

STATEMENT OF

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BEFORE THE

AGRICULTURE, NUTRITION AND FORESTRY COMMITTEE

U.S. SENATE

September 20, 2000

I am Dr. Stephen Ostroff, Associate Director for Epidemiologic Science, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I would like to thank the Committee for the opportunity to be here today with my colleagues from the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA)

Today, I will discuss CDC's role in the area of foodborne diseases and food safety, including how CDC has worked with other federal partners and used resources obtained through the National Food Safety Initiative to strengthen the Nation's ability to detect and respond to emerging foodborne disease threats. I will also discuss the public health burden of foodborne illnesses in the United States, highlight our progress in reducing foodborne illnesses, and provide examples from surveillance reports and recent outbreak investigations to demonstrate how National Food Safety Initiative resources are being applied to today's public health practice.

Today, more than 200 known diseases are transmitted through food. The causes of foodborne illness include viruses, bacteria, parasites, toxins, metals, and prions. The symptoms of foodborne illness range from mild gastroenteritis to life-threatening neurologic, hepatic, and renal syndromes. We estimate that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. Of these, known pathogens account for an estimated 14 million illnesses, 60,000 hospitalizations, and 1,800 deaths. Three pathogens, *Salmonella*, *Listeria*, and *Toxoplasma*, are responsible for 75 percent

of these deaths each year. Unknown agents account for the remaining 62 million illnesses, 265,000 hospitalizations, and 3,200 deaths.

In the wake of this public health burden on our Nation's health, I can report significant progress in reducing foodborne illness. CDC data show that from 1997 to 1999, illness from the most common foodborne pathogens declined by 20 percent. This decline represents nearly a million fewer Americans suffering illness each year from foodborne illness since the launch of the President's Food Safety Initiative. I am happy to summarize these data for you this morning.

Many factors may have contributed to these impressive two-year declines in foodborne illness -- the fact that they were seen across all of our active surveillance (FoodNet) sites suggests they are not surveillance artifacts. This further suggests that preventive measures, including those being implemented by the FDA and USDA, are working. Let me offer a few examples:

- *Campylobacter* (the most common foodborne bacterial pathogen) down 26%: Changes in poultry processing plants encouraged by USDA's Food Safety Inspection Service (FSIS) HACCP rule likely contributed here.
- *E. coli* O157:H7 infections down 22%: Improved sanitation in slaughter and processing plants and attention to hamburger cooking temperature likely contributed here. *E. coli* causes a serious disease which often leads to diarrhea and kidney failure, particularly in young children.

Salmonella enteritidis down 48%: FDA, FSIS, state and industry efforts to decrease contamination of eggs likely contributed here. The implementation of the Egg Safety Action Plan and FDA's pending final rule on egg refrigeration and labeling are expected to contribute to further decline.

Shigella down 44%: This decline follows a large outbreak in 1998 traced to imported parsley. The outbreak showed the need to improve sanitation on produce farms throughout the continent. Recent FDA/FSIS Good Agricultural Practices Guidelines focus on this need. FDA also has increased sampling and detection of imported produce, and supported education outreach programs in foreign countries.

Cyclospora down 70%: This decline follows rapid FDA action and subsequent production controls on imported raspberries.

Salmonella up 2% overall: This trend is partly due to large outbreaks in 1999 due to raw sprouts, unpasteurized orange juice, and imported mangoes. New FDA guidance on raw sprouts, pending juice regulations, and import sampling/detection strategies would be expected to contribute to future declines in illness.

These few examples show the importance of public health surveillance data and how such data can be used. Surveillance data document the incidence and prevalence of foodborne illness, and

suggest where preventive measures, including regulatory action, may be needed. Over time, surveillance data also help to document the effectiveness of these preventive measures.

Despite these impressive gains in reducing the burden of bacterial foodborne illnesses, we need to point out that many challenges remain. New foodborne pathogens are emerging, old foodborne pathogens are showing up in new foods, and antimicrobial resistance in foodborne pathogens is increasing. As we are here, another hearing is being conducted on the worsening trends in antimicrobial resistance, which will be a serious threat in future years.

CDC's Role in Foodborne Diseases and Food Safety

At its most fundamental level, CDC is the agency that keeps its finger on the pulse of the Nation's health. CDC is the cornerstone Federal agency responsible for identifying and monitoring foodborne and other illness and for documenting the effectiveness of prevention and control efforts, including both voluntary and regulatory measures. Using this information, we then work with partners to develop ways to improve disease control and prevention actions. CDC collaborates with State and local health departments, clinicians, academic centers, industry, other countries, and international organizations. In food safety, CDC works in very close coordination with the other agencies represented in today's hearing.

Foodborne and waterborne diseases is a target area in CDC's plan, Preventing Emerging Infectious Diseases: A Strategy for the 21st Century. Public health priorities in the plan are organized under four broad, interdependent goals, each of which can be applied specifically to

the prevention of foodborne illness: improving surveillance and response capacity, addressing applied research priorities, repairing the Nation's public health infrastructure and training programs, and strengthening prevention and control programs required to control emerging, reemerging, and drug-resistant infectious diseases.

CDC plays a critical and unique role as a monitoring, investigative, and advisory agency that is separate from regulatory agencies, but that works closely with them. CDC monitors the occurrence of human foodborne disease in the United States. This includes not only traditional public health concerns, such as illness caused by pathogens such as *Salmonella*, but also newer foodborne threats such as the bacteria *E. coli* O157:H7 and the parasite *Cyclospora*. We also monitor levels of antibiotic resistance in bacteria that cause foodborne illness. CDC works with State and local health departments to conduct ongoing surveillance of cases of foodborne illness and to investigate disease outbreaks, which often provide the first warning of new or different threats to the food supply. CDC uses both surveillance data and results of outbreak investigations to identify the factors responsible for illness so that immediate control measures can be taken and longer term prevention strategies can be developed. While other agencies measure success of interventions via reductions in food contamination, CDC's role in measuring the success of interventions is to see whether they translate into reductions in the number of human cases of foodborne illness. The ultimate test of all prevention efforts is whether they prevent human illness.

Once an outbreak is detected, the first response is usually from the State or local health department. CDC will often be invited by the State health departments to participate in the investigation if an outbreak is very large or complex, is thought to involve an unusual pathogen or unexpected food vehicle, affects multiple states or countries, or when preliminary investigations do not reveal a source. When investigating an outbreak of a foodborne illness, public health officials must combine laboratory diagnostic techniques and epidemiologic investigative methods to determine the causative agent of the illness, the food vehicle responsible for transmission, and the environmental factors that contributed to the outbreak. If a food is identified as the source of illness, CDC collaborates with FDA or FSIS on the investigation and control of the outbreak, based upon which agency regulates the suspected food.

In addition to our surveillance and response activities, CDC also conducts applied foodborne illness research. Some examples include developing laboratory diagnostic tests where none currently exist, such as detection of hepatitis A virus in food and detection of Norwalk-like viruses or *Cyclospora* in clinical specimens and foods; developing methods to subtype, or “fingerprint”, bacteria, viruses, and parasites causing foodborne illness; conducting risk factor studies for foodborne illness in special populations, such as the immunocompromised; and performing cost-effectiveness analyses of potential prevention measures such as routine use of hepatitis A vaccine in food workers.

The public health infrastructure is the underlying foundation that supports the planning, delivery, and evaluation of public health activities and practices. CDC’s ongoing effort to rebuild the U.S.

public health infrastructure that addresses infectious diseases is critical to improve the capacity of health departments, health care delivery organizations, and clinical and public health laboratories to detect and report cases of foodborne and other illness and to implement prevention and control strategies. Part of this effort includes enhancing capacity to respond to disease outbreaks and training public health professionals to be able to respond to emerging threats now and in the future. With respect to the prevention and control of foodborne diseases, these efforts are directed at enhancing the states' ability to investigate, control, and report all outbreaks of foodborne diseases.

CDC also engages in educational activities targeted to health care professionals and the public. Examples of assistance to health professionals include producing videos on laboratory methods to diagnose foodborne pathogens and materials on how to avoid foodborne illness among immunocompromised, high-risk persons. To educate the public, CDC actively participates with FDA, FSIS, and other Federal agencies, industry, and consumer organizations in the Partnership for Food Safety Education, an ambitious public private partnership created to reduce the incidence of foodborne illness by educating Americans about safe food-handling practices through many activities, including the national Fight BAC!TM Campaign. The purpose of the Fight BAC!TM Campaign is to help educate consumers about the problem of foodborne illness and motivate them to take basic sanitation and food-handling steps that will reduce the risk of foodborne illness.

The Challenges of Food Safety

Although the United States has one of the safest food supplies in the world, the public health burden of foodborne diseases is still substantial, and we continue to face challenges to the safety of our foods. New foodborne pathogens are emerging, old foodborne pathogens are showing up in new foods, and antimicrobial resistance in foodborne pathogens is increasing. The eating habits of Americans have changed. We now consume more fresh produce and seafood and demand a constant supply throughout the year. Changing food habits can result in a changing pattern of foodborne illness. To meet the demand, an ever increasing proportion of our food is imported, especially from developing parts of the world. As a result, we are being exposed to pathogens not commonly found in the United States, as demonstrated by the *Cyclospora* outbreaks associated with imported raspberries. The array of new products and processing methods, such as pre-packaged salad mixes, presents another challenge, as does mass production and distribution of foods, which has the potential to produce diffuse, nationwide illness outbreaks of unprecedented scale.

New challenges require new, creative ways to do our job more effectively and efficiently. The President's National Food Safety Initiative, launched in 1997, recognizes this need and is moving our food safety system forward. CDC has been an active partner in the development and implementation of the Food Safety Initiative. Our resources under this initiative have primarily been targeted to harnessing the information and laboratory technology revolution to propel our Nation's foodborne disease surveillance system into the 21st century.

FoodNet

I will provide two examples of CDC's progress in this area. First is the Foodborne Diseases Active Surveillance Network (FoodNet). The FoodNet system is a joint effort by CDC, FDA, USDA, and State health departments to capture a more accurate and complete picture of trends in the occurrence of illness caused by priority foodborne pathogens. It is built on the foundation of CDC's emerging infectious disease activities, which provides the basic infrastructure to conduct active disease surveillance. Before 1996, the Nation's foodborne disease surveillance system was based on passive reports of illness from clinicians and laboratories which were submitted to local health departments and then onward to the State health department and from the State to CDC. Such information lacks timeliness, is often incomplete, and is highly variable from one place to the next depending on the resources invested at the state and local level.

FoodNet is part of CDC's Emerging Infections Program (EIP). CDC funds EIP cooperative agreements with State and local health departments to conduct population-based surveillance and research that goes beyond the routine functions of health departments. In these sites, the program, which usually involves a partnership between the State health department and an academic center, canvasses laboratories and other data sources for illnesses caused by nine different pathogens on an active, ongoing basis using standardized data collection methods, standard definitions, and standard techniques. Special case-control studies are conducted across FoodNet sites in order to identify the major risk factors for sporadic illness. Community surveys are conducted to help determine the overall burden of foodborne illness. These can include mild cases of illnesses which do not come to medical attention or cases where there is no diagnostic

test performed. Data are electronically submitted to CDC for timely analysis. FoodNet gives high quality data never before available and also allows us to make determinations that differences across sites are real and not due to differing surveillance intensities or methodologies.

PulseNet

A second system to highlight is PulseNet, a system developed in partnership with State health departments and the Association of Public Health Laboratories and a winner of the Ford Foundation's "Innovations in American Government Award." PulseNet is a network of molecular subtyping (fingerprinting) laboratories at State health departments, FDA, USDA, and CDC, which enhances the ability of laboratory-based surveillance to rapidly identify clusters of related foodborne infections of certain pathogens, sometimes scattered over large geographic areas. This system uses a methodology known as pulsed field gel electrophoresis (PFGE) to digest bacterial DNA and produce unique patterns. Like human fingerprints, each bacteria and its offspring have a unique PFGE pattern. If two bacteria are found with an indistinguishable pattern, it is likely that they have a common source, meaning they may be part of an outbreak of many similar cases. CDC initially standardized PFGE methodology for *E. coli* O157:H7 and for *Salmonella*. In 1998, CDC also standardized PFGE methodology for *Listeria*, not long before there was a multi-state outbreak of listeriosis associated with contaminated hot dogs. Using funds obtained through CDC's Epidemiology and Laboratory Capacity (ELC) cooperative agreements and from the Food Safety Initiative, state health laboratories have obtained PFGE equipment, and CDC has provided training and standardized methodology to them to test for

foodborne pathogens. USDA and FDA laboratories also participate in the network to allow comparison between animal, food, and human isolates. Currently, 48 state public health laboratories in 46 states are linked into this network. Eventually, CDC hopes to include all state laboratories.

To enhance the power of the PulseNet system, in 1998, CDC created a national computer database of PFGE patterns that is housed at CDC. Now states can submit PFGE patterns to the database over the Internet. The computer then automatically scans previously submitted patterns searching for matches. If a match is found, a signal is given to the submitter that duplicate patterns are present and where they came from, so that an investigation can begin to look for a common source. When the system is fully implemented, all of this will happen in real time, allowing the early warning system for nascent outbreaks that we all desire.

The impact of PulseNet has been enormous, both in identifying outbreaks that would otherwise have gone unnoticed, and in allowing us to focus our investigations to determine the true source and extent of an outbreak. For example in late 1998, an increased number of cases of listeriosis were noticed. Using PulseNet technology, CDC tested the strains from several states and determined that many had the same PFGE pattern. Epidemiologic investigations found a strong association with hot dog consumption in patients with the outbreak strain, leading to recalls which occurred just before Christmas. CDC then continued to work with states to test all available *Listeria* isolates from patients from the previous summer in order to determine how many cases and deaths occurred as part of the outbreak and to confirm that the outbreak is over.

Some of the strains, which were tested, were different from the outbreak strain. Among these strains, a second cluster with a common PFGE pattern was found. Investigation of these cases found they were linked to consumption of a specific imported cheese. Other small clusters of cases have been identified and are under investigation. If not for the ability to do the subtyping, it is unlikely that these outbreaks would have been discovered and investigated, and prevention measures would not have been undertaken.

Another PulseNet example involves *Shigella*, a bacterial pathogen that can be foodborne but most often is not. The Minnesota Department of Health, a FoodNet site, routinely fingerprints *Shigella* isolates, and, in 1998 they identified a cluster of strains with a similar pattern.

Epidemiologic investigations found that illness was linked to eating chopped parsley at two different restaurants. By informing other states and searching databases for places with an increased number of cases, similar outbreaks were identified in five other states and Canada. The *Shigella* from these outbreaks also had the same PFGE fingerprint. All of the outbreaks were parsley associated. Working with FDA, the implicated parsley was traced to a specific farm. Again, if not for routine utilization of PFGE, the links between the outbreaks would have been missed, the source would not have been identified, and the outbreak would have spread much further.

PFGE is a powerful surveillance tool. It allows us to detect widely dispersed outbreaks and small clusters that would have previously been missed. This illustrates a central tenet of epidemiology: better surveillance leads to better and more accurate disease detection, which in

turn leads to more field investigations. This causes increased burdens, not only on CDC and other Federal agencies, but also on State and local partners.

Therefore, as surveillance improves, more outbreaks, not fewer, will be detected. However, this should not be interpreted as a failure. Rather, it represents success, because only by finding and investigating the outbreaks can we define risks, develop and implement interventions, and over the long term, identify and limit the risk.

National Food Safety Initiative at CDC

CDC will continue to direct its resources to developing the needed public health infrastructure throughout the Nation to detect, control, and prevent foodborne illness and to strengthen prevention and control programs required to control emerging, reemerging and drug-resistant infectious diseases. In short, CDC, in collaboration with others, will continue to build State and local health department capacity to conduct appropriate epidemiologic, laboratory and environmental investigations; and continue ongoing efforts to inform health professionals and the public about foodborne illness and prevention.

For example, we will continue to develop a national network of laboratories capable of using state-of-the-art laboratory methods and technologies. This includes increasing the number of States participating in PulseNet, and increasing the number of pathogens monitored by the system in order to detect additional outbreaks.

We intend not only to expand our development of state-of-the-art gene-based diagnostic and subtyping tools for bacteria, but also to develop a comparable system for identifying viral contaminants. We also will continue to support a system known as DPDx, which harnesses telemedicine technology to transmit images of parasites under the microscope to our experts at CDC for appropriate diagnosis. In addition to our efforts to improve epidemiology and laboratory capacity, we intend to work with the States to strengthen their environmental health capacity. For example, we plan to work with the States to assess the training needs of food protection specialists (environmental sanitarians) and develop food safety guidance for local food protection programs. We also intend to continue development of school-based prevention and control efforts, including development of a model coordinated school health and food safety program. We also will continue to update analyses and estimates of the public health burden of foodborne disease.

Conclusions

In conclusion, these activities represent a small sample of how CDC supports its State and local partners and other Federal agencies in monitoring, controlling, and preventing foodborne illness. Foodborne diseases remain a challenge for public health. To address this challenge will require continued investments in our public health infrastructure and strong partnerships among State and local health departments and Federal agencies.

Thank you for the opportunity to discuss the surveillance of foodborne disease. We will be happy to answer questions you or other members of the Committee may have.