Written Testimony of

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

The recent nationwide outbreak of *Salmonella* associated with produce, which began in late April, demonstrates 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 during outbreak investigations. A typical American meal includes foods from six different countries, fresh produce travels a mean of 1500 miles to get to our plates, feedlots can hold 300,000 head of cattle, outbreaks involving several hundred victims no longer shock us… a long list of dramatic statistics demonstrate the changing environment in which outbreaks are occurring. Recognized foodborne disease outbreaks increasingly involve multiple states and widely distributed products, including several recent examples associated with fresh produce. Much of this change reflects improvements in the surveillance and investigation of outbreaks, and the capacity of state and local health departments to successfully identify contaminated foods, prevent additional illness, and subsequently make the food supply safer.

Such outbreaks also highlight the interdependence of multiple agencies at all levels of government in responding to these events. Epidemiologists (such as those at CDC and state and local health departments), environmental health programs, laboratories, and regulatory agencies (such as FDA, USDA and state Departments of Agriculture) at the

local, state and federal level must all communicate well and coordinate activities rapidly for outbreak investigations to be effective.

Outbreak investigations typically go through a number of stages, at which various agencies have different levels of involvement. Outbreaks are typically recognized by epidemiologists and laboratories at the state and local levels. Epidemiologists generally work to identify the contaminated food, and regulators then participate in further characterizing the food vehicle and its distribution. Public notification is a critical part of this, at least for outbreaks that may be ongoing, and is usually handled by epidemiologists, regulators or both. It is important to understand that federal agencies (such as the CDC) do not typically initiate investigations of this sort. Thus, CDC is often in the position of reviewing and integrating the results of investigations done by state and local agencies, rather than doing de novo investigations.

The outbreak being discussed today has been particularly frustrating for all involved. It demonstrates the complexity of epidemiologic investigations, difficulties inherent in investigations of novel foods not typically implicated, statistical limitations in identifying one food item which is commonly consumed with other foods (salsa for example), inherent complexities of tracebacks of fresh produce, and challenges in public communication. Recent remarkable successes in investigations of spinach and lettuce-associated outbreaks and a number of other widely distributed products have led to high expectations which realistically can’t be met in all investigations.

There are important differences in the “cultures” of the many different agencies that must work together in investigating outbreaks, with widely disparate missions, mandates, legal authorities, and organizational structures. While these are generalizations, state and local public health epidemiologists frequently interact directly with the public during outbreak investigations, rapidly assessing data to allow identification of the cause of an outbreak and make recommendations for preventing additional disease. Federal epidemiologists typically collate information from multiple states, but may not if there are only a few involved. CDC is generally called upon to assess epidemiologic data before federal regulatory agencies will act. Epidemiologists do not routinely do things like inspect facilities, perform tracebacks, or do product recalls. Epidemiologic, laboratory and environmental data are used to inform regulatory agencies, such as the FDA and USDA, in carrying out their functions. These federal agencies have very different responsibilities, priorities, relationships with industry, and legal mandates and restrictions.

Because of the very different “cultures” and working environments of these groups, widely varying perspectives on the challenges and weaknesses in outbreak investigations are inevitable. Consumers might be expected to desire immediate intervention to prevent potential disease, erring on the side of caution by acting on data that may be quite preliminary. On the other hand, many food producers would not want to see their business suffer because of poorly substantiated suspicions, and would expect public intervention to occur only on the basis of comparatively definitive data. Investigating agencies must constantly balance the risk that delays in action might lead to additional preventable disease, with the risk of economic damage to large sectors of the food

industry that might be mitigated by waiting for more specific data. Clearly it is impossible to satisfactorily meet all of these demands and expectations, and every outbreak requires making judgments based on unique circumstances and data, quickly and under great pressure.

While there may be room for improvement, it is important to acknowledge that there are no rules, policies, or legal or administrative interventions which will obviate the need for difficult human decision-making in these situations. Moreover, it is important to realize that these decisions are not made by a single federal agency. States can and do act independently when ongoing risks are suspected, though it would be rare for that to happen without notification and consultation with federal agencies, particularly for products that are distributed across state lines. In addition, communication with industry may occur at the state or federal level.

There are over 3000 local health departments in this country, and 50 state health departments working under 50 independent sets of public health laws. Not unexpectedly, there is tremendous variability in the capacity to respond to disease outbreaks among different jurisdictions. A cursory review of outbreaks in recent years will demonstrate that a small handful of states appear to have successfully investigated a disproportionately large number of multi-state outbreaks. This is not an accident, and it is highly unlikely that those states really have more disease than others. Rather, this reflects discrepancies in the resources available, as well as the capacity and inclination to detect and investigate outbreaks. CDC does not in most cases have jurisdiction to come into

states and investigate outbreaks without invitation. The large majority of outbreaks are detected and investigated entirely at the local and state levels, without any need for federal agency involvement. State health departments of course have very different thresholds for consulting with federal partners and requesting their assistance. In this recent *Salmonella* outbreak, for example, the initial disease clusters were recognized and investigated by local and state public health authorities. As the scope of the outbreak grew, CDC was invited in, initially to help evaluate data already collected by other agencies, and subsequently to become increasingly involved in designing and directing the investigations. Likewise, the FDA became progressively more deeply involved as the investigation evolved. At all stages in this fluid continuum, participants are necessarily dependent on data already collected by others previously, and must wait as additional data are collected, which invariably takes more time than any of us would like.

I think that it is safe to say that many public health epidemiologists view regulatory agencies such as the FDA and USDA as a "black box", into which data are sent, but from which results are received frustratingly late, or never. 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 regulatory agency 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 that they are unable or unwilling to share data as fully and as quickly as we would all like, even in urgent situations. Federal regulatory agencies are frequently

prohibited from sharing proprietary information and “trade secrets” obtained during the course of their investigations, which can include names of facilities, suppliers, traceback information, brand names, etc. I also acknowledge that tracebacks and regulatory investigations are far more time-consuming and complex than many epidemiologists appreciate, and our expectations of prompt results from an understaffed, underfunded and overworked agency are unrealistic. All that being said, I think it is inarguable that faster product tracebacks and better communication would have helped bring this outbreak to a more prompt and satisfying conclusion. In order for this to be possible, however, investigating agencies must have adequate resources to get the work done, and the legal authority to collect and share their data promptly and appropriately.

I was recently involved in another outbreak which highlights similar limitations. During the investigation of a contaminated product under the FDA’s jurisdiction, investigators in that agency had information in their possession that would have allowed state public health officials to quickly identify and contact consumers at risk of serious disease. However, because of policies restricting sharing of proprietary data and information collected through related mechanisms, they were prohibited from sharing it with us. The situation was as frustrating for the FDA personnel involved as it was for us, but we find these types of restrictions during outbreak investigations unconscionable. Of note, it is possible for public health epidemiologists to become “commissioned” by the FDA to be allowed to receive confidential data such as those to which I just referred. Most of my colleagues have refused to pursue this, expressly to avoid the untenable moral predicament of having access to data which they would be legally unable to act upon.

To their credit, it is notable that both FDA and USDA have undertaken tracebacks and regulatory interventions in a number of recent outbreaks, based entirely on epidemiologic data, without first having laboratory confirmation of pathogens in a food or production facility. This has not been the norm in the past, and this growing acceptance of epidemiologic data has led to much prompter interventions to stop outbreaks and prevent additional disease. Clearly, careful consideration of the weight and implications of all data is critical, but I hope that the experience of the outbreak currently under discussion will not dissuade these federal agencies from acting rapidly on strong epidemiological data in the future to protect the public health.

Suspected produce-associated outbreaks 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. While large food service corporations and their suppliers often have excellent quality-control programs with impeccable records, many other companies don't, 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. Many consumers have difficulty identifying subtle differences in varieties of produce. Such items are frequently consumed as ingredients in other foods (salsa, for example), or in foodservice establishments where consumers can't know a food's origin, and may not even be aware of what they are eating. Even if very detailed information from victims can be supplied by public health

investigators to a regulatory agency (which is frustratingly difficult in and of itself), the challenges to performing subsequent tracebacks through such a complex food-handling chain are formidable.

It is important to delineate the jurisdiction and responsibilities of various agencies during outbreak investigations. Food safety is reportedly overseen by 14 federal entities, administering over 35 separate food safety laws, with the involvement of 28 congressional committees. That open-faced sandwiches are regulated by one agency and closed-faced sandwiches another, or jurisdiction differs based on whether a product contains more or less than 2% meat, can be complicated. I have been involved in outbreak investigations in which both FDA and USDA had regulatory authorities within the same production plant, and indeed the same production line, depending on the type of food topping being used that day, and each agency has strikingly different regulatory policies.

A substantial underlying cause of many of the problems I have described is a limitation of resources available to agencies responsible for responding to foodborne outbreaks. We are all familiar with the dramatic statistics describing the FDA's understaffing and responsibilities far exceeding their capacity to meet them, including the fact that only 50 staff are dedicated to inspecting all imported foods, and well under 1% of these products undergoes even cursory examination. CDC suffers from similar underfunding. More than one outbreak was occurring at this time, as is usually the case. Even with excellent staff, the agency simply cannot do its job if overtaxed. State and local public health agencies

are likewise pitifully underfunded. Although the front line in outbreak investigations is at the state and local levels, most of those agencies receive the large majority of their funding from federal grants.

Our outbreak-response capacity is in large part supported by funding granted for successive waves of high-profile crises, from bioterrorism and anthrax, to West Nile virus, followed by SARS, then pandemic influenza. These resources have subsidized a wide array of core public health functions, notably disease surveillance and outbreak investigation activities, which otherwise would be impossible to sustain. In recent years "preparedness" funding has been cut repeatedly, leading not only to the obvious direct effects, but also to adverse impacts on our capacity to respond to events like foodborne disease outbreaks, which do not usually attract national attention but occur daily and affect millions of Americans annually. I obviously recognize the importance of disaster preparedness, but also believe that we need to realistically apportion resources to address public health threats in a logical manner. When the "red phone" rings for a bioterrorism attack it is important that we be prepared to respond, but while the likelihood of such an event is impossible to measure, Americans eat a billion meals a day, day in and day out, and 75 million of us fall victim to foodborne disease every year.

My message is not all "gloom and doom". Americans today have access to one of the safest, most diverse and inexpensive food supplies in the history of mankind. Public health, regulatory agencies and industry work remarkably well together toward the common goal of food safety. Huge strides are being made in our capacity to identify,

respond to and prevent foodborne disease. FoodNet, a cooperative program among 10 states, the Centers for Disease Control and Prevention, USDA's Food Safety and Inspection Service, and FDA's Center for Food Science and Nutrition, performs internationally-recognized studies of a wide variety of foodborne disease issues. PulseNet, a CDC-based system for sharing of molecular "fingerprinting" data from foodborne pathogens with a variety of agencies has markedly improved disease surveillance and rapid recognition of foodborne outbreaks. OutbreakNet is a CDC-coordinated group of foodborne disease epidemiologists from all 50 states, as well as representatives from other food safety agencies, that is focused on ways to improve communication and response to outbreaks. Outbreak-response training programs are available, including Epi-Ready, which is a national effort to bring environmental health, laboratory, regulatory and epidemiology personnel together for coordinated training. The Food Safety Research Consortium is a non-governmental organization pursuing a variety of projects including a recent report, "Harnessing Knowledge to Ensure Food Safety: Opportunities to Improve the Nation's Food Safety Information Infrastructure". A variety of other academic, consumer-advocacy and industry groups are engaged in similarly important efforts to address many of the issues that have been discussed today.

The Council to Improve Foodborne Outbreak Response (CIFOR) is another important example of successful efforts to address barriers in the food safety infrastructure. CIFOR is a multidisciplinary working group convened in 2006 to increase collaboration among the various public health agencies involved in the investigation, control and prevention of foodborne illness. The Council of State and Territorial Epidemiologists (CSTE) and the

National Association of County and City Health Officials (NACCHO) are co-chairing CIFOR with support from the Centers for Disease Control and Prevention (CDC). Epidemiology, laboratory, environmental health and regulatory agencies at the local, state and federal levels are represented. CIFOR is now exploring ways to increase involvement of industry representatives appropriately into its activities. Recent CIFOR projects have included establishment of an online clearinghouse of foodborne-disease response resources, development of guidelines for responding to multi-jurisdictional outbreaks, development of performance indicators for assessment of outbreak-response programs, and writing comprehensive guidelines for multi-agency investigations of foodborne disease outbreaks.

I believe that there are a number of opportunities for continued improvement of the nation's food safety infrastructure:

- Adequate and consistent funding and resources must be dedicated explicitly to sustain effective public health and food safety programs, commensurate with the true risks associated with the public health threats they address.
- Federal regulatory agencies must have 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. This may require changes in laws governing those agencies, and trust among public health partners and industry that sensitive and propriety information will be used only for protection of the public's health.

- Though I do not believe that federal public health epidemiology programs should be merged administratively with federal regulatory agencies, there is great potential benefit to reviewing jurisdiction of food types, facilitating improved communication among these agencies, including developing mutually accessible databases, ensuring rapid sharing of data during public health emergencies, and continuing to develop inter-agency training opportunities.
- It is critical to support development of information technology adequate to sustain outbreak detection and response activities. This includes resources for the development of state-based disease surveillance databases that both serve state needs and that allow for the sharing of essential information with other states and federal agencies, electronic laboratory reporting from commercial laboratories to public health agencies, and open data standards that allow data sharing among all food safety and public health agencies.
- Opportunities for improved coordination with food industries should be explored. Many food industries conduct testing which could be valuable in identifying the sources and causes of foodborne illness and outbreaks. Data sharing by industry should be encouraged. In addition, while outbreak investigators require appropriate independence, the food industry has access to data that can be important to investigations. One example is the detailed information often contained in “frequent shopper cards”, which can include contact information and precise data on dates and products purchased. A limited number of stores have been very cooperative in sharing such data with public health investigators, but unfortunately this is not currently the norm. Many grocery chains enter into contracts with consumers that

they interpret to prohibit unilateral disclosure of sales information to public health agencies.

In summary, I believe that our nation's food safety infrastructure is strong, but substantial barriers to continued improvement remain. Important strides are being made to improve foodborne disease outbreak response, and with adequate support there are many additional opportunities for improvement. I applaud today's meeting as recognition of the importance of pursuing these goals. Thank you for the opportunity to discuss these issues with you today.

Summary

- Improving the nation's food safety infrastructure, and capacity to respond to outbreaks, will require addressing barriers in epidemiology, laboratory, environmental health and regulatory agencies, at the local, state and federal levels.

- Adequate and consistent funding and resources must be dedicated explicitly to sustain effective public health and food safety programs, commensurate with the true risks associated with the public health threats they address.

- Federal regulatory agencies must have 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.

- Formal mechanisms to facilitate effective communication, sharing of data, and inter-agency training among agencies, and with industry, should be developed.

- An adequate information technology infrastructure is critical to ensuring successful outbreak responses.

- Mechanisms should be developed to support and take maximum advantage of successful efforts, including those of non-governmental, academic, consumer and industry organizations, to improve the food safety infrastructure.