for managing the response and investigation and making key decisions;

- **Well-Defined Institutional Roles** – Clearly defined roles and responsibilities among all the federal, state and local agencies involved in the outbreak response and investigation and established procedures for their interaction and collaboration;

- **Expertise and Capacity** – A consistent and adequate level of expertise and capacity among federal, state, and local agencies to play their key roles in response and investigation efforts;

- **Traceback** – Rapid access to traceback information;

- **Data Collection and Sharing** – Standardized approaches to collecting and analyzing epidemiological and contamination data and seamless systems for sharing data among agencies;

- **Industry Engagement** – Established principles and protocols for engaging the food industry in investigations; and

- **Public Communication** – Established principles and protocols for communicating with the public during investigations.

The current "system" is lacking in every one of these basic elements.

- **Federal Leadership and Accountability** – CDC, the Food and Drug Administration (FDA) and the Department of Agriculture (USDA) (when meat and poultry may be involved) each play important roles in multi-state outbreaks, but no single federal agency or official is clearly in charge and accountable for the overall management of the effort.

- **Well-Defined Institutional Roles** – Federal, state and local agencies necessarily collaborate on multi-state outbreaks, but the collaboration is essentially ad hoc: there are no formally established mechanisms or protocols for such collaboration or even clarity about when responsibility for managing an outbreak properly shifts from the state or local level to the federal.

- **Expertise and Capacity** – The expertise and capacity of state and local agencies vary widely, and, in general, due to chronic under funding and lack of sufficient staff dedicated to outbreak investigations, capacity at all levels of government is thin.

- **Traceback** – There is no effective system for ensuring rapid government access to critical traceback information, which places extra burdens on already strained resources and delays investigations.

- **Data Collection and Sharing** – There are no standardized approaches to collecting and analyzing epidemiological data, which undercuts the scientific foundations of a multi-state investigation scientific, and conflicting interests and policies often obstruct the flow of information among agencies that should be operating as a cohesive team in managing a multi-state outbreak.

- **Industry Engagement** – There are no established mechanisms for tapping the expertise of the food industry on such matters as industry structure, practices, and distribution patterns, which could both expedite and improve the accuracy of investigations.

- **Public Communication** – The lack of clarity about who is in charge of an investigation can result in lack of clarity in communication with the public, as information about an outbreak is commonly made available from multiple government sources.

Mister Chairman, I wish I could say that these observations were new and original, but they are not. The fact is that leaders at a political level and professionals working in federal, state and local agencies have known for a long time that we lack key ingredients of an effective system for managing multi-state outbreaks.

In December 2000, as an outgrowth of President Clinton's Food Safety Initiative, top officials of the Department of Health and Human Services (HHS), USDA and the Environmental Protection Agency entered into a memorandum of understanding to establish an inter-agency body called the Foodborne Outbreak Response Coordinating Group (FORCG). This group, to be co-chaired by the Assistant Secretary of Health at HHS and USDA's Under Secretary for Food Safety and to include representatives of state and local agencies, was intended to address many of the system problems I have outlined, including the need for a high-level federal focal point for managing multi-state

outbreaks, defined roles and responsibilities, and better communication among agencies and with the public.

FORCG was on the right track, but it disappeared with a change in administration.

More recently, professionals working at CDC, FDA, USDA and in state and local agencies came together in 2005 to form the Council to Improve Foodborne Outbreak Response (CIFOR). In June of this year CIFOR issued for public comment a detailed set of draft guidelines for improving response to foodborne outbreaks, including better planning and preparation, model approaches for harmonizing data collection, better coordination and communication, and clearer definition of leadership roles, especially in multi-state and other multi-jurisdictional outbreaks.

Again, CIFOR is on the right track, but the implementation of its draft guidelines will require sustained political-level commitment and leadership, policy change, and new resources.

So, Mister Chairman, the lessons of the current Salmonella outbreak are not new lessons. The challenge now is to act on these lessons and establish a system for managing multi-state outbreaks that really is a functioning, effective system.

In considering how to do that, it is important to be clear about why it hasn't happened before now. There are many reasons, but I see two fundamental underlying obstacles that must be addressed.

The first is the natural centrifugal force that drives government agencies into their separate corners of the bureaucratic landscape, where they focus first and foremost on their particular mission and part of the problem, rather than the system and problem as a whole, and focus too much on defending their turf, prerogatives, and established ways of doing things, often to the detriment of solving the larger problem. FORCG was a top-down initiative, driven by the White House. When the administration changed, the agencies returned to their corners.

Let me be clear. There are many caring and competent people working on food safety in federal, state, and local government and doing their best within the existing institutional framework, but the framework is wrong.

The second underlying obstacle to improving multi-state outbreak response has to do with policies and priorities. Put simply, the political-level commitment to improving outbreak response has been intermittent and inadequate. Outbreak response tends to be seen only as part of the traditional, reactive approach to food safety. Yes, it's important to react well and contain outbreaks, but once that happens, attention shifts elsewhere, and little attention is paid to preparing for the next outbreak, much less learning from the last one.

I believe this is due, at least in part, to the fact that Congress has never given FDA or USDA a modern public health mandate to prevent foodborne illness. If that were the mandate, improving foodborne illness surveillance and investigation of foodborne outbreaks would immediately gain a higher priority. It is simply not possible to do prevention well unless we do surveillance well and learn everything we can from outbreaks. Thus, a mandate for prevention is a de facto mandate for investment in learning about and learning from foodborne illness, through outbreak investigations and other means.

It is right for Congress, through hearings such as this, to examine how well agencies are doing their jobs within the institutional and policy framework that exists today, but only Congress can change the framework.

Let me now outline some specific recommendations concerning a system for managing multi-state outbreaks, but with the caution that these need to be considered as an integral part of the more comprehensive modernization of the food safety system that Congress is considering. I will say more about that at the end of my testimony.

Recommendations for Improving Outbreak Response and Investigation

The creation of an effective system for managing multi-state outbreaks and learning from them will require new authority, new resources, and structural change at the federal level. That is why it is a job Congress must tackle. The starting point for creating such a system

is the recognition by Congress that there is a strong national interest in modern surveillance of foodborne illness, such as through PulseNet, and effective outbreak response and investigation, for the reasons outlined earlier in this testimony.

States and localities have their own important interests and responsibilities when outbreaks occur within their jurisdictions, and they must continue to play a critical frontline role even in the largest multi-state outbreak. Nevertheless, the compelling national interest in containing major outbreaks promptly and using the knowledge that can be gained to be more effective in preventing illness justifies building a national system, of which states and localities are an integral part.

To achieve that goal, Congress should address each of the elements of an effective national system for outbreak response and investigation. The following are my recommendations for reform.

Federal Leadership and Accountability

To address the lack of clarity concerning who is in charge and accountable at the federal level for managing multi-state outbreak investigations and driving planning and preparedness for future ones, Congress should:

- Mandate the designation of a single official and office reporting directly to the Secretary of Health and Human Services and acting on behalf of the Secretary to

be responsible for managing the federal government's role in outbreak response and investigation.

- Require the establishment of a coordinating mechanism, based on the FORCG model, to ensure effective collaboration among all relevant federal agencies (FDA, CDC, USDA and EPA) and with state and local agencies.

- Provide the Secretary the legal mandate and authority to drive development of an effective national system for both preparedness and response and to take charge of multi-state investigations in appropriate cases.

Well-Defined Institutional Roles

To address the lack of clarity in institutional roles and the need for a more cohesive, integrated approach to outbreak investigations, Congress should:

- Direct the Secretary to define and coordinate the roles of CDC and FDA in each phase of an outbreak response investigation.

- Direct the Secretary to establish, in consultation with states and localities, protocols spelling out the roles and responsibilities of federal, state and local agencies in responding to and investigating multi-state outbreaks, including criteria for determining when responsibility for managing an outbreak properly shifts from the state or local level to the federal level.

Expertise and Capacity

In light of the need for adequate expertise and capacity to respond to and investigate outbreaks, Congress should:

- Direct the Secretary to analyze current gaps and disparities in expertise and capacity at federal, state and local levels, and develop a plan for addressing them, including determination of the base level of expertise and capacity that should be in place at federal, state and local levels.

- Appropriate to the Secretary the resources required to have the needed expertise and capacity in place at the federal level.

- Create and fund a program through which the Secretary could provide matching grants to bolster state and local expertise and capacity.

Traceback

Because traceback information is vital in many cases for promptly identifying the food vehicle and getting to the root cause of an outbreak, Congress should pass traceback legislation to:

- Create a duty for food processors, wholesalers, distributers, and retailers to establish systems that enable them to provide FDA and other authorized

investigators with complete traceback information, in accordance with regulations issued by the Secretary.

- Direct the Secretary to establish by regulation commodity-specific performance standards that specify the time within which a firm must be able to provide the required information, taking into account what's feasible with available technology but providing firms flexibility to choose the system that works best in their operation.

- Require that all traceback records be subject to routine inspection and audit by FDA and that firms be required to test regularly the effectiveness of their traceback system and make the test results available to FDA.

Data Collection and Sharing

Because harmonization of data collection and more seamless sharing of information among government agencies are essential to effective outbreak response and investigation, Congress should:

- Authorize and direct the Secretary, in consultation with state and local officials, to standardize, as fully as appropriate scientifically, protocols for collecting and reporting data in the course of an outbreak investigation.

- Establish the goal of eliminating all barriers to the flow of relevant information among federal, state and local agencies in the course of an outbreak response and investigation.

- Direct the Secretary, in consultation with state and local officials, to identify any such barriers to the flow of information and to report regularly on the steps the Secretary is taking to eliminate them.

Industry Engagement

Recognizing that the food industry is both the source of information that could assist outbreak response and investigation and has a critical need for information from the government in outbreak situations, Congress should:

- Direct the Secretary to establish an on-going mechanism for consultation with the food industry on matters related to outbreak response and investigation, including both preparedness and the exchange of information during an outbreak.

Public Communication

Because the clarity, coherence and balance of government communication during an outbreak can have profound impact on both consumers and industry, Congress should:

- Direct the Secretary to devise, in consultation with state and local agencies, protocols for public communication in multi-state outbreak investigations, which

would include the designation of a single focal point for all federal government communications and agreed upon allocation of communication roles among federal, state and local agencies.

- Direct the Secretary to contract with the National Academy of Sciences or other appropriate expert body for a study and recommendations on effective risk communication during foodborne illness outbreaks.

The Bigger Picture of Food Safety Reform

As I discussed earlier, Mr. Chairman, the problems we have today with outbreak response and investigation are just symptoms of more fundamental underlying problems, including (1) the lack of a congressional mandate for the federal agencies to implement a well-integrated risk-based food safety system focused on prevention; (2) chronic under funding of food safety programs; and (3) the well-documented fragmentation of our food safety system at federal, state and local levels.

Thus, while I think the suggestions I have outlined here for improving outbreak management deserve consideration, they will fall short in the absence of congressional action to address these more fundamental concerns. Bills introduced in this and previous Congresses, including the Safe Food Act of 2007 (H.R. 1148), would bring about both the statutory modernization that is needed to have an effective, prevention-oriented food safety program and the unification in a single agency of all federal food safety programs (including those at the Department of Health and Human Services (HHS), USDA, and

EPA). Over the long run, such unification under a modern statutory mandate is the only way to make cost-effective use of all the resources the federal government invests in food safety.

I know the Energy and Commerce Committee is working on legislation to modernize FDA's legislative mandate for food safety, and I agree FDA and its authorizing statute are the right places to start. But I hope the committee and the Congress won't stop there. Successful food safety reform at FDA – and improved outbreak response and investigation – require action on all three fronts of food safety reform: statutory mandate, resources and organizational structure.

I'll summarize briefly needed steps in these three areas as they relate to FDA and the goal of improving outbreak response and investigation.

Modernize FDA's Statutory Mandate

Congress should modernize FDA's food safety mandate to, among other things:

- Explicitly make prevention of foodborne illness FDA's primary food safety mission;

- Establish by law a duty for all those in the food business to implement preventive controls appropriate to their particular operation, subject to FDA's implementing regulations and guidance;

- Direct FDA to establish and enforce performance standards that make companies accountable for implementing effective prevention measures;

- Make importers legally accountable for assuring that foreign producers and processors shipping products to the United States are meeting U.S. standards;

- Provide leadership in building an integrated, national food safety system that is science- and risk-based and makes efficient use of available resources to improve food safety.

A modernized mandate focused on risk-based prevention and a codified duty for food companies to implement science-based preventive controls make improved illness surveillance and outbreak investigation a necessity for government and industry alike. Under the current reactive system, government investigators have little incentive (and even less human and financial resource) to follow through on outbreak investigations, discover root causes, and draw lessons for prevention. A modernized legislative mandate would help change that.

Provide FDA an Adequate and Stable Resource Base

FDA's resources for food safety have been eroding for years as the agency's food safety challenge gets larger. The total operating budget for FDA's Center for Food Safety and Applied Nutrition – the resources available to take action after the staff and rent are paid – is down to around $25 million. This is a paltry sum for an organization charged with

driving food safety progress across 80% of the American food supply, while also regulating dietary supplements and food labeling, ensuring the safety of infant formula and food additives, and attempting to provide food safety leadership internationally.

An agency with all these responsibilities that can't conduct or commission research, adequately equip its staff, or travel simply can't do its job. And it certainly can't drive the substantial efforts that are required to improve both preparedness for and management of large-scale, multi-state outbreaks of foodborne illness.

Congress has a responsibility to act. In addition to meeting FDA's immediate needs through the 2008 and 2009 budget processes, Congress should undertake a serious study of how to establish an adequate and stable funding base for FDA's food safety program for the long-term. Just as it is fair to hold the food industry accountable for doing its food safety job, it is fair to hold FDA accountable for the leadership and effective action we expect from that agency, but only if it has an adequate and predictable resource base.

Congress should explore a range of resource options, including:

- Requiring FDA to prepare for Congress a five-year financial plan and an annual "professional judgment" budget sufficient to implement a modernized statutory mandate.

- Funding that budget entirely through appropriated funds.

- Establishing by law a statutory inspection mandate, with consequences built in for failure to meet it, to serve as an anchor for appropriated resources.

- Authorizing FDA to collect establishment registration fees and import fees to provide a steady base of resources for the food safety program.

Unify and Elevate the Organizational Elements of the FDA/HHS Food Safety Program

The third key ingredient for the success of any agency – after an appropriate statutory mandate and adequate resources – is an organizational framework suitable for its purpose. Action is needed now to create within HHS an effective organizational framework for food safety. HHS needs a framework that enables it to provide national leadership on food safety and run a coherent, well-planned program that makes the best use of available resources to improve food safety. For several reasons, the current structure of FDA does not provide such a framework.

First, within FDA, the food program consistently takes a back seat to the drug and medical device programs in the competition for management attention and resources. This is due in part to the intense interest that drug and device companies, health professionals, and patients all have in FDA's "gatekeeper" role for therapeutic products. It is reflected in the fact that most FDA commissioners come from a biomedical or health care background. This strong tilt toward drugs and devices was exacerbated by the drug

and device user fee laws, which have further focused FDA management attention, accountability, and resources on the therapeutic side of the agency. History has taught that the job of providing effective national leadership simultaneously on both therapeutic products and food safety is too big a job for any one person.

Second, FDA's organizational structure for food safety is fragmented and lacks a clear focal point for leadership. CFSAN ostensibly has the lead on food safety at FDA, but CFSAN actually shares food safety jurisdiction with the Center for Veterinary Medicine, which regulates pet food and animal drug and feed additive residues in human food, and with the Office of Regulatory Affairs, which manages the majority of FDA's food safety resources through its field force of inspectors, compliance officers and laboratory personnel. The recent establishment in the Office of the Commissioner of an Associate Commissioner for Foods only makes this fragmentation more pronounced. The associate commissioner serves as a spokesperson and coordinator but lacks budget or line authority for programs, further clouding responsibility and accountability for food safety within FDA.

Finally, food safety leadership at FDA rests at least two bureaucratic layers removed from the Secretary of Health and Human Services. As decisionmaking in the executive branch continues to be centralized at higher and higher levels, with OMB having enormous influence on regulatory policy, the full time leader of the nation's premier food safety program needs to have the necessary clout in the system that comes from being presidentially appointed and reporting directly to the Secretary.

In my view, the solution to these problems lies in unifying the food-related components of FDA into a single organization and elevating that organization within HHS under the leadership of a presidentially appointed official reporting directly to the Secretary. This official would be responsible and accountable for leading the necessary transformation of the FDA (and HHS) food safety program.

This needed structural reform would also go a long way toward addressing the federal leadership and accountability problem associated with management of major outbreaks. Still, it would not go far enough. It is essential that the food safety epidemiology function now housed at CDC be made directly accountable to the Department's senior food safety official and become better integrated into the national effort to prevent foodborne illness.

Conclusion

Recent events, including the current Salmonella outbreak, provide an enormous learning opportunity, and I hope strong motivation to act to improve our nation's food safety system. I applaud the subcommittee's efforts to drive change. For the most part, we know what to do. The challenge now is to do it.

Thank you again, Mr. Chairman, for the opportunity to testify today. I look forward to your questions.

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Key Points

- The outbreak of illness associated with *Salmonella saintpaul* illustrates recent improvement in detecting outbreaks through such innovations as PulseNet, but also underscores that our capacity to respond and investigate has not kept up.

- The fact is we have no system for managing multi-state foodborne illness outbreaks that deserves to be called a system. Many capable people work hard and do the best they can, but they work within a set of institutional arrangements and with tools that are not up to the task.

- Multi-state outbreak investigations are inherently difficult due to scientific limitations and the large number of government and private parties involved.

- The inherent difficulty of responding to and investigating multi-state outbreaks demands planning and preparedness that ensures someone is in charge and accountable at the federal level for the overall effort, roles and procedures at all levels of government are clearly defined and coordinated, the right expertise and tools are in place, and pre-planned mechanisms exist for good communication with the industry and the public.

- The current "system" for multi-state outbreak response and investigation is lacking on every key element of planning and preparedness and needs to be fixed.

- The problems with outbreak response and investigation are just a microcosm of long-documented problems with the nation's food safety system as a whole, including: (1) the lack of a congressional mandate for the federal agencies to implement a well-integrated risk-based food safety system focused on prevention; (2) organizational fragmentation of our food safety system at federal, state and local levels; and (3) chronic under funding of food safety programs.

- Only Congress can fix the fundamental problems that impede the effectiveness of the nation's food safety system;

- Congress should act to give the executive branch the prevention-oriented statutory mandate, unified organizational structure, and adequate resource base it needs to be successful and then hold it accountable for delivering the oversight that industry and consumers need and rightfully expect.