FOOD SAFETY: OVERSIGHT OF THE CENTERS FOR DISEASE CONTROL MONITORING OF FOODBORNE PATHOGENS

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

SECOND SESSION

MAY 23, 1996

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THURSDAY, MAY 23, 1996

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2247, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Souder, Davis, Gutknecht, and Towns.

Ex officio present: Representative Clinger.

Staff present: Lawrence J. Halloran, staff director and counsel; Anne Marie Finley and Robert Newman, professional staff members; Thomas M. Costa, clerk; and Cheryl Phelps, minority professional staff member.

Mr. SHAYS. The subcommittee will come to order.

I would like to welcome our witnesses and our guests.

Guess who's coming to dinner? Tonight, when many Americans sit down to eat, they will be joined by uninvited, and very unwelcome, guests. Foodborne pathogens—the bacteria, chemicals, viruses, parasites, and unknown agents that can cause illness when ingested—pose a growing threat to the public health.

Today, we examine the dimensions of that threat, and our capacity to meet it.

First, the good news: The American food supply is among the safest in the world. We enjoy an abundant, diverse, and nutritious larder kept wholesome by producers, processors, packagers, and purveyors working under the watchful eye of State and Federal regulators.

The bad news is that as many as 9,000 deaths will be directly attributed to foodborne pathogens this year. Incredibly, estimates of food-induced illnesses range from 6½ million to as many as 81 million.

And even those figures don't describe the full extent of the problem. Many food-related illnesses are treated only symptomatically, without any identification of the offending pathogen. Even when the cause of an illness is known to be contaminated food, the necessary data is not always reported by physicians and State health

authorities. As a result, national surveillance data on the prevalence and sources of foodborne pathogens is obviously inadequate.

This is very serious, potentially grave problem. Without accurate information, public health officials cannot identify the level of risk, potential sources, or the populations most vulnerable to foodborne illnesses. Without a clear assessment of risk, it is impossible to maintain adequate preventive and corrective measures.

But we do know the risk is increasing. The General Accounting Office [GAO] recently observed the food supply is changing in ways that can promote foodborne illnesses while making outbreak detection more difficult. Food production and handling practices can permit the introduction and spread of pathogens. Increasingly, national food distribution patterns can, before we know it, disperse contaminated products to more people in more places, often masking the extent of a problem.

And there is an increased risk from newly discovered pathogens. Three of the four pathogens considered most important by the Centers for Disease Control and Prevention [CDC] were unrecognized as causes of foodborne illnesses just 20 years ago.

Campylobacter infection has been identified as a major triggering factor in Guillain-Barre syndrome, one of the leading causes of paralysis from disease in the United States. *E. coli* O157 was first identified in 1982, and emerged into the public consciousness with deadly force in 1993, when four children died after eating undercooked ground beef, and causing meningitis and stillbirths with a mortality rate between 20 and 40 percent. It can survive even refrigerated foods. Only aggressive control and public education programs are effective.

While the food supply becomes more vulnerable to old pathogens, and nature continues to conjure new ones, the food safety system on which we rely appears fragmented and time-locked. The risk from foodborne pathogens is increasing. But our capacity to protect the public health is not.

The CDC, the Food and Drug Administration [FDA], and the U.S. Department of Agriculture's Food Safety and Inspection Service, [USDA/FSIS], all have essential, but separate, responsibilities for food safety. For example, USDA is responsible for the wholesomeness of eggs, as long as they are in the shell. Once the shell is broken, the FDA has jurisdiction. But *salmonella* bacteria can travel both in eggs and on them.

Many of the other pathogens that infect our food also refuse to observe any neat jurisdictional boundaries. With increasing frequency, pathogens are slipping through the cracks in the regulatory shell that protects U.S. food safety.

Two years ago this subcommittee, under the outstanding leadership of my colleague, Ed Towns, held extensive hearings on reinventing the Federal food safety system. The hearing is found in this book. There was the promise of closer coordination, better surveillance and implementation of scientifically based hazard control systems.

Today, we ask our witnesses what, if any, progress has been made to address the weaknesses in public health surveillance and the overly compartmentalized Federal regulation discussed in those

hearings. The health of a great many people and the health of our Nation depends on the answers.

Again, we welcome all of our witnesses here today, and I look forward to their testimony, as does my colleague, Mr. Towns.

Mr. Towns.

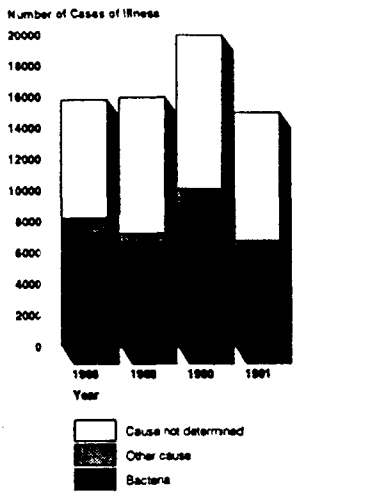
[The charts referred to follow:]

Estimated Annual Impact of Three Major Foodborne Pathogens in the United States

Pathogen	Cases	Deaths	Cost
Salmonella	2,000,000	1000 - 2000	$1 - 1.5 billion
Campylobacter	2,000,000	100 - 360	$1 billion
E. coli O157:H7	7 - 20,000	150 - 400	$230 - 600 million

CDC Subcommittee Briefing, February 20, 1996.

Figure I.1: Reported Cases of Illness From Foodborne Outbreaks by Cause, 1988-91



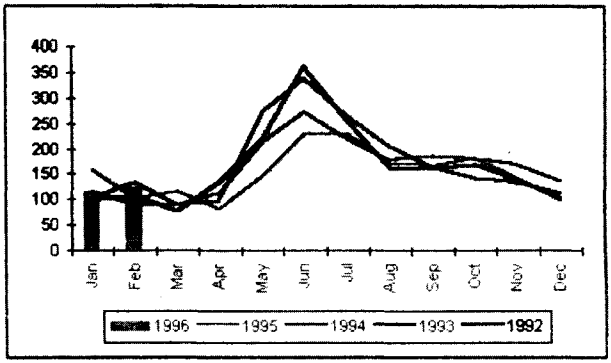
Note: Other causes include chemicals, viruses, and parasites.

Source: CDC.

General Accounting Office, Report on Food Safety: Information on Food borne Illnesses, May 1996, (GAO/RCED-96-96).

CAMPYLOBACTER

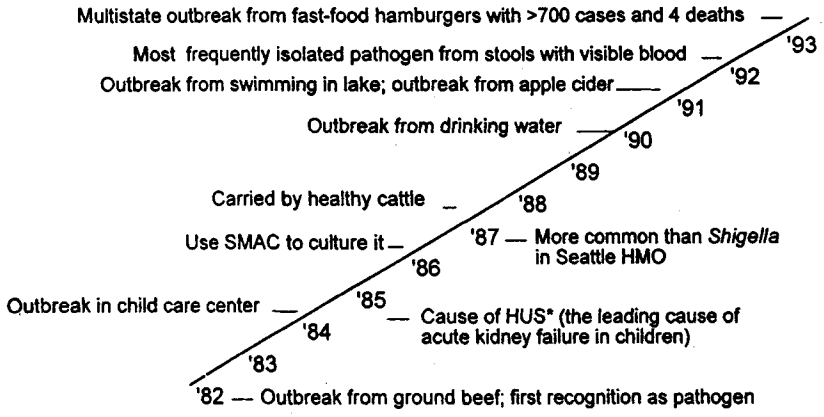
ISOLATIONS



BREAKDOWN FOR FEBRUARY 1996

Camp.jejuni	49
Camp.species	76

E. coli O157:H7 Time Line



SMAC = sorbitol MacConkey medium
HUS = hemolytic uremic syndrome

Most of this work done by CDC

CDC Subcommittee Briefing, February 20, 1996

The radura symbol above has been adopted internationally as a label for irradiated food. In addition, FDA requires that the label include the words "treated with radiation" or "treated by radiation" and "keep refrigerated" or "keep frozen."

from the Council for Agriculture, Science and Technology (CAST) Issue Paper #7 - Radiation Pasteurization of Food, April 1996

Mr. TOWNS. Thank you very much, Mr. Chairman, for holding this hearing.

Every time I eat a hamburger or pour my granddaughter a glass of milk, I rely on the knowledge that the U.S. food supply is the safest in the world. It is. But nevertheless, the General Accounting Office is here today to present us with some sobering facts.

Fact No. 1: Foodborne illnesses range from 6.5 to 81 million incidents annually, with more than 9,000 resulting in death.

Fact No. 2: Annual costs due to medical treatment and loss of productivity range from $5 billion to $22 billion. We are not even sure what the numbers are.

Fact No. 3: More than half of all foodborne diseases and deaths are caused by contaminated meat and poultry products.

Fact No. 4: All indications are that the risk of foodborne diseases are actually growing, and that troubles me.

Fact No. 5: We don't have enough data to know the facts. That is a problem.

The FDA, CDC, and USDA have critical, unique, and interdependent missions to ensure food safety. Our continued confidence in our Government's ability to contain the risks of foodborne diseases depends on the development and deployment of a food safety strategy that effectively incorporates the functions of these agencies.

Mr. Chairman, serious questions can be raised that current Federal efforts are inhibited by deficiencies in surveillance data, interagency cooperation, and the use of appropriate technologies to detect and eliminate agents. But it seems to me that questions can also be raised that advances in technology and methodologies that can reduce the incidences of potentially deadly foodborne diseases often fail to find sufficient physical and political support.

For example, the CDC active surveillance system is widely considered to be an improvement over the current passive system. However, funds for the cooperative initiative were zeroed out in the appropriations. And in order to preserve the program, both FSIS and FDA assumed its costs, tapping into their own scarce resources. That should not happen. That is wrong.

Mr. Chairman, food safety is not a partisan issue and we should not make it a partisan issue. Unless you know something that I don't know, there are no Republican cartons of milk, and there are no Democratic cartons of milk. I don't think there is any Republican ground beef, and I don't think there are any Democratic eggs. We need to understand that today, more than ever, and join hands to work to bring about some real solutions to these problems.

I welcome the testimony of our witnesses, and look forward to a candid assessment of the strengths and weaknesses of the Federal effort to address the risks of foodborne disease.

I also look forward to working with you, Mr. Chairman, as I have done in the past, to ensure that the political will and fiscal resources are in place to support the development and deployment of a safety strategy that is responsive to the concerns raised here today.

Let me close by saying I really feel that the time has come where a serious commitment must be made on both sides, and when I say on both sides, I am talking about the fact that we need to put the

dollars there to make certain that the resources are in place to do the kind of job that needs to be done.

So Mr. Chairman, I want to let you know I want to work very closely with you in making certain that this is done. When you have 9,000 people losing their lives, we know for a fact that we can do a lot better than what we are doing.

So I would like to yield back the balance of my time and to say to you this is a very timely hearing; one that I am happy to participate in.

Mr. SHAYS. Well, thank you, Mr. Towns.

[The information referred to follows:]

THE WASHINGTON POST

LETTERS TO THE EDITOR

Polio: The Problem With Multiple Injections

Sam Katz, a noted vaccine researcher and academician, has suggested an approach to polio vaccination that causes great concern for many on of us the immunization front lines [op-ed, April 26].

Oral vaccine (OPV) has proven to be of great benefit to physicians and health provider agencies, not only because of its high level of effectiveness in protecting children against polio but also because its oral administration facilitates the actual immunization process by avoiding an additional injection.

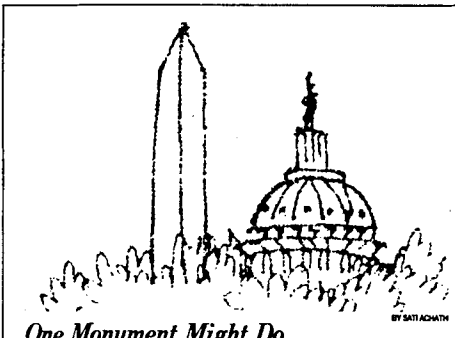
Although the multiple new antigens that are available today provide outstanding protection against a number of diseases, their effectiveness is contingent on their being properly administered, as well as on completion of the full immunization schedule. Unfortunately, there is not yet a combination product that is included in one injection. If Dr. Katz had his way, infants might be required to receive four injections in one visit. This would be logistically difficult for immunization providers and troubling to most parents.

Study after study has demonstrated that parents resist multiple injections. If inactivated polio vaccine (IPV), which must be administered by injection, replaces OPV's oral administration, it is likely that the additional injection would contribute to immunization noncompliance. As a result, society could be at increased risk not only for exposure to polio but also from possible outbreaks of other diseases that are normally vaccine preventable in those instances where an additional injection proves a deterrent to completion of the immunization schedule.

The impact of a change in polio immunization will be especially demanding in inner cities, where crowded clinics are already burdened by the multiple injections required under the current schedule. Experience has taught us as recently as the 1989-90 measles epidemic that disease will not be confined once immunization compliance has lapsed. For the good of us all, those concerned with the public's health should take seriously the pleas of immunization providers not to change the polio immunization schedule until the problem of multiple injections can be solved through introduction of new combination vaccine products.

NORMA J. GOODWIN
[illegible]

The writer is president of Health Watch, a national nonprofit organization concerned with minority health care.



BY SATI ACHATH

One Monument Might Do

Architect Paul D. Spreiregen complains that designs for the new World War II memorial aren't open to enough competition [Close to Home, May 5]. But whatever the final outcome might be—at least in the eyes of this Navy vet—it is bound to be a disaster. In its planned location, at the east end of the Reflecting Pool, the structure will ruin one of the great views of this world: the glorious, uncluttered vista that links the Washington Monument and the Lincoln Memorial.

Each morning, before breakfast, I jog from my home near Dupont Circle down to the Lincoln Memorial and up its steps. And each morning, I marvel at the beauty: the 2,000-foot pool fashioned after lakes at Versailles and the Taj Mahal, ducks and geese splashing around; the two fountains at its eastern tip, framing the grassy knoll beyond topped by the Washington tower. Both memorials mirrored lovingly in the serene waters of the Reflecting Pool. Trees everywhere . . .

All this pristine beauty will be destroyed if a monolithic World War II memorial is placed smack in its midst.

When I came to live in Washington 30-odd years ago, I was most enchanted

What's a Leader?

In the article "Students Go the Extracurricular Mile for Admission to Elite Colleges" [front page, May 7], Eric Wee relates how a young lady at Washington-Lee High School became class vice president after she was advised that she needed to show colleges some leadership skills. Is holding office being a leader? Leaders are not motivated by self-interest.

It is no wonder that the United States' political environment has deteriorated, if that is what we are teaching our children. Plato, in "The Republic," describes the ideal political leader as a "reluctant leader." Leaders reluctantly accept office out of a sense of responsibility and service, not self-interest.

Graduates of so-called elite colleges are presumably the leaders of the future. We should be teaching them responsibility and service, not self-interest.

JEROME T. PAULL
Arlington

Nice Radio? Not Yet.

While Marc Fisher makes some interesting points in his premature requiem for radio ranter Bob Grant ["A Fond Farewell to Foul Mouths," Outlook, April 28], he's wringing his hands a bit too hard over the fate of radio's baddest boys.

Mr. SHAYS. When you were chairman of the subcommittee, you held three outstanding hearings on this issue, and it is really a continuation of those hearings that we have today.

I do have some housekeeping information that I need to get out of the way.

One, we would note for the record that we have a quorum, and that I would ask unanimous consent that all members of the subcommittee be permitted to place any opening statements in the record and that the record remain open for 3 days for that purpose, and without objection, so ordered.

I also would ask unanimous consent that our witnesses be permitted to include their written statements in the record, and without objection, so ordered.

I would also say that there may be a time that Mr. Towns chairs this committee or another Member in the majority. We are debating the minimum wage; we have a number of amendments. Both Mr. Towns and I support an increase in the minimum wage, and there is one amendment in particular that we would consider a killer amendment that we want to make sure doesn't survive, or the bill will die. So we have that other concern, and I would just explain that would be the only thing that would keep one of us or the other away.

With that, as we do with every witness, Members of Congress, and secretaries, we swear in all of our witnesses, and we would just ask if you would stand and raise your right hands.

[Witnesses sworn.]

Mr. SHAYS. I love the fact that our other witnesses stood up as well. That saves a lot of time. We will just have to remember who didn't stand up. I will note for the record, though, that the four witnesses in the front have all answered in the affirmative.

And with that, we will go with our first witness. I think we will start with Dr. Satcher, who is the Director of the Centers for Disease Control and Prevention, and you will start us off.

Doctor, it is wonderful to have you here at the committee. Thank you for coming.

STATEMENT OF DAVID SATCHER, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, ACCOMPANIED BY MORRIS E. POTTER, ASSISTANT DIRECTOR, NATIONAL CENTER FOR INFECTIOUS DISEASES

Dr. SATCHER. Thank you very much, Chairman Shays and Congressman Towns.

I am Dr. David Satcher, Director of the Centers for Disease Control and Prevention, and I am accompanied today by Dr. Morris Potter, who is with CDC's National Center for Infectious Diseases. We are very pleased to be here with our colleagues from the FDA and USDA to discuss CDC's programs to monitor, prevent, and control foodborne diseases in the United States, but also to discuss our coordination and collaboration with FDA and USDA.

If I may, Mr. Chairman, I would like to say just a word about the fact that this year represents CDC's 50th anniversary. As you know, we were founded in 1946, and while I am not here to talk about those 50 years in any way of celebration, I do want to say that we are concerned about what we have learned from our 50

years and how those lessons will shape our programs today and tomorrow. So I would like to briefly share with you what we consider to be the five most important lessons that come from our history.

The first one is the importance of good, rigorous science and the fact that there is no substitute for good, rigorous science. That includes well-trained people, people who are in the epidemic intelligence service, but also includes quality laboratories and other quality programs.

The second lesson that we have learned is the value of prevention, and that prevention is, in fact, the best investment. I think we are here today because we believe that we can do a better job of prevention when it comes to foodborne diseases.

The third lesson which we like to point to is the importance of partnerships: Partnerships at the Federal, State, and local level, partnerships with other governmental agencies, but also, public-private partnerships, and those are increasingly important in all that we do at CDC.

The fourth lesson is that public health is global, and especially in the area of infectious diseases, emerging infections. We know that microorganisms do not respect national boundaries. I think as we discuss problems in foodborne diseases, that point is again made very vividly. Because of changes in the way food is produced, processed and moves across national boundaries, our problem has increased.

The last lesson that we have talked about this year is the fact that in all that we do, there are certain principles and values which we must adhere to. One, of course, relates to the way we use science, but another is the respect for the dignity and worth of individuals regardless of race, gender, nationality, or what have you.

With those lessons, I would like to say that we agree that this problem of foodborne diseases is a serious problem. The magnitude of foodborne disease is great, and even though we don't have exact figures because of the inadequacy of surveillance systems, we know that millions of people are affected every year and that thousands of people die because of this problem.

Earlier I spoke with you about CDC's plan for addressing emerging infections. As you remember, in 1992, the Institute of Medicine released a report on emerging and re-emerging infectious diseases, in which they pointed out major concerns, including the problem of foodborne diseases. In that report, the Institute of Medicine addressed the need for CDC to provide leadership in responding to emerging and re-emerging infections. In 1994, CDC published its plan for addressing emerging infectious diseases, and we are very grateful that Congress provided funds in 1995 and 1996 to begin to implement that plan, some of which I will speak to briefly.

Also, you will probably remember that I chaired the Committee on International Science Engineering and Technology, which included 20 Federal agencies, to look at the whole issue of the global emerging infectious disease problem and the need for global surveillance and response. Many of the recommendations from that report are relevant. We have submitted both reports for the record, the CDC's plan, and the CISET committee report, which was done as a part of the National Science and Technology Council.

Let me say that many aspects of CDC's plan deal with infectious foodborne diseases and complement sections of the Food and Drug Administration's 1995 Food Code and the hazard analysis, critical control points-based food safety program being designed and implemented by both FDA and USDA. That collaboration is very important and it also includes personnel being stationed at CDC by both the FDA and the USDA to ensure better coordination. I think the concern you have about coordination and collaboration is a very important one and we are attempting to address that in several ways.

I would like to speak briefly then about three topics: One, CDC's foodborne disease surveillance program; second, about this problem of antimocrobial resistance and the impact that that is having; and then briefly the approach that we took to *E. coli* O157:H7 and *salmonella.*

Let me say that there are four components to our foodborne surveillance program. It is interesting to compare and contrast them. The first component is a physician-based surveillance system. This program relies on reports from physicians who see patients. The advantage of this system is that it is very rapid. When physicians see patients with an illness, they report. The disadvantage is that it is not always accurate. And another disadvantage, of course, it is limited to people who go to physicians when they get ill, and as you know, many people who become ill from foodborne diseases don't seek care from physicians. But this part of our surveillance system is a very important one.

The second surveillance system that we have in place is a laboratory-based surveillance system. It is a system that relies on reports from local laboratories. Clinical, private clinical laboratories report to State laboratories, and they in turn are reporting to CDC.

We have a very sophisticated public health laboratory information system where the results of these State laboratory tests are sent immediately to CDC, using PC monitoring. This information system has proved to be very valuable. It is very rapid.

Let me say that the strength of the laboratory-based surveillance system is its accuracy. It may not be as rapid as a physician-based system, but the accuracy is what is so important. It is limited, just as the physician-based system is, by the fact that it relies on people who show up at a physician's office or somewhere else to get a laboratory test done. So I think both systems are limited in this regard.

The third surveillance program that we have in place is the outbreak investigation. And as you know, if you look at CDC's history, the outbreak investigation has been very characteristic of what we do. In fact, the Epidemic Intelligence Service has played a major role in terms of providing trained people to States to investigate outbreaks. Also CDC is often called upon to investigate outbreaks in other countries. We realize in this country that we are tied very closely to other countries when it comes to the spread of infectious diseases.

Outbreak investigations allow us to probably gain more information about the nature of the food causing the illness, or the nature of the people infected in many cases. It has its limitations, because we receive reports of only about 400 to 500 outbreaks a year, and that involves about 12,000 people. So we know that even though

we do outbreak investigations, that it has its limitations in terms of the number of people impacted and the number of outbreaks that are actually detected and reported.

That brings me to the fourth area, and that is the active foodborne disease surveillance, which we think is really critical. As I said, in 1995 and 1996 Congress provided funds to establish an active foodborne disease surveillance program. We have done two kinds of things. No. 1, we have been concerned about the quality of the public health laboratory at the State level, and in fact in many cases those laboratories have deteriorated in quality over the last several years.

In the first phase of our funding, and we had approximately $18.4 million in 1995 and 1996, we have now funded 15 States and local health agencies to strengthen surveillance and response capacity, such as infections caused by *E. coli* O157:H7. This is the emerging infectious disease strategy that we implemented in 1994.

Another very important part of that strategy is the establishment of the emerging infectious disease programs. We have now funded four States, California, Oregon, Minnesota, and Connecticut, as States that are a part of an emerging infections program. There is also a program in Atlanta, GA. All together, these programs cover about 13.5 million people, about 5 percent of the Nation's population.

The advantage of them is that these programs are allowing us to ask some very critical questions about the nature of outbreaks, the nature of the foods involved, the nature of the people involved. It allows us to gather samples from people who die from unknown etiologies. So it is the most aggressive program that we have had, to date, to try to learn more about the magnitude of foodborne problems.

We have had support, as you have heard, from the FDA and USDA in developing the collaboration for the system, as Congressman Towns said. That part of the proposal was not funded, but they have provided funds so that we have developed together these five sites throughout the country so that we can monitor emerging infectious diseases and especially the foodborne diseases, which is what we use our collaborative funds for. So we feel that the active foodborne disease surveillance provides us with an opportunity to get information that we could not otherwise gain.

President Clinton has requested an addition of $27 million in the 1997 budget for these emerging infectious disease programs. If we receive this funding, we will add at least 15 States to our surveillance and response program, strengthening the laboratories. We will hopefully add at least three more emerging infectious disease programs. That means that we will have 30 States in the country that we have worked with intensely to strengthen their capacity to respond—to detect and respond to foodborne illnesses and other emerging infectious diseases. So we think this is an example of a good investment, and that it is an example of where investing up front in prevention will save us a lot of money later in treating problems.

As you have heard, the cost of dealing with foodborne infections is significant and certainly much greater than we know, but we

know that it is way in the billions of dollars. We believe that this would be a very good investment.

Mr. SHAYS. Thank you, Dr. Satcher.

[The prepared statement of Dr. Satcher follows:]

Good morning. I am Dr. David Satcher, Director of the Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. Morris Potter with CDC's National Center for Infectious Diseases. We are pleased to be here this morning to discuss CDC's programs to monitor, prevent, and control foodborne diseases in the United States.

The public health burden of foodborne diseases in the United States is substantial. Each year we estimate that millions of persons become ill and thousands die from foodborne diseases. The cost of these illnesses to the U.S. economy is several billion dollars a year. Many different pathogens and toxins have been described as causes of foodborne disease and new ones continue to be identified. Although I will be addressing infectious foodborne diseases, natural and environmental toxins may sometimes also be present in our foods. Foodborne diseases are common and, in principle, preventable. Many foodborne problems that were formerly important are now well controlled by standard prevention strategies, such as pasteurizing raw milk, appropriately managing the canning of food, and ensuring that restaurants and other food preparation areas are clean and well maintained. However, new challenges continue to arise, and new efforts are required to understand, prevent and control them.

Preventing foodborne disease requires a coordinated program of risk assessment and risk management involving Federal, State, and local agencies. CDC's primary role in this coordinated effort is that of characterizing the risk of foodborne disease.

In a 1992 report, *Emerging Infections: Microbial Threats to Health in the United States*, the Institute of Medicine (IOM) stated: "The potential for foods to be involved in the emergence or

reemergence of microbial threats to health is high, in large part because there are many points at which food safety can be compromised." This IOM report underscored the ongoing threat from emerging infectious diseases and stressed that increased vigilance and enhanced response capacity are needed to overcome years of complacency. The report provided specific recommendations for action by CDC and other federal and state agencies and emphasized a critical leadership role for CDC in a national and global effort to monitor, prevent, and control emerging infectious diseases.

CDC took the recommendations in the IOM report very seriously. In 1994, after extensive consultation and input from numerous outside organizations and experts, CDC released a plan, "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States." This plan addresses necessary action for revitalizing our Nation's ability to identify, contain, and prevent illness from emerging and reemerging infectious diseases. Particularly critical to meeting the challenge are CDC's partnerships with both domestic and international organizations. With the $18.4 million provided by Congress, CDC has begun implementation of some of the highest priority steps in this plan.

Many aspects of CDC's plan deal with emerging infectious foodborne diseases and complement with sections of the Food and Drug Administration's (FDA) 1995 Food Code, and the mandatory HACCP-based food safety program being designed and implemented by FDA and the U.S. Department of Agriculture (USDA).

Beginning in December 1994 and during 1995, I chaired an Interagency Working Group, established under the aegis of the Committee on International Science, Engineering, and Technology Policy (CISET) of the President's National Science and Technology Council. This working group, representing almost 20 agencies, reviewed the global threat of infectious diseases. The report of the CISET working group cites CDC's role as the lead U.S. agency in domestic disease surveillance, prevention and control, and emphasizes that surveillance and response capacity must be enhanced. It also emphasizes that we need the capacity to assist other countries and the World Health Organization in investigation and control of outbreaks that may affect the health of our Nation.

I have provided copies of CDC's plan and the CISET working group report to members of the committee.

To monitor, prevent, and control foodborne diseases, CDC has developed and used a number of strategies. Today, I will review several of these strategies. In my testimony I will provide: (1) an overview of CDC's foodborne disease surveillance systems, and (2) an overview of the public health impact of antimicrobial resistance in the pathogens that cause foodborne disease and CDC's monitoring system for this problem. Additionally, I will give an example of CDC's approaches to an emerging foodborne pathogen, *E. coli* O157:H7, and to a reemerging foodborne pathogen, *Salmonella* serotype Enteritidis.

FOODBORNE DISEASE SURVEILLANCE SYSTEMS

When a person becomes ill with a foodborne disease, he or she may be part of an outbreak -- a cluster of patients who all have the same illness after consuming the same food -- or may have a sporadic illness -- an illness that is not part of a recognized outbreak. Investigations of outbreaks can rapidly determine the source and nature of the illness and identify the control measures needed. However, most persons have sporadic illnesses and these sporadic illnesses often are not diagnosed or identified as being caused by food. Even if they are recognized as being foodborne, it is usually not possible, for single cases, to determine which food is the source of the infection. Since sporadic cases are far more common than outbreaks, they are a prime target for prevention efforts.

Effective public health surveillance is key to identifying and monitoring the prevalence of foodborne disease. CDC, in collaboration with State and local health departments, conducts surveillance for foodborne diseases in several different ways. The goals of surveillance are to estimate the magnitude of the problems posed by specific foodborne pathogens, to monitor changes over time in order to guide prevention efforts, and to detect outbreaks so that emergency actions can be taken,. CDC uses four principal surveillance systems to obtain information on diseases caused by foodborne pathogens.

Physician-based Surveillance

One system we use to obtain information is physician-based surveillance. In this system, physicians report specific disease entities case-by-case to local health departments. Physician-based surveillance is relatively fast but, because it depends on clinical assessments, it may not always be completely accurate. It is also relatively incomplete, since it requires that patients seek medical care, and that physicians recognize the foodborne nature of the illness, request the appropriate tests, and notify local health authorities. Despite these limitations, it is a good system for public health emergencies requiring rapid response. For example, CDC maintains physician-based surveillance for botulism. The occurrence of this disease is a public health emergency because of the severity of the illness and the likelihood that one case may herald an outbreak. CDC encourages physicians who suspect they may have a patient with botulism to report it to the state health department authorities immediately. CDC maintains a 24-hour emergency consultation service to discuss suspect cases of botulism and to provide emergency diagnosis and treatment, including emergency provision of a limited supply of botulism antitoxin.

Clinical Laboratory-based Surveillance

A second way CDC obtains information is from clinical laboratories. This method depends on a laboratory diagnosis of a specific infection and notification of public health authorities. For some infections, the pathogen will then be referred to the state public health laboratory for more detailed identification. Laboratory-based surveillance information is more accurate than physician-

based surveillance because the infection is definitively diagnosed; however, this system is somewhat slower than physician-based surveillance. Neither physician-based nor laboratory-based surveillance detects illness in persons who do not seek medical care. Laboratory-based surveillance also will not detect illness in those patients for whom the pathogen that caused the illness is not determined. As an example of laboratory-based surveillance, CDC tracks *Salmonella* infection in the United States. Each year about 40,000 culture-confirmed cases of human infection are reported. Public health laboratories in each state further characterize these *Salmonella* isolates by dividing them into different subtypes. Information from the laboratories is transmitted electronically to CDC by the Public Health Laboratory Information System (PHLIS) which is a PC-based software application developed by CDC in cooperation with the Association of State and Territorial Public Health Laboratory Directors. This surveillance system can detect outbreaks of a particular type of *Salmonella* even if it occurs in a number of states. Some isolates are submitted to CDC's reference diagnostic laboratories for further characterization.

Outbreak Investigations

A third source of surveillance data we use to track foodborne diseases is information gathered during outbreak investigations conducted by local and State health departments and, when requested, by providing CDC assistance to these health departments. Due to limited resources at the State and local levels, only a small fraction of outbreaks are actually recognized, investigated, and have the results reported . Approximately 400-500 outbreaks are reported to CDC each year, accounting for 10,000 to 12,000 persons with foodborne illness. The outbreaks

that are investigated tend to be the most dramatic. The outbreak investigation surveillance system is useful for providing detailed information on particular diseases and on the type and severity of outbreaks that occur in various locations, for example, in nursing homes. Outbreak investigations are often critical in identifying contaminated foods that can then be removed from the marketplace, and in elucidating the problems in food production that lead to foods being contaminated with disease-causing organisms.

Active Foodborne Disease Surveillance

A fourth source of data is CDC's recently developed active foodborne disease surveillance system. With funding provided by Congress in FY 1995 and 1996 to begin implementation of CDC's plan for emerging infectious diseases, including foodborne diseases, we have begun to address the highest priorities of the plan. Included in these priorities are cooperative agreement funding to 15 state and local health agencies to strengthen surveillance and response capacity for infectious diseases, such as infections caused by *E. coli* O157:H7. Emerging Infections Programs (EIP) have also been established in four health departments (California, Connecticut, Minnesota, and Oregon), in partnership with universities and other organizations and agencies, to address key questions regarding foodborne and other illnesses nationally, as well as issues related to infectious diseases of special concern to their own state.

CDC's active foodborne disease surveillance system is conducted in CDC's four Emerging Infections Program sites and in metropolitan Atlanta. The FDA and USDA's Food Safety and

Inspection Service (FSIS) are providing financial assistance and are collaborating with CDC in this system. These five sites represent about 5% of the U.S. population. At these sites, we actively seek out information on foodborne illnesses identified by clinical laboratories and collect information from patients about their illnesses. We then conduct investigations to determine the foods linked to specific pathogens. As data are collected, this surveillance system will provide important information about changes over time in the burden of foodborne diseases and will help the agencies evaluate current food safety initiatives and develop future food safety activities.

Initial data from this surveillance system have already identified an outbreak of *Yersinia enterocolitica* infections among infants in Atlanta and an outbreak of *Salmonella* infections in Oregon traced to alfalfa sprouts. This surveillance system has also confirmed that *Campylobacter* is the most frequently isolated foodborne bacterium from persons with diarrhea. Recognizing the high incidence of *Campylobacter* infections, with the potential for complications such as Guillain-Barre syndrome, CDC investigators anticipate conducting a case-control study in 1997 to pinpoint the major foods and other risk factors responsible for *Campylobacter* infections. This information will be important in designing and implementing prevention strategies.

The EIP sites can provide a framework for conducting surveillance for many other infectious diseases as well as physician-diagnosed syndromes such as hemolytic uremic syndrome (HUS). The President has requested an additional $26 million for FY 1997 for further implementation of the CDC plan. Included in our plans with additional funding, is the establishment of three

additional Emerging Infections Programs and support to 10-15 additional State and local health departments to strengthen their surveillance and response capacity.

ANTIMICROBIAL RESISTANCE AND FOODBORNE PATHOGENS

We are also using the Emerging Infections Program sites to actively monitor for the increasing problem of antibiotic-resistant foodborne pathogens. Bacteria become resistant to antibiotics as a consequence of antibiotic use in humans and animals. Antibiotics used in humans can lead to resistant bacteria that can be spread in communities. For example, we are seeing significant increases in resistant pneumococcus (a cause of pneumonia), gonococcus (the cause of gonorrhea), and *Mycobacterium tuberculosis* (the cause of tuberculosis). In addition, many pathogens that are spread among patients in hospitals are highly resistant, and these antibiotic-resistant infections can be life-threatening and untreatable with currently available antibiotics.

The use of antibiotics in animals similarly leads to resistant bacteria in animals. Bacteria from healthy animals can contaminate food and cause human illness. When the bacteria from animals are resistant to antibiotics, the resulting human infection may be more difficult to treat. There is a clear relationship between the use of antibiotics in animals and the appearance of resistant human infections. For example, most human *Salmonella* infections can be traced to foods of animal origin, and CDC's periodic surveys have documented an increase in antibiotic resistance of *Salmonella* strains isolated from humans from 16% of strains in 1979 to 31% in 1990. Although

most persons with *Salmonella* infection recover without antibiotic treatment, antibiotics can be life-saving in severe infections which spread to the bloodstream.

One particular class of antibiotics, fluoroquinolones, has been particularly important in the treatment of severe infections of humans. Resistance to fluoroquinolones has emerged in some human pathogens. One fluoroquinolone was recently approved by FDA for use in food animals. Slowing the emergence of resistance depends on prudent use of antibiotics in both humans and animals. Approval of this fluoroquinolone was restricted to specific uses as a prescription product in one species, and use for other purposes and in other animals is discouraged by FDA.

In early 1996, because of concern about the possibility of emergence of resistance, CDC began collaborating with FDA on a surveillance system for antibiotic resistance in *Salmonella* strains isolated from humans. In parallel with this surveillance of human strains, USDA, also in collaboration with FDA, is monitoring for occurrence of resistant *Salmonella* strains isolated from animals, meat, poultry, and eggs. This collaborative effort, designed specifically to detect the emergence of antibiotic resistance in foodborne pathogens, is an important component of our efforts to improve surveillance for new and emerging pathogens.

EMERGING FOODBORNE PATHOGEN - E. COLI O157:H7

In the last 15 years, several bacteria not previously recognized as foodborne pathogens have become important public health concerns. These include *E. coli* O157:H7, *Campylobacter jejuni*,

and *Listeria monocytogenes*. The example of *E. coli* O157:H7 can be used to illustrate how CDC and the public health community monitor, detect and control emerging foodborne pathogens.

E. coli O157:H7 was first recognized as a cause of human illness in 1982 during an investigation by state health departments and CDC of outbreaks in two states of bloody diarrhea associated with eating hamburgers from fast-food restaurants. We now know that about 5% of *E. coli* O157:H7 infections are complicated by renal failure, hemolytic uremic syndrome (HUS). HUS can lead to stroke and death and is the most common cause of acute kidney failure in children in the United States. These first outbreaks of *E.coli* O157:H7 represented our initial recognition of an emerging foodborne pathogen -- that is, describing the disease and developing public health strategies for the prevention and control of the new microbial pathogen. CDC laboratories developed easy methods for identifying *E. coli* O157:H7 that could be used by clinical laboratories. Over the next 10 years, CDC's investigations of outbreaks answered a number of additional questions. We defined the foods that typically cause the outbreaks, identified cattle as the usual reservoir of illness, and demonstrated that either beef or raw milk produced from healthy cattle could be contaminated by this serious pathogen. The emergence of *E. coli* O157:H7 is associated with severe disease and the organism is present in healthy cattle herds.

In 1993, the largest outbreak of *E. coli* O157:H7 infections in the United States occurred in California, Idaho, Nevada, and Washington. This outbreak was caused by hamburgers served at many restaurants of one fast-food chain. Over 700 persons became ill, 195 were hospitalized, 55

developed hemolytic uremic syndrome (HUS), and 4 children died. Rapid action by CDC, USDA, and State health departments resulted in recall of the contaminated hamburgers, and an estimated 800 more cases were prevented. Following this outbreak, CDC intensified efforts to improve recognition of *E. coli* O157:H7 infections. We produced a videotape on the laboratory diagnosis of *E. coli* O157:H7 infections to encourage clinical laboratories to begin screening for this bacteria in stool specimens. CDC also worked with the Council of State and Territorial Epidemiologists to encourage states to make this infection reportable. As a result of these enhanced surveillance efforts, the number of illnesses and outbreaks recognized as due to *E. coli* O157:H7 each year since have markedly increased. Earlier this year, CDC worked with the Association of State and Territorial Public Health Laboratory Directors to train personnel from 14 state health departments in DNA fingerprinting of this organism. DNA fingerprinting has been a valuable tool in investigating foodborne outbreaks and determining the source of foodborne bacterial contamination.

E. coli O157:H7 is the most frequently recognized member of a family of *E. coli* bacteria. Organisms in this family cause similar diseases around the world. These other *E. coli* varieties are more difficult to detect and may be an important cause of HUS in the United States. In fact, cases of HUS can be a marker for the presence of these bacteria in the community, and surveillance for HUS can be an important way of tracking the presence of these *E. coli* in the food we eat. CDC is planning to begin national surveillance for HUS this year in collaboration with the newly established Emerging Infections Programs and other participants. This surveillance will provide

early warning of other *E. coli* bacteria which may be as important as *E. coli* O157:H7 in the future.

REEMERGING FOODBORNE PATHOGEN - *SALMONELLA*

Foodborne *Salmonella* infections emerged as a public health problem in this country in the 1940s and since then have been routinely reported by physicians to health departments in many states. Of the more than 2000 different serotypes of *Salmonella,* one particular type, *Salmonella* serotype Enteritidis (SE), is now a rapidly increasing cause of infection in the United States and other countries. Examination of the recent SE problem associated with shell eggs offers insight into the public health consequences of reemerging foodborne diseases. In the 1970s, SE represented just 5% of all *Salmonella* in the U.S. This proportion had increased to 26% by 1994, which probably represented between 200,000 and 1,000,000 actual infections. The number of infections began to increase in the northeastern United States as early as 1979, in the mid-Atlantic states around 1984, and in the Pacific region just within the past year.

CDC determined that there was a link between the increase in human SE infection and contamination of shell eggs. In 1986, CDC, several State health departments, and the FDA investigated a large outbreak of SE infections associated with a commercial stuffed pasta product. Cases were identified in at least 7 states and 3300 people were infected. The pasta was made with a stuffing that included raw eggs. The eggs used in the stuffing mix were traced to several farms in the Northeast and SE was isolated on those farms. Since then, over 500 outbreaks of SE

infections have been reported to CDC. A specific food vehicle was identified in half of these investigations, and grade A shell eggs accounted for 80% of those outbreaks for which a vehicle was determined. The unusual feature of this problem is that Grade A inspected shell eggs are the source. CDC proposed that the eggs were contaminated internally in the hen before the shell was formed, and this hypothesis has since been amply confirmed by experimental investigations in hens and has led to a collaboration among CDC, State health departments, FDA, USDA, and industry to limit the spread of infections among chickens and to protect consumers who are at high risk.

Eggs can be pasteurized, and the use of pasteurized eggs, particularly in high-risk settings, such as nursing homes and hospitals, has been an important public health prevention recommendation since 1987. CDC worked with FDA to produce a training video for food service workers in high risk settings addressing these problems. Investigations by USDA to determine how chickens become infected have demonstrated that mice are an important reservoir of SE. The mice on farms transfer SE from one flock of chickens to another. In Pennsylvania, an aggressive program of *Salmonella* control in egg flocks included rodent control, verification that hens were not infected, and pasteurizing eggs if infection were detected. A general decrease in SE infection in the Northeast has been noted. The spread of SE out of the Northeast, and the recent appearance of SE further west confirms that larger scale nationwide prevention measures are needed.

CONCLUSIONS

New foodborne pathogens like *E. coli* will continue to be identified; and other known but rare foodborne pathogens like SE may reemerge as important public health problems. Infections may arise from changes in the microbes, changes in the industrial technology that underlies food production and processing, changes in our choices concerning the foods that we eat, how they are prepared, and where we eat them, and changes in the demographics of the U.S. population. The increasing number of elderly and chronically ill are at particular risk for severe illness caused by foodborne pathogens.

While research will continue to identify new causes of foodborne infections that are currently unrecognized, improved surveillance can measure the impact of these infections and help to define better means of preventing them. Prevention of foodborne disease will continue to bridge many disciplines and agencies, because there are many points of control between the farm and the consumer. At CDC, the response to the continuing challenge of foodborne disease includes enhancing scientific outbreak investigations by applying sophisticated epidemiologic and microbiologic techniques to field investigations and using these techniques to trace the source of contaminating microorganisms. We are improving surveillance efforts by continuing to improve CDC's electronic transmission system, the Public Health Laboratory Information System in State health departments, as well as by adding automated reporting and outbreak detection analysis. Collaborative active surveillance systems for foodborne disease will help determine the magnitude of these diseases and address questions that cannot be answered by routine surveillance.

Collaborative efforts to educate food preparers and inform consumers of choices will be key to our prevention strategy.

History tells us that infectious diseases will remain important evolving, complex public health problems. To meet these challenges, we must strengthen our capacity to address the threat of emerging infectious diseases. Investments in surveillance and response, laboratory research and training, and epidemiologic investigations will ensure that we are better prepared to respond and lessen the impact of infectious disease threats.

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 subcommittee may have.

Mr. SHAYS. We will now go with Dr. Fred Shank, the Director of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration.

STATEMENT OF FRED SHANK, PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

Mr. SHANK. Good morning. I am Fred Shank, Director of the Center for Food Safety and Applied Nutrition. Thank you for your invitation to participate in this hearing to continue our discussion on our testimony for the hearing on May 10. With your permission, I will take only a few minutes to summarize some of the key points on today's topics of monitoring and prevention of food-borne pathogens.

In the United States, the protection of the public from unsafe microorganisms and foods rests largely with the industry. Oversight of industry efforts is a shared responsibility between the Food and Drug Administration, CDC, and the U.S. Department of Agriculture at the Federal level, and State and local government agencies at their respective levels. The coordination and cooperation between the food protection agencies that I have just mentioned is excellent. We have been working together for decades, and every year we seek improvements and adapt to changing circumstances as necessary to protect the public health. We would be pleased to hear your suggestions for improving these coordinating efforts.

While FDA has traditionally collaborated with USDA and CDC, the intensity of our cooperation has increased in the last several years.

If I can have that first chart, Mike.

While he gets the chart, let me go ahead and point to the fact that in 1985, there were several foodborne outbreaks that prompted FDA and CDC to look at a more active foodborne disease surveillance effort. Active surveillance of disease had not been a widely utilized tool in the area of food safety prior to that time. Beginning in 1988, FDA provided funds to CDC to be used for surveillance of listeriosis illnesses with trace-backs to foods. The right-hand side of this chart lists the funds that were provided to CDC for these initiatives.

Beginning in 1989, FDA provided funds for CDC's epidemiologic and laboratory characterization of sporadic *Campylobacter* infections. FDA also placed a staff fellow or a researcher at CDC. By 1995, FDA and USDA had placed full-time liaisons at CDC to ensure that all foodborne illness activities are fully coordinated between these three agencies.

CDC, USDA, and FDA also initiated a disease reporting system that has just previously been described to us to analyze the illness data in more depth from those five sentinel sites.

The Federal agencies have also increased collaboration and cooperation with State and local agencies that have primary responsibility for regulating the retail segment of the food industry. We work closely with State health departments in following up on reported illnesses and taking quick and appropriate action from product recall to shutting down the source of the contamination. We also have increased collaboration with trade associations and nu-

merous other agencies in the private and public sectors as described in our testimony.

But coordination and communication alone are not enough. As you know, there are several reasons why we must update our system of ensuring the safety in the food supply. Using periodic visual inspections supplemented with end-product testing that FDA has utilized in the past has been criticized as being ineffective and relying on detecting and correcting problems after they occur, rather than preventing them in the first place.

Hazard Analysis and Critical Control Point [HACCP] systems place emphasis on the prevention of problems and provide a comprehensive food safety system, rather than being dependent on testing after the food is produced. It is a system that stresses cooperation and recognition of the mutual food safety interests shared by the food processors and the Government. FDA is in the process of implementing this HACCP program for all seafood products, and this program will be mandatory for all firms in December 1997.

Mr. Chairman, you expressed interest in how we are addressing the emerging pathogens such as *Campylobacter* and *E. coli* O157:H7. *Salmonella, Campylobacter, E. coli* O157:H7, and *Listeria monocytogenes* are the four most important foodborne pathogens in the United States, based on the number of reported cases of illnesses that occur and their severity. Reducing illnesses caused by these four pathogens is a cornerstone to Healthy People 2000, a national strategy developed by Federal agencies and other interested parties in the 1980's for improving the health of the Nation through the 1990's.

Briefly, in addition to our inspections, we use multiple mechanisms to assist in detection and prevention of illnesses from emerging foodborne pathogens. FDA conducts research, we develop analytical methods, we conduct consumer education, especially for high-risk populations, and we give guidance to our State and local counterparts for their role in providing for food safety at the retail level.

These methods of detection and prevention combined with our surveillance and inspection efforts are the cornerstones in protecting the public from emerging pathogens.

That concludes my remarks, and I would be pleased to respond to questions at the appropriate time.

[The prepared statement of Dr. Friedman follows:]

Mr. Chairman,

Thank you for the opportunity to participate in today's hearing on "Protecting the U.S. Consumer from Food Borne Illnesses." My name is Dr. Michael Friedman. I am the Deputy Commissioner for Operations at the Food and Drug Administration (FDA). With me today are Dr. Stephen Sundlof, Director, Center for Veterinary Medicine and Dr. Fred Shank, Director, Center for Food Safety and Applied Nutrition.

As you are aware, the United States food supply is one of the safest, most abundant, and most affordable in the world. This has been accomplished through a program that relies on science, cooperative efforts with government agencies at all levels, increased cooperation with our international counterparts, as well as interaction with academia, industry, and consumers. FDA is committed to ensuring safety, and working to protect the American consumer from unsafe, adulterated, or misbranded food. The agency strives to improve its existing monitoring programs, research, product approval processes, and enforcement efforts. To these ends, we welcome your ongoing interest in this subject.

My discussion of food safety will center on foodborne pathogens in food derived from animals, which you have indicated is the focus of this hearing. I plan to describe what FDA is doing to protect the food supply from these pathogens; the roles of FDA's Center for Veterinary Medicine (CVM) and Center for Food Safety and Applied Nutrition (CFSAN) in developing policies to control foodborne pathogens; and how we work collaboratively with our federal and state counterparts to protect the public health by safeguarding the food supply.

FOOD SAFETY

Virtually all food available to the U.S. public is wholesome and unlikely to cause illness to the consumer. However, as with most things, health risks do exist. Foodborne illness originates from a variety of sources. Pathogenic organisms, such as viruses, bacteria, and parasites, represent the most widely recognized causative agents and are the focus of my remarks as you have requested in your letter of invitation. Other foodborne risks such as naturally occurring toxicants, animal drug residues, pesticides, and environmental contaminants also have the potential, individually or in combination, to be the cause of

illness. Moreover, food production practices, processing, storage, distribution, handling and home preparation techniques either individually or in combination have the potential to increase the risk of microbiological or chemical caused illness. However, risks caused by chemical contaminants and food production practices are not the focus of my remarks for today's hearing.

Foodborne illness is not a new form of disease, nor is it one-dimensional. Foodborne illnesses have been with us as long as man has walked the earth. In the United States, foodborne microbial illness is a major cause of personal distress, preventable death, and avoidable financial loss. Several studies conducted over the past 10 years have indicated that an estimated 6.5 million to 81 million people become ill from pathogens in food every year, resulting in an estimated 9,000 deaths.

It is worth noting that the majority of the illnesses that occur are mild and of short duration and frequently are not even diagnosed. However, a small fraction can produce immediate, acute effects, sometimes involving many people in a single episode, with reactions ranging from gastrointestinal upset to

death. There is also the potential for chronic, or long term risks, but these are not as clearly quantifiable.

Examples of some foodborne pathogens originating in animals include *Salmonella spp.*, i.e., *Salmonella enteritidis*, *Campylobacter jejuni*, and *Escherichia coli* O157:H7.

Salmonella spp. are bacteria that cause gastrointestinal disease (nausea, vomiting, abdominal pain, diarrhea, fever, and headache), that is sometimes fatal. The illness has been associated with consumption of many different foods, including raw meats, poultry, eggs, milk and dairy products, fish, shrimp, frog legs, yeast, coconut, sauces and salad dressings, cake mixes, cream-filled desserts and topping, dried gelatin, peanut butter, cocoa, chocolate, and melons. The infectious dose may be very small. Infections with *Salmonella* may be followed by chronic arthritis symptoms three to four weeks after onset of acute symptoms. *Salmonella enteritidis* bacteria cause gastrointestinal disease (abdominal pain, nausea, diarrhea, vomiting, and fever) which has often been associated with consumption of undercooked or raw eggs. As with other *Salmonella spp.*, the infectious dose may be very small, and infection may be

followed by enteric fever, septicemia, or chronic arthritis symptoms.

Campylobacter jejuni bacteria cause campylobacteriosis, a gastroenteritis (watery diarrhea, malaise, fever, abdominal pain) associated with consumption of foods of animal origin, especially poultry and raw milk. A chronic symptom which may follow infection includes Guillain-Barré syndrome.

Escherichia coli O157:H7 is a verotoxin-forming bacterium that causes hemorrhagic colitis and may, in the very young and the elderly, cause the sometimes fatal hemolytic uremic syndrome. Hemolytic uremic syndrome is characterized by renal failure. The infectious dose may be very low. Undercooked or raw ground beef, salami, mayonnaise-based salad dressings, raw milk, yogurt, and apple cider have been implicated in outbreaks and sporadic cases.

As you can see from the list above, the most likely animal-derived foods which present risks of food-borne disease are meat, poultry, milk, seafood and eggs. Food derived from animals can

be exposed to these pathogens on the farm, at slaughter, or through mishandling anywhere from the farm to the table.

REGULATING FOOD SAFETY

FDA is responsible for regulating the safety of a great many foods, including eggs, seafood, and dairy products. The U.S. Department of Agriculture (USDA) has the primary authority for regulating meat and poultry. FDA also is responsible for the safety of animal feeds. A significant part of FDA's responsibility is to keep both human foods and animal feeds free of microorganisms such as fungi or bacteria, and their toxins (mycotoxins and bacterial toxins), illegal residues of drugs, pesticides, and environmental contaminants that are harmful to public health. Our agency carries out these responsibilities in cooperation or partnership with other federal or state organizations by: working with the animal health industry to ensure that safe and effective drugs are available to treat animal diseases, particularly those that may impact human health; conducting and facilitating research in the area of food safety; inspecting firms; sampling and analyzing products to determine if the producers of these goods have complied with the provisions of

the FDC Act; taking appropriate enforcement actions when the agency finds that firms are not complying with the law; and providing guidance, training, and technical assistance. But, the law places the burden of ensuring that animal drugs are used safely and appropriately and that contaminants are controlled as much as possible in the production of food through observance of good manufacturing practice (GMP), on food manufacturers, producers, and distributors.

FDA's food safety programs have evolved over many years to become both broad reaching and highly specialized. This evolution occurred due to a number of factors that, together, make the regulation of food an unusually complex undertaking.

Our program has three fundamental safety objectives: (1) targeting our efforts toward controlling known "acute" type pathogens (e.g., salmonella), through the use of safe and effective animal drugs and feed additives to treat infected animals, and other prevention programs; (2) monitoring the food supply in coordination with other agencies in order to prevent the consumption of unsafe food and to gather information on the known or emerging pathogens (i.e. transmissible spongiform

encephalopathies); and (3) learning more about potential long term problems and taking steps to lower long term risk.

I would now like to describe some things that we are doing to meet these objectives with regard to foodborne pathogens.

CENTER FOR VETERINARY MEDICINE (CVM)

Prevention of human illness from foodborne pathogens may begin with control of the pathogen in its animal host. CVM is responsible for evaluating and approving drugs to prevent, control, and treat diseases in animals. This includes food-producing animals, as well as companion pets and exotic animals. FDA requires drug sponsors to show that each new animal drug, including those intended for use in animal feeds, is safe and effective for its intended use before it can be approved for marketing. When a drug is used in food producing animals, CVM's charge is to assure that any food derived from the animals (meat, eggs, seafood, or dairy products) is free from potentially harmful drug residues. Evidence substantiating safety and effectiveness in the target animals, and safety of any food

derived from treated animals must be submitted by the drug sponsor to CVM for evaluation by its scientific review experts.

Once a drug is approved, CVM monitors the drug's continued safety and effectiveness through post-marketing surveillance programs. An estimated 80 percent of U.S. livestock and poultry are treated with an animal drug during their lifetime. The availability of safe and effective drugs for use in food-producing animals has benefited the consuming public by increasing production at reduced cost, and improving the quality of these food items, while ensuring the safety of these foods.

The challenges faced by CVM in the area of food safety have become more complex over the last several years as the technology of food production has advanced. Animals are now grown in high density production facilities which have increased the efficiency of food production, but which also have put additional stress on the animals and made the control of diseases critical. Furthermore, recent changes in drug manufacturing production technology have created new and more sophisticated types of animal drugs for CVM to evaluate. Each of these advances presents a unique situation that must be evaluated before the

drug can be approved. And, because of the newness of the technology associated with some of these drugs, the CVM has also had to respond to concerns about the public's perceived threat from the use of these new technologies. Such was the case in recombinant Bovine Somatotropin.

Aside from new safety issues in food production, technological advancements in recent years have also had a significant effect on the number of requests by drug sponsors to CVM for review. During the last six fiscal years, CVM has experienced a 29% increase in the number of submissions for review (from 5880 in 1990 to over 7595 in 1995). At the same time, the CVM's resources have decreased in terms of budget and manpower. In the face of increasing workloads and decreasing resources we have searched for innovative ways to lessen the impact of these trends.

Reinventing the New Animal Drug Approval Process

Recently, CVM has undertaken a major initiative to reengineer the review and approval process for new animal drug applications (NADAs). This initiative has already proven to be a more speedy and effective process, which will serve to make more animal drugs available to treat animal disease.

The traditional animal drug approval process was very segmented. The drug sponsor decided what information would prove that a drug was safe and effective, and then the information was collected, compiled and submitted to the CVM for review. The CVM evaluated all the data and informed the sponsor of its assessment. If there were any deficiencies, the firm would collect more data, compile and submit it, and wait for CVM's decision. This process resulted in numerous iterations before the drug was finally approved. It was also very resource and time intensive.

Our new approach focuses on encouraging sponsors to involve CVM in their drug development process as early as possible, and encourages an interactive approach throughout the planning, research, and review of the drug. In this way, CVM and the drug

sponsor can agree on requirements for the approval of a drug used for the specific indication, and identify any data needed. This approach helps the sponsor reach an understanding with CVM before development is started so that any project undertaken has an increased probability of resulting in the approval of the product. It also allows for modifications to the drug development plan to address any unexpected results as information becomes available.

The response from the participating sponsors has been very positive. They believe this new approach has proven itself to be beneficial in increasing the efficiency of the drug approval process. It also benefits them by assisting in management and coordination of their limited resources during drug development.

Some specific initiatives that are part of this reengineered drug approval process are:

Pre-Submission Conferences - CVM is encouraging sponsors of new animal drugs to participate in pre-submission conferences where the sponsor's objectives and CVM's requirements are discussed in detail. The result of these conferences is agreement on the

information necessary to support approval for the desired use of the drug. These conferences help the sponsors to focus their efforts toward conducting studies which are pivotal in determining whether the drug is safe and effective, and help to decrease complaints about unexpected new requirements.

Review of Study Protocols - Although not required by regulation or statute, CVM is strongly encouraging sponsors to submit protocols for any pivotal studies for CVM's input and concurrence. Using this procedure to assure that the design of a study will result in adequate information to evaluate the drug, any subsequent shift in review personnel is seamless to the process. Although resource intensive to FDA, CVM believes this initiative will ultimately save time and make the drug approval process much more efficient, and has committed itself to a 50 day review time for protocols. The review of protocols enable reviewers to evaluate studies in a more timely manner, and the sponsors to embark on a development plan with more comfortable understanding and agreement with FDA on the requirements.

Phased Review of Data Submissions - Instead of waiting until all the supporting information is collected and compiled, the

sponsors are now encouraged to submit critical studies during their drug development in the form of an Investigational New Animal Drug Application (INADA). CVM will then review the results of these studies so that any new concerns can be addressed prior to submitting a full NADA. It is advantageous to both the drug sponsor and CVM in identifying unexpected problems in the research, and facilitating any necessary modifications to the drug development. For example, early review of a dose determination study will ensure that clinical trials for efficacy and target animal safety are conducted with the effective formulation and dose of the drug.

Direct Review of Submissions - Another innovation to increase the efficiency of the review process is the distribution of administrative processing responsibilities to those areas responsible for the scientific evaluation of the data submitted for review. Previously, CVM endorsed the concept of a project manager for each drug product. This added a point of quality control with one CVM employee responsible for the drug product and its current status, but it was extremely resource intensive. This direct review process, linked with the phased review policy, has encouraged a more interactive and efficient review process.

This distribution is only possible because the Center has a tracking system that can be used as a "Virtual Project Manager" that monitors the current status of the drug development. Although the tracking system and this policy is relatively new, both the sponsors and the scientific review staff believe this level of interaction has benefited the drug approval process tremendously.

Sponsor-Monitored Methods Trials - We have shifted the primary responsibility for validation of regulatory methods to the sponsor. Instead of relying on government laboratories (with other competing priorities) to schedule and complete a method trial, the sponsor may now contract with non-government laboratories to conduct method trials. This ensures prompt conduct of the necessary trials, and although both USDA and FDA laboratories may still participate in the method trial, this change assures that there is an adequate number of laboratories available for timely completion of this phase of drug approval.

CVM has implemented several other initiatives to improve drug availability, reduce regulations, increase food safety, and

support the reengineered drug approval process. These initiatives include:

Expedited Review Status for New Animal Drugs - New and innovative products, such as a new chemical entity not yet approved for use in animals, or a drug targeted for a disease condition that has no approved therapy are important advances that may significantly impact on food safety. If a drug qualifies for CVM's expedited review program, target times for review of data are reduced from the statutory 180 days to 90 days. Since 1982, the center has granted expedited review status to 32 documents (3 NADAs, 1 Public Master File, and 28 INADAs for expedited data review).

Updated Guidance Documents - CVM has also focused on updating several guidance documents. These serve as aids to industry for various portions of drug development. Over the last several years, documents have been finalized to provide guidance for development of study protocols, clarification of responsibilities of clinical investigators, evaluation of food additives for fish, and submission of manufacturing chemistry master files. Several other documents are in various stages of preparation or revision,

including efficacy and/or animal safety requirements for carcass quality, anticoccidial, anthelmentic and mastitis drugs.

Data Integrity - Improvements in the regulated industry's data collection and quality assurance is increasing the efficiency of the data review process within the CVM. This has been accomplished through use of guidance documents, workshops, and other educational initiatives. With the drug sponsors assuming more responsibility for the type and quality of data submitted for review, we can focus our resources on the evaluation of the studies with regard to the effect of the drug.

Treatment INADs for Minor Species - Approval of drugs for minor animal species (i.e., many pets, aquaculture species, exotic animals) provide limited incentive for traditional pharmaceutical sponsor drug development, and these voids in availability of therapy can impact on food safety. CVM has developed a system of "treatment INAD's" and "public master files" that allow clinical data to be gathered by those that need the drugs. The collected data are placed in public master files for future reference by pharmaceutical sponsors in support of NADAs. Public funds from USDA's National Research Supported Project No. 7 (NRSP-7) are

also directed to this effort. NRSP-7 is a federally funded program established to assist animal producers and veterinarians obtain FDA approval of drugs for minor uses.

Environmental Requirement Changes - Based upon ten years of reviewing environmental assessments for animal drugs, CVM has found that many of the applications and requests that currently require assessments have no significant impact on the environment. Therefore, the agency is proposing to exclude these uses from preparing an environmental assessment. In most cases, elimination of these environmental assessments will result in no additional risk to the environment and will provide a substantial savings to the regulated industry and CVM. However, we will be coordinating this policy with EPA in case there are situations that do not have the potential for environmental impact. This focuses the agency's environmental review resources on those areas that have potential for significant environmental impacts.

STARS - CVM implemented a new Submission Tracking and Reporting System (STARS) in November 1992. This database plays a critical function in monitoring the status of CVM's pending applications and files. It assists in coordinating scientific reviews and

CVM's responses to the industry's requests. With this new system, prioritized time frames are assigned to submissions based on the type of request and the amount and complexity of the data the firm submits. STARS has helped CVM focus to assure a complete and coordinated response to sponsors' applications. This database has also enabled the implementation of phased review and direct review of drugs, by providing a tool to help manage the complex process associated with drug approval.

CVM's Food Safety Programs

CVM has initiated several programs and research projects that are designed to help prevent harmful pathogens from being transmitted to humans through the food supply and/or the environment. These include CVM's:

Bacterial Susceptibility Monitoring Program - CVM has initiated a collaborative bacterial susceptibility monitoring program with other FDA Centers, USDA, and the Center for Disease Control and Prevention (CDC), in response to the recommendations of an FDA Advisory Committee on fluoroquinolone antibiotics and a 1995 American Society of Microbiology Task Force on Antibiotic

Resistance. This program grew out of concerns by FDA and other scientific experts about how to best maintain antibiotic effectiveness, ensure safety, and increase the availability of new products to veterinary practitioners and the food animal industry. Because the development of bacterial resistance to existing drugs or to future approved products would negatively impact both efficacy and safety, FDA has made the susceptibility monitoring a priority program.

The national surveillance program will monitor changes in bacterial susceptibilities of zoonotic pathogens from human and animal clinical specimens, from healthy farm animals, and from carcasses of food-producing animals at slaughter plants. Prior to this program, there was no comprehensive national or global surveillance system for monitoring antimicrobial resistance of enteric pathogens in humans or animals and none at all which combined the two populations.

Through this new program, baseline susceptibility patterns of *Salmonella* isolates from animals and *Salmonella* and *E. coli O157:H7* isolates from humans already have been determined. The susceptibility profiles of these isolates form a baseline to

which future changes in susceptibility and emergence of new resistance can be compared. On-going monitoring is underway at USDA's Agricultural Research Service's National Animal Disease Center in Ames, Iowa and at CDC's Foodborne Disease Laboratory in Atlanta.

The problem of antimicrobial resistance is complex and requires collaborative efforts by several agencies; the establishment of FDA's monitoring program is a significant milestone to its solution.

Salmonella Control Program in Feed and Feed Ingredients - In September 1990, CVM announced a program for attaining *Salmonella* negative feed ingredients and finished feeds. Since then, CVM has held numerous meetings with representatives of industry, academia, and other Federal and State agencies to coordinate the work of achieving *Salmonella* negative feed.

CVM initiated the formation of a Federal-State Steering Committee in July 1991. The Committee requested that the United States Animal Health Association (USAHA) serve as a scientific forum for debate on the means to best eliminate harmful microbial

contamination from feed. In October 1991, USAHA established the Feed Safety Committee to serve as a venue for the forum. The work of this committee was divided among four subcommittees. The subcommittees are live production (poultry, beef, pork, dairy, and aquaculture); microbiology (sampling and techniques); feed manufacturing (to include ingredients, equipment, and additives); and feed transportation. The membership of the Feed Safety Committee and the Subcommittees consists of members of government industry and academia.

We believe that the best way to reduce Salmonella contamination in feed is through a quality assurance program and to achieve this we are focusing on the Hazard Analysis Critical Control Points (HACCP) approach. The *Salmonella* contamination which occurs during the production, and during storage and transportation, is largely preventable. Major segments of the feed industry have developed HACCP plans. To further reduce *Salmonella* contamination of feed requires that each manufacturer tailor a HACCP plan to each feed manufacturing facility. Currently, several firms in the feed and feed ingredients industries are working on developing generic HACCP plans. CVM encourages the feed industry to actively seek industry wide

acceptance of HACCP-based plans. CVM is prepared to offer comments on specific plans if requested.

CVM also has reveiwed five Food Additive Petitions (FAP) for chemicals or processes to control Salmonella in feed have been accepted for review. Two have been approved, one is under review, and two are inactive because of the lack of adequate information from the sponsor.

On September 28, 1995, the regulations were amended to permit the irradiation of complete poultry feeds and poultry feed ingredients to achieve *Salmonella* negative feed. Based on the scientific information, we believe that this irradiation will also be effective against *E. coli*.

On April 9, 1996, the regulations were amended to permit the use of formaldehyde as an antimicrobial food additive for maintaining poultry feeds *Salmonella* negative for up to 14 days. Again, while the specific approval is for *Salmonella* control, the scientific literature suggests that the formaldehyde will also be effective against other common microbes in feed.

The approval of FAPs with antimicrobial activity is an important step toward the goal of *Salmonella* negative feed and of improving the safety of feed for animals and ultimately, increasing the safety of food products of animal origin.

Research - Research in CVM has as its mission the application of current scientific procedures to the solution of CVM regulatory issues. The primary focus of CVM's research is food safety. While CVM's food safety responsibilities encompass foodborne diseases, its resources address this particular aspect of human health primarily through the need to ensure that safe and effective animal drugs are available to treat these diseases.

Particular importance is placed on the priority for research in CVM. Recent Congressional interest in CVM has focused on the potential for drug residues in animal derived food and the availability of residue detection methods for monitoring. Drug residues in milk have been of particular interest to Congress and the subject of GAO reports.

The food safety focus of CVM research also has included the development and evaluation of procedures necessary to detect

unsafe residues of unapproved animal drugs, metabolism studies in domestic animals as well as fish, evaluation and approval of drug residue screening tests for milk, and current issues on zoonotic disease of importance in domestic animals. All these programs are directed to food safety by ensuring that there are no unsafe drug residues in animal derived food; and by minimizing the human risk from animal disease by ensuring the health of domestic animals. Through a Federal/State/industry cooperative program, involving the National Conference on Interstate Milk Shipments and the milk industry, all Grade A milk is now screened with evaluated screening tests for beta-lactam drugs prior to introduction into the food chain.

Under the umbrella of food safety, CVM has supported studies on zoonotic disease in animals which could be transferred to humans. Animal feeds are considered a source of *Salmonella spp.* in animals and therefore, a source of this disease in humans. CVM research has been directed to the evaluation of procedures to detect *Salmonella spp.* in feeds.

CVM has previously conducted studies on the human health issue of the transfer of resistance organisms from animals to humans.

Earlier studies were designed to develop data on comparison of *Salmonella spp* and *Campylobacter jejuni* in foods of animal origin and the occurrence of human illness caused by those two organisms. Other CVM research on the area of zoonotic disease has been to quantify the extent of drug resistance in select pathogenic bacteria isolated from food-producing animals. These studies were a primary reason for the current regulation requiring the development of data for new antibiotics on the shedding of resistant organisms from the use of the antibiotic in food producing animals.

Animal Drug Availability Legislation

FDA also recognizes that statutory changes also may be appropriate to make more animal drugs available to treat sick animals. FDA has worked very closely with the animal health industry to develop language that will provide adequate flexibility in the approval process while maintaining public and animal health safeguards. Although the agency still has several significant concerns with language proposed in bills before Congress, the agency has been actively involved in discussions with the animal health industry coalition to address our

concerns. Our discussions have also included the possibility of an important new category of animal drugs for use in feed, "Veterinary Feed Directive Drugs." We are encouraged by the way these discussions are moving and hope that they may result in a bill that both the industry and Agency can support.

MONITORING THE FOOD SUPLY

In the United States, the protection of the public from unsafe microbes in food is a shared responsibility between FDA, CDC, and USDA at the federal level, and state and local government agencies at their respective levels. CFSAN and FDA's Office of Regulatory Affairs (ORA) have the primary responsibility in this area for the Agency.

CDC Surveillance Program

Effective surveillance is key to tracking foodborne pathogens. Such surveillance provides policy makers and health professionals with the basis for developing, implementing, and evaluating control policies that will lead to a healthier United States population in the new millennium.

Science is providing the regulatory community with new information, often through the use of sophisticated genetic techniques, which help us identify weaknesses in our system and points where preventive intervention strategies may be applied. From current epidemiologic data, we can conclude that our most important foodborne hazards are microbial, primarily *Salmonella* spp., *Campylobacter jejuni*, and *Escherichia coli (E. coli)* O157:H7. The Public Health Service has included foodborne disease risk reduction in the national health promotion and disease prevention objectives of Healthy People 2000. These objectives include reductions in the numbers of foodborne infections with *Salmonella spp.*, *Campylobacter jejuni*, and *E. coli* O157:H7, and reductions in the number of outbreaks of *Salmonella enteritidis* infections.

CDC's experience with newly emerging foodborne pathogens, well-recognized pathogens appearing in new foods, and foodborne illnesses in immunocompromised consumers, suggests that foodborne disease is an ever changing public health challenge--a problem of emerging infectious disease. In partnership with representatives from state health departments, other federal agencies, medical and public health professional associations, and international

organizations, CDC has developed a strategic plan entitled "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States."

To assure close coordination and adequate support for this program, CFSAN has assigned one of its employees to CDC as a full-time liaison. FDA and USDA have also transferred funds to CDC to help support this program.

FDA's Role in Monitoring the Food Supply

One important aspect of FDA's food safety program is its inspectional strategy. Inspections can determine the adequacy of conditions in a food plant at the time of the inspection, but not whether the company is operating reliably and consistently, over the long term, to produce safe food. Furthermore, the current system of regulatory controls is reactive, not preventive. That is, the system generally relies on detecting and correcting problems after they occur, rather than preventing them in the first place. Only in certain limited areas, such as low-acid canned foods, are mandated preventive controls currently in place.

FDA believes that it is time to consider improvements in the system and adopt a Hazard Analysis Critical Control Point (HACCP) approach to food safety, particularly for seafood. Such a change has been endorsed by such authoritative organizations as the National Academy of Sciences (NAS), the Codex Alimentarius Commission and the National Advisory Committee on the Microbiological Criteria for Foods (NACMCF).

As described by the NACMCF, HACCP has seven basic steps. It begins with an in depth analysis of potential hazards, followed by identification of points in the processing operation (critical control points) where the failure to control the hazard is likely to result in illness or injury to the consumer. Steps three and four are the establishment of critical limits associated with each identified critical control point and delineation of procedures to monitor the limits. The firm identifies corrective action procedures to be taken when monitoring indicates that a critical limit has been exceeded. Then, an effective recordkeeping system must be in place to document the HACCP system. Finally, the HACCP system should be verified to assure that it is functioning properly.

Actually, HACCP is not new. The FDA's low acid canned food program, established in 1973, uses HACCP principles. This program has been very effective in assuring the safety of canned foods.

In December of 1995, FDA issued a final rule for mandatory HACCP for the seafood industry, to become effective on December 18, 1997. Because we believe the future of food safety lies with the HACCP approach, FDA announced, in an August 1994 advance notice of proposed rulemaking, that it is considering the development of HACCP regulations for other segments of the U.S. food supply, including domestic and imported foods. FDA also initiated a program to help the agency obtain additional information and experience on whether, and how, to design HACCP systems for foods other than seafood. Seven major food companies are participating in FDA's HACCP pilot program, and the products involved represent a wide range of foods, manufacturing processes, and hazards.

HACCP takes on even more importance with globalization of the food supply and the need for a consistent system for assuring trading partners of the safety of imported products. The U.S. is importing more food, often in processed form rather than raw,

than ever before. In the early 1970's, all imported products regulated by FDA numbered approximately 500,000 formal entries (i.e., those valued at $1250 or more). In 1995, 1,300,000 food products alone entered the U.S. Likewise, U.S. exports are increasing yearly. The U.S. must be prepared to demonstrate that American products introduced into international commerce meet high standards of quality and safety. Industry use of HACCP procedures is one way of accomplishing this. In fact, the European Union has incorporated the HACCP system into food safety standards and directives.

FDA's model *Food Code* also incorporated a framework for the application of HACCP at retail. The Food Code provides a set of food handling recommendations that can be used as models for retail establishments such as restaurants, grocery stores, vending operations and nursing homes. Its primary focus is the prevention of foodborne illness. The Food Code includes input from many sources, including the Conference for Food Protection, Association for Food and Drug Officials, industry, other federal agencies and academia.

Cooperation with Other Organizations

One of the most important and cost-effective ways in which FDA works to assure the safety of the nation's food supply is through cooperative efforts with other federal, state, and private organizations. While FDA has traditionally collaborated with USDA and CDC, the intensity of our cooperation has increased significantly in the last several years. FDA and USDA have placed full-time liaisons at CDC to ensure that all foodborne illness activities are fully coordinated.

The federal agencies have also increased collaboration and cooperation with state and local agencies that have primary responsibility for regulating the activities of the retail segment of the food industry. We also have increased collaboration with trade associations, such as the National Food Processors Association and the Grocery Manufacturer's Association, to gain their support and cooperation in implementing food safety programs, and with training organizations, such as the Food Marketing Institute and the Educational Foundation of the National Restaurant Association,

which conduct training programs and disseminate information on food safety to their members.

The agencies participate in numerous forums to discuss foodborne disease. These forums include:

Healthy People 2000: National Health Promotion and Disease Prevention Objectives, a prevention initiative to improve the health of the American people during the decade of the 1990s. One of the 22 priority areas is food and drug safety. FDA is the lead agency for this priority area, working closely with CDC and USDA and through the states and non-government organizations. Healthy People 2000 tracks yearly progress in food safety improvement through four objectives, including tracking the incidence of five foodborne bacterial diseases.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), an advisory committee formed in 1987 by USDA and coordinated by FSIS, FDA, National Marine Fisheries Service, and the Department of Defense. The Committee provides impartial scientific advice to federal food regulatory agencies for use in the development of an integrated food safety system approach to

ensure the safety of domestic, imported, and exported foods. NACMCF has provided the agencies with outstanding advice, including development of HACCP principles, which are now incorporated in the HACCP programs mentioned above.

The Conference for Food Protection, comprises representatives from regulatory agencies at all levels of government, the food industry, academia, and consumer organizations. Its goal is to promote food safety at retail by identifying and addressing problems, providing uniform procedures, and promoting mutual respect and trust by establishing a working liaison among all parties concerned with food safety.

The Food Safety and Nutrition Education Task Force, co-chaired by FDA and an industry trade group, comprises food and nutrition consumer affairs and education representatives from industry, trade, consumer and public health organizations, government agencies, and public affairs firms. This group focuses on education strategies and initiatives.

The National Center for Food Safety and Technology (NCFST), a cooperative government/academia/industry research endeavor that

includes the Illinois Institute of Technology (IIT), the IIT Research Institute, the University of Illinois Food Science Department, FDA/CFSAN, and food-related industries. Cooperative research endeavors at the NCFST provides FDA scientists access to highly technical expertise and provides the opportunity to conduct critical food safety research, which could not have been attained by FDA alone.

The Columbus Center CFSAN seafood and molecular biology researchers will soon be located at the Columbus Center in Baltimore's Inner Harbor. They will focus on applying new technologies to enhance the safety of the food supply for the American consumer. In this state of the art facility, CFSAN scientists will combine their expertise conducting research in molecular biology and seafood safety. Their research will be used to develop and evaluate new scientific approaches which aid the FDA in accomplishing its mission.

The University of Maryland On April 15, 1996, FDA entered into a partnership with the University of Maryland. Under this partnership, internationally recognized scientists from both organizations will share their expertise on significant issues

pertaining to food safety, nutrition, and food science. We believe that pooling resources will enhance our ability to acquire and maintain state-of-the-art science facilities and equipment. Four areas of emphasis include: 1) the development of enhanced methods for detecting foodborne pathogens, contaminants, and toxins; 2) the designing of nutrition and clinical studies to better assess nutrient quality, safety, and proper labeling; 3) the evaluation of technological innovations that will assist in the review of food ingredients, risk assessment, international standards, and educational research; and 4) the ability to better anticipate and respond to technological developments that affect consumers, their behavior and the food industry.

Seafood HACCP Alliance and the Meat and Poultry HACCP Alliance, an affiliation of federal, state, industry, and academic organizations that, working together, have developed curricula to conduct training programs to facilitate the implementation of HACCP. These training programs will formally begin in the summer of 1996.

The *Salmonella enteritidis* Interagency Working Group, an integrated coordinated approach to the control of *S. enteritidis*

in eggs. The group comprised representatives from USDA (FSIS, APHIS, Agriculture Marketing Service, Agriculture Research Service); CDC; FDA (Center for Food Safety and Applied Nutrition); the U.S. Animal Health Association; representatives from the egg industry; state animal health departments; and state departments of public health. The working group has considered issues like quality assurance programs as an alternative to the USDA *S. enteritidis* traceback regulation and requirements for the refrigeration of eggs during transportation and storage.

Implementation Group on Emerging Infectious Diseases, an interagency working group of the Committee on International Science, Engineering and Technology (CISET), formed in December, 1994. It published a report on emerging and re-emerging infectious diseases, including foodborne diseases, in September, 1995. Five sub-working groups, chaired by representatives from CDC, FDA, the National Institutes of Health (NIH), U.S. Agency for International Development, the Department of Defense (DOD) and the State Department, and including outside experts from academia, industry, and non-profit organizations are now working on implementation of recommendations from that report.

Research FDA cooperates with other agencies in research on a wide variety of topics including food safety. Research is joint, collaborative, or funded by other agencies. CFSAN cooperates with the CDC, USDA, NIH and DOD(NAVY), the National Aeronautics and Space Administration, the Department of Veterans Affairs, the National Institute for Standards and Technology and other agencies. The research function and ability to collaborate is essential to solving food safety, food technology and epidemiology questions.

Other Cooperative Endeavors

We would like to highlight several special scientific collaborations that have resulted in successful outcomes. Two examples are illustrative:

A) FDA is providing CDC with $190,800 in FY-96 to continue active surveillance of listeriosis in 5 geographic areas with a total population of 15,000,000. The active surveillance project found a decline in incidence of listeriosis between 1986 and 1992 which coincided with: (1) efforts by FDA, CDC, and USDA to

increase publicity about how foodborne listeriosis is transmitted; (2) increased regulatory activity; and (3) publication of recommendations for prevention of foodborne listeriosis. This low level of disease has continued through 1994. It is unclear at present whether the decline is permanent, and as such, continued surveillance in at least a part of the current surveillance area is crucial.

B) FDA and CDC using DNA fingerprinting technology to analyze *Salmonella tennessee* isolates from numerous dry soy- and milk-based infant formulas and other products, the environment, and two ill Canadian infants were able to link the plant environment and products contained within the facility to illness among consumers. This resulted in the recall of powdered infant formulas, medical foods, whole milk powder, nonfat dry milk, ice cream mixes, powdered drink for meal replacement and a powdered supplement for use by lactating or pregnant women, which were dried and/or packaged at the food processing plant.

ADDITIONAL ISSUES

Mr. Chairman, in your letter of invitation you requested that I speak today about FDA's regulatory actions related to the Transmissible Spongiform Encephalopathies (TSEs), and the relationship between *Campylobacter jejuni* and Guillain-Barré Syndrome. While FDA shares responsibility in these areas with other federal and state agencies, we also have important information to provide.

***Campylobacter jejuni* and Guillain-Barré Syndrome**

Campylobacter jejuni is the most common cause of bacterial gastroenteritis in the U.S., causing an estimated 125,000 culture-confirmed and perhaps three million total cases of diarrhea annually. The predominant source of *C. jejuni* infections is raw or undercooked chicken. Poultry is regulated by the United States Department of Agriculture. Among the commodities which FDA regulates, *C. jejuni* outbreaks in the U.S. are primarily associated with the consumption of raw milk. Other foods regulated by FDA demonstrated to serve as vectors (rarely)

for the dissemination of *C. jejuni* include mushrooms, raw or poorly cooked fish, and raw shellfish (mussels and oysters).

Guillain-Barré syndrome can appear as a late developing illness following a *C. jejuni* infection. It may also follow illness caused by other bacterial pathogens, viral infections, immunizations, major surgery, and other (unknown) causes. The syndrome is characterized by acute neuromuscular paralysis in both adults and children. It develops one to three weeks after an acute respiratory or gastrointestinal infection. It is rare (only about four to five thousand cases per year) and most patients fully recover.

Research/Analysis - FDA conducts applied research on methods to quickly and accurately recover and identify *C. jejuni* in commodities under our jurisdiction. The FDA Bacteriological Analytical Manual contains a chapter on the "Isolation of *Campylobacter* Species from Food and Water." FDA Field Laboratories perform analytical tests for the presence of *Campylobacter* spp. in food commodities regulated by the FDA. To date, we have detected *C. jejuni* in only one sample of shellfish

collected from a shellfish growing area that had been closed to harvesting.

Consumer Education - In a 1991 issue of FDA Consumer, FDA outlined ways to prevent foodborne illness in the home, including prevention tips on safe storage of food items, the importance of cleanliness, the need to keep hot foods hot and cold foods cold, and organisms that can cause disease and their likely source. Other information on *C. jejuni* and its relationship to seafood is available through the FDA Seafood Hotline. The Hotline is available 24 hours a day, seven days a week.

Retail Practices--Guidance - The 1995 *Food Code* published by the Food and Drug Administration serves as guidance to local, state, territorial, and tribal authorities, and to federal agencies in enforcement of their food safety laws covering, restaurants, food stores, institutional feeding, and vending operations. The 1995 *Food Code* includes specific poultry and seafood cooking advice and a consumer advisory regarding the risk associated with the consumption of raw or undercooked animal foods.

Prevention - The prevention of campylobacteriosis relies upon the avoidance of cross contamination in food-handling, maintenance of good kitchen hygiene, adequate cooking of meat and poultry, and the avoidance of those foods known to be vectors. Pasteurization is an effective way to eliminate *Campylobacter jejuni* in milk because the organism is sensitive to heat.

On May 2, 1990, FDA approved the irradiation of poultry up to a dose of 3 kGy for pathogen reduction. Treatment of poultry with radiation had been shown to be effective in significantly reducing the load of several pathogenic microorganisms on poultry products, among them, species of *Salmonella*, *Yersinia* and *Campylobacter*.

Other Activities - CDC, USDA, and FDA have initiated a pilot diarrheal disease reporting system. Working in cooperation with state health departments, CDC will collect and analyze illness data from five "Sentinel Sites" around the country (California, Connecticut, Georgia, Minnesota and Oregon). Data collected will provide a framework for identifying current and emerging trends in foodborne illness. The survey will collect data on diarrheal diseases (including campylobacteriosis) associated with dairy

products, fruits, vegetables, and seafood, which are regulated by FDA, and with meat and poultry, which are regulated by USDA.

Food safety goals are part of the PHS program, Healthy People 2000: National Health Promotion and Disease Prevention Objectives. One of the goals is the reduction of infections caused by key foodborne pathogens including *Campylobacter jejuni*.

Transmissible Spongiform Encephalopathy

Transmissible Spongiform Encephalopothies (TSEs) are a group of transmissible, slowly progressive, degenerative diseases of the central nervous systems that are invariably fatal. Scrapie in sheep and goats, bovine spongiform encephalopathy (BSE), transmissible mink encephalopathy, chronic wasting disease of deer and elk, and Creutzfeldt-Jakob Disease (CJD) in humans are examples of TSEs. The agents believed to be responsible for transmitting TSEs are highly resistant to procedures that modify or destroy nucleic acids of living infectious organisms.

FDA has been active in the trying to understand TSEs. Since 1988 when UK scientists discovered an epidemiological link between

rendered ruminant products in cattle feed and BSE, FDA has participated in BSE discussions nationally and world-wide to understand the agent and epidemic. Collaborations with such organizations as CDC, USDA and NIH have helped the Agency focus on appropriate actions.

USDA has confirmed that no cases of BSE have been diagnosed in the United States. However, as a means of helping to prevent the occurrence of BSE in the US, FDA issued a proposed rule (PR) on August 29, 1994. The PR declared specified offal from adult (more than 12 months of age) sheep and goats as not generally recognized as safe (GRAS) for use in ruminant feed. Since the PR issued, the Agency has evaluated the comments submitted on the proposal and monitored the scientific advances made in understanding the interrelationships among the animal TSEs.

Epidemiological evidence from the United Kingdom (UK) suggests that an outbreak of BSE may be linked to feeding of ruminant proteins to cattle. BSE has been diagnosed in over 155,000 head of cattle from almost 33,000 herds in the UK. A UK ban on the feeding of ruminant protein to ruminants is believed to have resulted in a steady decline in the number of cases of BSE.

Ten cases of CJD with a new neuropathological profile have been identified recently in the UK. Although sporadic cases of CJD occur world-wide at a rate of 1-2 cases per million population per year, these 10 cases appear to represent a new variant of CJD (v-CJD), which might be unique to the UK. The appearance of these 10 cases of v-CJD raises the possibility that they could be causally linked to BSE. However, a link with BSE cannot be confirmed on the basis of this epidemiological evidence alone.

Because of this potential association, an advanced notice of proposed rulemaking (ANPRM) will publish imminently in the Federal Register announcing that FDA is soliciting comments on the issue of using protein-derived from ruminants in ruminant feed. The Agency believes that this action will better protect the health of animals and minimize any risk which might be faced by humans. FDA will be soliciting comments on all aspects of the ANPRM, including, among other things: 1.) the occurrence in the United States of TSEs in animals, including BSE; 2.) how TSEs occur and are spread among animals, and among humans and what vectors might be involved; 3.) scientific information on the ecology of TSEs; 4.)scientific information supporting the exclusion of any ruminant-derived proteins from the proposed

prohibition; 5.) establishment of Hazard Analysis Critical Control Points (HACCP) for the rearing of ruminants, and the rendering or other processing of ruminant derived feed ingredients, that could reduce the need to prohibit the feeding of ruminant protein to ruminants; and 6.) details of rendering or processing practices that may inactivate the TSE agents, and information and evidence of the effectiveness of rendering in the inactivation of TSE agents.

In addition to TSEs and *Campylobacter*, you have asked that I speak about the effect that regulatory delay may have on food safety. The agency currently faces a greater number of challenges and stresses than ever before. New food processing and packaging technologies, new food distribution and consumption patterns, increasing public health concerns about low levels of certain chemical contaminants, and new microbial pathogens all contribute to today's food safety challenges. The size, diversity, and international character of the food industry add to the stress on FDA's food safety assurance program as well, with FDA's current inventory listing over 49,400 food establishments. The number of foreign food products shipped to food products to the United States is continuing to increase. In

1995 alone, there were well over 1.3 million food import entries.

Given the current constraints on government resources, it is unlikely that FDA will ever have sufficient resources to inspect, sample, and analyze more than a small percentage of all food products, domestic as well as imported. Thus, it is FDA's goal to use our resources in the most effective way to minimize consumer exposure to unsafe products. The Agency is developing and implementing new and innovative strategies to meet these goals, through partnerships, improved product review and approval processes, HACCP, reduced number of regulations and environmental assessments.

FOOD ADDITIVE PETITION PROCESS

Mr. Chairman, we would like to take this opportunity to highlight some of the activities that have taken place with regard to the agency's food additive petition process since we last testified before the Subcommittee on this issue and to announce several changes to be made to this process. As you know, on June 22, 1995, the Interim Deputy Commissioner for Operations, Ms. Linda Suydam, testified before this Subcommittee on the subject of food

additive regulation. Ms. Suydam described the changes being made to speed up the food additive review process and additional planned reforms. Since then, we have made some important strides in reducing the petition inventory. I'd like to briefly describe these efforts for you:

At the time of the June 1995 hearing, there were a total of **295** petitions in the inventory. Program staff have made a commitment to have reached a final decision on **at least 100** of these petitions by the end of FY 1996, and I am pleased to be able to report that as of April 30, 1996, **72** of that cohort of petitions have been acted on. (Of course, petitions continue to be received; for example, for the 12 months following May 1, 1995, 56 new petitions were received, and final actions were taken on a total of **82** petitions; of these **53** were approvals. Both of these latter two numbers are higher than for any calendar year since 1986). These gains were achieved because of steps we took during the last year, including:

o reassignment of 23 laboratory scientists to the petition review effort;

o use of the Threshold of Regulation policy, finalized in July, 1995, to exempt from the requirement for a regulation certain low-risk substances used in food packaging;

o increased use of outside scientific experts in resolving novel questions in food additive petitions;

o use of a Special Project Team to expedite review of certain petitions for food packaging materials;

o the dropping or withdrawal of petitions that are incomplete or inadequate.

o establishing objective criteria for judging each employee's performance.

We have also initiated actions that will result in new efficiencies in the process, and further reductions in the petition inventory, including the following:

o We have allocated approximately $1.5 M for the upgrading of information management capabilities to allow modern petition indexing, information retrieval, and document tracking;

o On April 3, we issued a proposal, under the Reinventing Government Initiative, to exempt many petitions from the requirement to prepare an environmental assessment, saving both petitioner and reviewer effort;

o In another REGO initiative, we are preparing a proposal to replace the current lengthy and burdensome GRAS affirmation petition process with a simplified and streamlined notification process;

o We are exploring new ways to improve the quality of submitted petitions, for example, by holding workshops for petitioners, and by making guidance for petitioners more readily available through the World Wide Web;

o Finally, on April 19, we issued requests for proposals for two contracts for review of certain petition data, that will materially assist us in clearing the inventory of unreviewed studies; we anticipate that this action will ultimately have the greatest single impact on inventory reduction of any of our initiatives.

I am convinced that by following through on these initiatives, we will substantially reduce the pending petition inventory to the point where a newly submitted petition can receive the prompt attention of reviewers in all necessary disciplines; only then can we make real progress in improving timeliness and predictability of action on all new incoming petitions. To that end, I am personally following closely the progress being made in

reducing the inventory: weekly, I am receiving regular reports, and will, in the next few weeks, be working with the CFSAN to establish more ambitious performance goals and measures for inventory reduction, and will be looking at any opportunities to provide additional resources for this effort.

At the June 1995 hearing, Chairman Shays noted that the statutory timeframe for review was 180 days, and that any review period in excess of that was in violation of the statute. Mr. Shays urged FDA to deal forcefully with the overdue petitions and requested FDA to suggest a new statutory timeframe that was achievable in practice.

In response to that request, FDA began a comprehensive review of its food additive review program. The results of this review were summarized in a concept paper that was submitted to the Department of Health and Human Services on October 2, 1995. The reform ideas outlined in the concept paper have been discussed with Subcommittee staff, and have, in addition, been the springboard for numerous discussions with representatives of interested food-industry and consumer groups.

FDA proposes a number of substantive changes that would significantly improve its food additive petition review performance, thereby achieving predictable and significantly faster petition reviews. A number of these changes would require amendments to the FD&C Act, and several others would require that new regulations be promulgated or that existing regulations be amended. Today I will describe in detail only the suggestions for statutory changes.

The primary recommended statutory change is that the present 90-day statutory time frame for petition approval (extendable for an additional 90 days) be changed to a:

6-month statutory time frame for conducting complete reviews (extendable for an additional 6 months) for food contact material (so-called "indirect additive") petitions; and

12-month statutory time frame for conducting complete reviews (extendable for an additional 12 months) for so-called direct food additive petitions.

These deadlines will be phased in and become effective over a five-year period. FDA's ability to achieve these statutory requirements and meet these timeframes will depend on reasonable flexibility to reallocate existing resources or development of new external resources, in conjunction with our initiatives to increase efficiency of the process.

By "complete review," FDA means that at the end of the specified time period, the agency will have completed the technical and scientific review and will have either made a decision that the petition is approvable and published a regulation, or has informed the petitioner that the petition is not approvable and the reasons that it is not. The petitioner would have the right to appeal a decision to deny a petition. These deadlines could be extended at the petitioner's request (if, for example, the petitioner prefers an extension to a denial).

These suggested statutory timeframes recognize the fact that some petitions are scientifically more complex than others and, therefore, require longer review. This fact was also recognized in the December 21, 1995, report of the Committee on Government

Reform and Oversight on the food additive petition review process.

I should add an important note: There is currently no distinction between direct additives and food contact materials in the statute. This distinction would need to be established by regulation.

Phased implementation of performance goals

As noted earlier, FDA proposes to phase in its accomplishment of these deadlines over the next 5 years. FDA has already begun to act to reduce the backlog, and will continue to work toward its goal to eliminate the backlog within two to three years. Once the backlog is significantly reduced, FDA's goals are as follows:

For food contact material petitions, FDA's goal is to act on 60% of new petitions within 6 months in the first year of implementation of the new program; 75% of new petitions within 6 months in the second year; and 90% of new petitions within 6 months in the third and subsequent years.

For direct food additive petitions, FDA's goal is to act on 50% of new petitions within 12 months in the first year of implementation of the new program; 65% of new petitions within 12 months in the second year; and 80% of new petitions within 12 months in the third and subsequent years.

Additional recommended statutory changes

FDA recommends that additional statutory changes be made to direct the establishment of new appeal procedures, to streamline rulemaking procedures, to exempt food additive petition review from certain provisions of the Federal Advisory Committee Act and to amend section 721 of the Act to provide for parallel changes for color additive petition review.

Necessary administrative changes

Several other reforms will be needed in order for FDA's overall goals to be met. Perhaps most important among them is the promulgation of regulations to raise the threshold for filing petitions. Such regulations will improve the completeness and

overall quality of petitions, which in turn will increase the likelihood that petitions, once accepted by the agency for review, will be approvable. In addition to the REGO proposals, mentioned earlier, other reforms are also contemplated, among them a requirement that petitioners certify that the data contained in a petition have been properly and correctly recorded, analyzed, and reported.

Likely outcomes of reform in the absence of additional resources

In FDA's June 1995 testimony, the agency committed to improve its food additive review performance without the benefit of additional resources. The reforms identified in the testimony and those discussed above will strengthen FDA's ability to speed petition reviews, and will go some distance toward structuring a workable program of food additive review. However, FDA anticipates that, unless the quality of the petitions it receives is significantly improved, many petitions will not be considered sufficient for filing, and many filed petitions will be denied because they contain unresolved safety questions. This is an outcome that both FDA and the food industry wish to avoid.

These points deserve amplification. With current resources, FDA is unable to devote sufficient resources for consulting with prospective petitioners before filing, because to do so would divert resources needed to review pending petitions. Without pre-filing consultation, and with a new filing threshold that sets higher standards for the information that petitions must contain, many submitted petitions are likely to be found insufficient for filing. For petitions that are filed, the situation is similar. With current resources, FDA is not able to devote the level of effort required to complete all scientific reviews and resolve all safety questions for filed petitions within a time period satisfactory to industry or to FDA. While this cooperative process has added significantly to the likelihood that petitions ultimately will be approved, it has also added significantly to the time required to approve petitions, contributed significantly to development of the present overly long average review times, and has therefore ultimately worked to the detriment of the goal of timely reviews. Were FDA to commit to new statutory deadlines to reach a decision within 12 to 24 months for direct food additive petitions, FDA scientists would be unable to continue their current practice of working substantively with petitioners to resolve the scientific

issues and safety questions that arise during review. If required to reach a decision by the statutory deadline, it is likely, therefore, that FDA would deny many petitions as containing insufficient data to support approval.

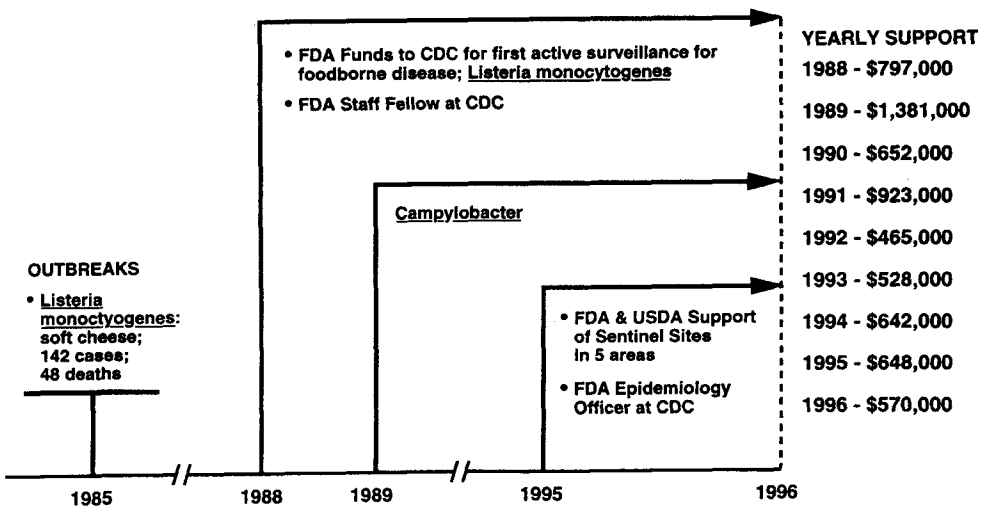
CONCLUSION

The American food supply is among the safest if not the safest in the world. This has been achieved by incorporating the best science available in our regulatory research, by monitoring, and by education. Changing technologies, rapidly emerging and virulent pathogens, as well as globalization of the food supply present new and unique challenges to maintaining a safe food supply and protecting the consumer. FDA cannot do this alone and indeed has not - but in this time of decreasing resources, as outlined above, we are forming new partnerships, as well as strengthening others with our federal, state, and local counterparts as well as academia and industry to leverage our resources and capitalize on the needs and expertise of our counterparts and customers. These cooperative efforts also include a review of how we currently do business and how best to carry out our mission. As mentioned above, we have made changes

such as in our new animal drug review process and will make changes in other areas to improve the way we function.

Thank you.

FDA Support of Foodborne Disease Surveillance at CDC



Mr. DAVIS [presiding]. Dr. Morris.

STATEMENT OF GLENN MORRIS, M.D., DIRECTOR, EPIDEMIOLOGY AND EMERGENCY RESPONSE PROGRAMS, U.S. DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION SERVICE [FSIS]

Dr. MORRIS. Thank you, Mr. Chairman and members of the subcommittee.

I am pleased to have the opportunity to testify before you today to discuss foodborne pathogens. As you requested, I will address the steps being taken by the Department of Agriculture's Food Safety Inspection Service to gather accurate information on foodborne illness and to prevent illness which occurs as a result of pathogens in the meat and poultry supply.

Again, by way of introduction, the Food Safety Inspection Service of the Department of Agriculture is responsible for the safety, wholesomeness, and accurate labeling of meat and poultry products. By way of introduction, I serve as the Director of the FSIS Epidemiology and Emergency Response Program. The Epidemiology and Emergency Response Program was established in 1984 to provide leadership to FSIS in public health matters, to provide rapid response to foodborne illness, and to recommend changes in meat and poultry inspection practices to reduce the risks of current and emerging pathogens that cause foodborne illness.

Essentially, we are involved in a number of different activities. The key element is liaison, forming a source of communication between USDA and USDA activities and what is going on at FDA and CDC. We are on the Wonder Network which links us directly by computer with CDC. Basically I or members of my staff talk daily with CDC, either via computer or by telephone. We have a full-time staff member from my office who is stationed at CDC. We are involved in recalls; we are involved in investigations, outbreak investigations.

To conduct our outbreak investigations, we have a team of 22 field epidemiology officers who serve on collateral duty with other responsibilities within the agency who are available to go to States, to assist State health departments, CDC, and FDA in terms of the outbreak investigation and to serve essentially as a single point of contact for USDA activities in the outbreak investigation.

We also are involved in active and passive surveillance systems. We have consolidated all of the various passive surveillance systems within FSIS to provide us a computer basis for reports of foodborne disease outbreaks that come into the agency, but probably more critical has been our support and very strong backing of the development of the sentinel site surveillance program.

As has been mentioned by all of the speakers today, I think the sentinel site surveillance system is really a model of Federal-State cooperation. It is an instance where we have three different Federal agencies, FSIS, FDA, and CDC, who have come together to set up something that has been needed for a long time, and it is being done in conjunction with four State and one local health department. This is something that was initially recommended in the *National Academy of Science's* expert report in 1987, and we are doing it. We are putting together the type of system we have to have to

get the data we need to understand foodborne disease in this country.

In terms of the FSIS regulatory policy, under our current regulatory policy, an *E. coli* O157:H7, raw ground beef contaminated with *E. coli* O157:H7 is considered adulterated under the Federal Meat Inspection Act. This decision was based on a number of factors including the recognition that the presence of this strain of the *E. coli* bacterium in raw ground beef poses a serious risk to public health. As a result of this decision, any raw ground beef contaminated with *E. coli* O157:H7 must be excluded from commerce.

We also have been conducting a sampling program of *E. coli* O157:H7 in raw ground beef under our microbiological testing program; 8,327 samples have been collected to date, 5 of which have been positive for *E. coli* O157:H7.

Ready-to-eat meat and poultry products are considered adulterated if any pathogens are detected in final product samples. We collect and analyze over 19,000 samples per year of ready-to-eat products such as hot dogs, luncheon meats, cooked meat patties, chicken salad, and a variety of sausages. However, the key of where we are going over the next—or where we have been headed over the last year or so is our new HACCP rule proposal.

The cornerstone of a sound, science-based regulatory program for food safety is what we call Hazard Analysis and Critical Control Points, and we are in the process of putting in a regulation which will establish mandatory HACCP throughout the meat and poultry industry. We feel that this program is critical to providing the appropriate safety for meat and poultry products for the American public.

What we are coming into now is essentially a transition year. We have the final regulation for HACCP, which is moving very rapidly toward publication, and as we begin to implement what is involved in this regulation, we still will need to maintain the current system. We can't get rid of one without starting to put the other into place. So what this does, as I said, is create a transition period.

For this transition year, to support implementation of the HACCP systems, the administration has requested $8.1 million in fiscal year 1997 to support increases in the frontline scientific capabilities of FSIS. We have also asked for $5.9 million to help retool in terms of our ability to handle the new responsibilities that are coming with HACCP, as well as $2.8 million to work in the area of preharvest food safety.

In conclusion, Mr. Chairman, USDA is committed to reducing the incidences of foodborne illness through the implementation of a science-based inspection system designed to reduce and prevent the presence of pathogens. To effectively and efficiently fulfill this commitment, USDA relies on CDC for surveillance data and expertise on human illness and utilizes the technical advice and expertise of FDA.

Thank you very much for the opportunity to testify, and again, I will be happy to answer any questions.

Mr. DAVIS. Thank you very much.

[The prepared statement of Dr. Morris follows:]

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

Statement of Dr. J. Glenn Morris, Jr.
Director, Epidemiology and Emergency Response Program
Food Safety and Inspection Service
U. S. Department of Agriculture
Before the U.S. House of Representatives
Committee on Government Reform and Oversight
Subcommittee on Human Resources and Intergovernmental Relations

May 23, 1996

Mr. Chairman and Members of the Subcommittee, I am pleased to have this opportunity to appear before you today to discuss foodborne pathogens. As you have requested, I will address the steps being taken by the Department of Agriculture's Food Safety Inspection Service (FSIS) to gather accurate information on foodborne illnesses and to prevent illnesses from pathogens in the meat and poultry supply.

FSIS is responsible for the safety, wholesomeness, and accurate labeling of meat and poultry products. The Agency is committed to reducing and preventing *E. coli* O157:H7, *Salmonella, Campylobacter*, and other pathogens in meat and poultry that cause foodborne illness.

EPIDEMIOLOGY AND EMERGENCY RESPONSE PROGRAM

By way of introduction, I serve as the Director of FSIS' Epidemiology and Emergency Response Program (EERP). The EERP was established in 1994 to provide leadership to FSIS in public health matters, respond quickly to outbreaks of foodborne illness, and to recommend changes in meat and poultry inspection practices to reduce the risks of current and emerging pathogens that cause foodborne illness.

EERP operates a foodborne hazard control center to which reports of imminent and actual outbreaks of foodborne disease are directed. Additionally, EERP implements a wide variety of programs to identify, evaluate, monitor, reduce, and prevent foodborne illness. We also maintain liaison with other Federal, State, and local public health officials involved in detection and control of foodborne disease. We also lead and coordinate all traceback and recall activities. The Program has 22 Field Epidemiology Officers who are trained in epidemiologic investigative procedures and travel to outbreak sites to assist State and local health departments. These Officers serve as single points of contact for State and Federal Agencies involved in the investigations.

An example of the Clinton Administration's efforts to improve the safety of the nation's food supply is EERP's participation with the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and health departments in five States on a project begun in 1995. The goal of the project is to collect precise information about the numbers of people who are affected by harmful bacteria in food. Currently, it is estimated that from 6 million to 33 million people develop foodborne illness each year, and as many as 9,000 die annually. These numbers reflect the magnitude of the problems associated with foodborne pathogens but are not precise enough to conduct quantitative risk assessments or to evaluate the effect of food safety program changes.

Data from five project sites located throughout the country will be used to establish baseline data on the incidence of diarrheal diseases, especially those caused by *E. coli* O157:H7 and *Salmonella*. As a result of this project, FSIS, FDA, and CDC will be able to monitor, over time, changes in the incidence of foodborne disease. This information will help us evaluate our current food safety initiatives and aid in the development of future food safety activities.

This project follows the model of the *Listeria monocytogenes* program. In 1989, CDC provided initial surveillance data on listeriosis rates in the U.S. population. USDA and FDA subsequently adopted a "zero tolerance" policy for *Listeria monocytogenes* in processed food products. These regulatory efforts, combined with aggressive education campaigns, contributed to a 44% decrease from 1989 to 1993 in the incidence of listeriosis in this country.

CURRENT REGULATORY POLICY ON PATHOGENS

Under our current regulatory policy on *E. coli* O157:H7 raw ground beef contaminated with *E. coli* O157:H7 is considered adulterated under the Federal Meat Inspection Act. This decision was based on a number of factors including the recognition that the presence of this strain of the *E. coli* bacterium in raw ground beef poses a serious risk to public health. As a result of this decision, any raw ground beef contaminated with *E. coli* O157:H7 must be excluded from commerce.

Since October 1994, FSIS has been collecting samples of raw ground beef at the rate of 5,000 per year under our microbiological testing program for *E. coli* O157:H7. Samples are collected from federally and State inspected establishments, at the retail level, and at import facilities. Five of the 8,327 samples collected to date have been confirmed positive for *E. coli* O157:H7. We have received cooperation from industry in taking appropriate action when FSIS or industry testing has determined the presence of *E. coli* O157:H7 in ground beef samples.

Ready-to-eat meat and poultry products are considered adulterated if *any* pathogens are detected in final product samples. FSIS collects and analyzes over 19,000 samples per year of ready-to-eat products such as hot dogs, luncheon meats, cooked meat patties, chicken

salad, and a variety of sausages. Microbiological testing for the presence of *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, and staphylococcal enterotoxin are performed. In cases of a positive test result, the entire product lot from which a sample was drawn is considered adulterated and not fit for human consumption.

MODERNIZATION OF MEAT AND POULTRY INSPECTION

Even though the current Federal inspection program makes very significant contributions to food safety and consumer protection, improvement is needed to deal adequately with the problem of pathogenic microorganisms on raw meat and poultry. The current system does not directly target and systematically reduce harmful bacteria on raw product. It also does not provide FSIS inspectors with the scientific and regulatory tools needed to ensure slaughter establishments are meeting acceptable food safety performance standards; its "command and control" orientation also deprives plants of the incentives and flexibility needed for innovation to improve food safety.

The Department of Agriculture's strategy for modernization of the Federal inspection system began with our Hazard Analysis and Critical Control Points (HACCP)/Pathogen Reduction rulemaking proposal, which was published February 3, 1995, and which is now being finalized. Our HACCP rulemaking provides the framework for significantly improving food safety by incorporating science-based preventive controls into industry production processes and establishing an objective measure of slaughter process control and food safety performance with respect to harmful bacteria.

For example, a hazard analysis of poultry slaughter will likely identify *Campylobacter* as a leading contaminant of raw product leaving the slaughterhouse. Coincident with this recognition comes the responsibility to develop interventions as necessary and to establish appropriate control points to limit contamination of raw product with *Campylobacter*.

The regulations under development reflect a major step in what FSIS believes should be the proper role of government in protecting the public health. A system that is based less on "command-and-control" prescriptions of how industry should produce its products and more on clearly defined responsibility for process control and practical food safety performance standards will better improve food safety. The government should also provide incentives to industry to innovate and to develop and use new technology, and the regulations under development reflect this objective as well.

The move to HACCP-based process control and performance standards will pave the way for our inspection resources to be devoted to tasks that provide the greatest possible return in terms of public health protection. We plan to look at the farm-to-table continuum and identify, through risk assessment, points along the continuum where there is the greatest risk to the public health. We will focus inspection and other efforts at those points and determine more specifically what roles our employees should play while products are being transported, stored, and offered for sale at retail.

For example, we know that temperature control after products leave the federally inspected plant is critical. We believe FSIS has a role to play in setting standards for proper temperatures throughout distribution, from manufacturer to user, and ensuring that they are maintained. We also see a potential role for FSIS in such areas as training State and local regulatory officials on methods of inspecting meat and poultry handling and processing in retail and food service environments and working cooperatively with producers and producer groups to foster good production practices before animals reach the slaughter plant.

To support implementation of HACCP systems, the Administration has requested $8.1 million in Fiscal Year 1997 to support increases in the frontline scientific capabilities of FSIS in four areas. First, the Agency is projecting that 125,000 samples will be collected for microbiological testing next year -- more than double the current level. Second, FSIS has plans to reconfigure its laboratories, upgrade utilities, and install laboratory equipment to accommodate the likely increased and expanded use of laboratories associated with HACCP implementation. Third, FSIS intends to pursue the adaptation of new technologies to food safety inspection. Adapting automated and sensory technology to food safety applications will enhance the inspection system by improving the Agency's ability to evaluate food safety hazards. Sensor technology can be used for temperature measurement and to assess the sanitary status of facilities and equipment. FSIS also plans to work in collaboration with small businesses through pilot and demonstration projects to develop cost-effective alternatives to technologies designed for larger operations. Fourth, FSIS hopes to add six public health professionals to the FSIS staff next fiscal year. These additional public health professionals are critical to the Agency's efforts to establish and maintain a close working relationship with State and local health departments, coordinate investigations of outbreaks associated with meat and poultry, and maintain surveillance of foodborne disease. Increasing USDA's strength in the principles of epidemiology and risk assessment will enable the Agency to better evaluate the effect of food safety activities, such as HACCP and pathogen reduction, on the incidence of foodborne illness.

CONCLUSION

In conclusion, Mr. Chairman, USDA is committed to reducing the incidence of foodborne illness through the implementation of a science-based inspection system designed to reduce and prevent the presence of pathogens. To effectively and efficiently fulfill this commitment, USDA relies on CDC for surveillance data and expertise on human illness and utilizes the technical advice and expertise available at FDA. Thank you for the opportunity to testify. I will be happy to answer any questions that you or the other Members of the Subcommittee may have.

Mr. DAVIS. The last systematic CDC study on the incidence of foodborne bacterial, viral, and parasitic infections was conducted in 1983. In light of the recent outbreaks of severe foodborne illnesses, a new study is urgently needed. Let me ask what has changed in the area of foodborne illness since the 1983 study and what are the plans for an updated CDC study?

Dr. SATCHER. Well, in terms of things that have changed since 1983, there are a few things. One of course is that we have had a continuing emergence of new infectious diseases, including in the food supply. I think technology has changed in terms of the way——

Mr. DAVIS. These are just diseases that didn't exist before?

Dr. SATCHER. Yes. I think you will note that in the last 15 years, *E. coli* O157:H7, *listeria monocytogenes,* and *Campylobacter jejuni* have all emerged, and so this continuing emergence of new infectious diseases, plus the increasing antibody resistance, and that is especially important in the food supply. Antibiotic resistance in the food supply is influenced both by what we do with animals and what we do with humans. Some animals are fed antibiotics to stimulate growth, or treated with antibiotics, and even though they may carry bacteria that are not harmful to the animals, when those bacteria are transmitted to humans, they can be very harmful in many cases. So those kinds of changes have taken place.

But on the positive side, I think the active foodborne surveillance system is the most important change. I think we have now implemented an active foodborne surveillance system. It includes the 15 States where we are strengthening surveillance and response, and I mentioned earlier that we would like to add 15 more States to that in 1997. But it also includes these five sites where FDA, USDA, and CDC have collaborated in developing five emerging infectious disease sites to look at foodborne illnesses. And so this active study of foodborne diseases now covers about 13.5 million people in the country. And so we are actively looking at foodborne infections, we are studying cases, we are getting epidemiological reports on the people affected. So this is an ongoing program and should make a big difference in the future.

Mr. DAVIS. Well, antibiotic resistance, I guess you would call it, is an arms race against nature.

Dr. SATCHER. Right. In a sense.

Mr. DAVIS. Can we win that?

Dr. SATCHER. I think so, but it is going to require a lot of changes in our behavior as humans, because sometimes we think the microorganisms are winning right now. I think we misuse antibiotics. Physicians sometimes prescribe inappropriately, and because of that, antibiotics are misused and they are used in such a way that microorganisms tend to become more resistant. Sometimes patients overuse antibiotics, and that is a problem also, if you use them sporadically as opposed to completing a course. We have seen this with tuberculosis and other problems.

And then I mentioned earlier in the way we deal with the food supply and the way we deal with animals, stimulates the development of antibiotic resistance. If you think about what has happened in the last 20 years, pneumococci, gonococcal organisms, and tuberculosis have all developed significant drug resistance and are

major problems for us. The same thing is true in the food supply. Even though we don't use antibiotics as much for illnesses like *Campylobacter* or *salmonella,* the risk is still there and we are very concerned about it.

Mr. DAVIS. Connecticut is part of the active—this, I know Mr. Shays wants me to ask this. Connecticut is part of the active surveillance pilot. What is the significance of the recent survey of Connecticut laboratories finding a high incidence of antibiotic resistant microbes?

Dr. SATCHER. Well, I think it is significant. Let me use the example that I know best. We compared Atlanta with Connecticut in terms of strep pneumonia, a major cause of childhood ear infections. And in Atlanta, 25 to 30 percent of the pneumonia organisms were resistant to penicillin. In Connecticut, that figure was 3 to 5 percent. So here, you have two different locations in the country with a significantly different prevalence of antimicrobial resistance to penicillin.

Mr. DAVIS. There seems to be a perception that consumers will never like irradiated foods. A recent survey indicated that about 45 percent of consumers would accept irradiated foods. The Radura symbol, which the Members have, has been adopted for irradiated foods.

What is the panel's perception of consumers toward irradiated foods and the symbol?

Dr. SATCHER. I will be brief. CDC feels that the irradiation of foods is both effective and safe, and we are following FDA's lead on that. We believe that the time has, in fact, come for this technique to be used. We believe that one of the major barriers is public education. That is not new. We actually went through something similar to that with immunizations. There was a time when people, the majority of the people were afraid of immunizations, and I think if you go back to 1955 and the polio immunization program and it got off to a bad start, and it caused problems for years.

But I think in time, public education will solve the problem of public resistance to irradiation.

Mr. DAVIS. Does FDA have a comment on that?

Mr. SHANK. Sure. Let me, first of all, say that we agree that irradiated foods are safe and that labeling is not needed to warn some of the dangers about consuming these foods because it is a safe food. However, you mentioned the symbol, the international symbol to indicate that the food had been irradiated. We believe that the protection of public health is not the only valid reason for requiring labeling.

For example, processing information that informs consumers that fruit juice is reconstituted from concentrate allows the consumer to distinguish between these two products.

Now, let me give you a specific example for irradiation. Irradiation has effects on the characteristic of the food that are sometimes important to the consumer. For example, if strawberries are irradiated to slow down maturation, the consumer needs to know this. However, if the strawberry is used in preservative—in preserves where it would not carry the irradiation symbol, then it has no impact on the product, and therefore, it is not appropriate under

those circumstances. So there are certain situations where this type of labeling is a benefit to the consumer and we feel necessary.

Mr. DAVIS. OK. Let me recognize Mr. Towns.

Mr. TOWNS. Thank you very much.

Let me begin by saying, I was listening to, I think Dr. Satcher, you indicated that, about the State labs. How do you ensure that States are aggressively carrying out their end of the data collection activities? Since current compliance is voluntary and quality and quantity of data is inconsistent, how will the new programs you have discussed deal with this issue?

Dr. SATCHER. I think we have a program, as you know, that allows us to look at the quality of laboratories, even private laboratories. But we are not, you know, in general, we are not a regulatory agency, even though we have some clinical laboratory regulation authority.

But specifically to answer your question, we believe that the States need more support to strengthen the quality of the laboratories in terms of surveillance and response. And therefore, when we wrote our plan for emerging infectious diseases, a major part of that plan was that CDC would provide funds to States and technical assistance to States to strengthen their laboratories, their ability to detect microorganisms, like *E. coli* O157:H7. The majority of the States in the country, the laboratories, were unable to detect *E. coli* O157:H. So we believe that every State should be brought up to the point that they could detect *E. coli* O157:H7.

So part of what we are doing with these 15 States, and hopefully we will be able to add 15 more, and in time all of the States or regional laboratories, to have the capacity to detect new microorganisms or emerging microorganisms. So we are working very closely with the States. We are providing technical assistance, we are providing funds, and we have this reporting—the public health laboratory information system is one of the most sophisticated reporting systems that we have ever developed in this country.

Mr. TOWNS. I understand that you are not a regulator. But I think my concern is that if you find the State that is really not cooperating, we know that that is going on, what do we do? Actually I am asking for suggestions I guess more than anything else.

Dr. SATCHER. I should point out that CDC has a very close working relationship with the Association of State and Territorial Public Health Laboratory Directors. They have a very close working relationship. We have a very close working relationship with the Council of State and Territorial Epidemiologists, and I think that working relationship is what we are using in order to get States up to par.

We are not using regulation, but we are using our funding relationships, which are very important. We can—we are in a position to reward States, if you will, to provide incentives for States to improve their laboratories. So that is the strategy that we are using right now, primarily.

There is some regulation authority that we have in terms of certain basic requirements, but we are trying to get beyond the basic requirements.

Mr. TOWNS. Right. Let me be specific, because, you see, I am not going to leave this.

Should there be specific national reporting requirements? I think that is really what I am trying to get to. I mean, should we have national reporting requirements?

Dr. SATCHER. Well, I think we have to decide if that is necessary. So far, we have allowed States to, working together, to decide on what diseases are reportable. CDC has had a lot of input into that. So, so far, we think that that has gone very well in terms of what diseases are reportable and what are not. There are some that should be reported, but that are still not, but we have made a lot of progress in recent years of adding diseases to that list of reportable diseases.

I think your question is an excellent one, and I am not trying to bypass it, I am just saying that the process that we have had is a cooperative process, not with individual States, I don't mean to imply that, but with the organization of State leaders and public health. Working with that organization, the Association of State and Territorial Directors, we have been able to agree on reportable diseases. That process is working pretty well. But I think it is always appropriate to re-evaluate it periodically.

Mr. TOWNS. Well, let me just move on to something else.

You mentioned in terms of the surveillance system which is in place in five States, and you gave some statistics about how many people that it really covered. How many was that?

Dr. SATCHER. I said about 13.5 million people. So we estimate about 5 percent of the population is now covered by this first phase of active food borne surveillance system, four States and the city of Atlanta.

We have a site in Atlanta. We would add three more of those if we get the funding that we are requesting in 1997, and as you understand, these are primarily research programs. So in addition to the State Health Department, they include a major university system in Connecticut. For example, Yale is involved. In California, it is the University of California, Berkeley and San Francisco. So in every one of these major programs, we have a relationship between the State, between university systems, and sometimes the private sector, in making sure that we have in place strong programs to better collect data and to act on it.

Mr. TOWNS. I have just been informed that we have to go for a vote, break for a vote.

But you know, I am just sort of concerned about the fact that why we would go expand it nationwide, and show a real commitment?

Dr. SATCHER. Let me tell you what our strategy——

Mr. TOWNS. How much would it cost?

Dr. SATCHER. I think it is a good question. Our strategy calls for a national system of surveillance and response, the kind that you have been describing, that is reliable. And if we get funding in 1997, we will have 30 States where we are developing very strong surveillance and response programs. We would like to feel in time that all 50 States are up to par in terms of surveillance and response. The question is whether we need research programs in all 50 States or the kind that we are describing for these five sites and aid sites, I think that is debatable, but we certainly would like them to be regional.

Mr. TOWNS. I sure would like to get one in New York so that I could ask the question that Mr. Shays asked.

Mr. DAVIS. Maybe next time.

We are going to recess the hearing. We are going to go vote and we will be back in probably 10 or 15 minutes.

[Brief recess.]

Mr. GUTKNECHT [presiding]. I am going to call the hearing back to order, and I apologize to the witnesses and the others in the audience that we have a number of votes going on, and people in other meetings—so people are going to come in and out.

I have a particular interest in this for several reasons. First of all, I represent Minnesota where we have an awful lot of food processors. Second, I may be the only Member of Congress who has had food poisoning twice during his life. Once I got it from eating at one of the most expensive restaurants in the Twin Cities. The other was when I had breakfast at the Governor's Mansion in St. Paul. So sometimes bad things happen despite our best efforts, and I want to thank the panel for joining us. I have appreciated the testimony.

I wonder if I could ask about—and as a neophyte, can you tell us or tell me a little about *Campylobacter* and what is happening with it, and why we haven't been a bit more aggressive? Anybody?

Dr. MORRIS. *Campylobacter* is a pathogen that we really have only recognized within the last 20 years or so. So while it has probably been around for quite a while, it is clearly a newly recognized pathogen.

We are just now beginning to learn about where it is, how it is transmitted, and appropriate risk reduction approaches. So I think part of the response has to be that we are still in something of a data-gathering mode in terms of *Campylobacter.* But I think the other side of it is that, as we learn more about *Campylobacter,* we are beginning to identify sources. One reason I am sitting here is that when we talk about *Campylobacter,* poultry is clearly a major source for *Campylobacter,* and there are some studies, some studies in Washington State, Dr. Kobayashi will be speaking later, that show as many as 39 to 50 percent of cases in this country can be attributed to poultry. Consequently, for us at USDA with regulatory responsibility for poultry, *Campylobacter* is, indeed, a major source of concern.

Mr. GUTKNECHT. Can you tell me, what are the consequences? Is it life threatening or is it principally just diarrhea?

Dr. MORRIS. The acute illness basically is acute diarrhea. I have taken care of a number of patients with *Campylobacter.* It is not the sort of thing that you really would want to get. You tend to be ill for a couple of days. It can be really fairly nasty with bloody diarrhea, but nonetheless, it does not cause septicemia; the bug does not get into the bloodstream unless it is a patient with AIDS or some other patients with a problem with their immune system.

There are potential long-term consequences, is what we have learned, and clearly the Guillain-Barre syndrome is one. Guillain-Barre syndrome is a syndrome of ascending paralysis, whereby in severe cases, essentially the patient stops breathing, which is not good. And what it generally requires is prolonged stays in intensive care units and it can be an extremely expensive illness, not to men-

tion a severe illness which can cause a great many problems with the individual. It is estimated that we may have as many as 4,000 or so Guillain-Barre cases in this country per year.

Again, the estimates are very soft, and there are people coming on subsequent panels who may be able to give better characterization or CDC may be able to. But essentially, of those, probably 20 to 30 percent may be attributable to prior instances of campylobacteriosis.

So again, it is a significant health problem, it is one of the health problems which has caused USDA to target the implementation of a new regulatory strategy for meat and poultry. Again, the focus of this administration has been on food safety and development of new regulatory approaches, and at USDA, that is highlighted by our new HACCP rule, which will be focused on trying to reduce the incidence of this and similar hazards in raw meat and poultry.

Mr. GUTKNECHT. Could you share with us what you think are the most effective risk reduction factors that USDA and producers can take?

Dr. MORRIS. Well, again, I think this needs to be taken in the framework of HACCP, which basically is a hazard analysis critical control point system, which means that it is the responsibility of industry to identify the hazards and to develop appropriate interventions and monitoring points, control points along the way to make sure that these interventions are being done and that we are trying to minimize the pathogens that are present. Obviously, any HACCP program for poultry has got to take into account *Campylobacter,* as *Campylobacter* is one of the major hazards associated with raw poultry.

There are a number of new technological innovations which can be applied during the slaughter and processing procedures which can reduce *Campylobacter*. Actually, one can sort of look at it on two levels. *Campylobacter* infects a number of—you know, a percentage of flocks of chickens. It tends to be flock specific so that certain flocks are infected, others are not. Obviously, one critical control point would be looking at the flocks as they come into the processing plant to see whether or not they are infected.

Mr. GUTKNECHT. Visually? Can you tell?

Dr. MORRIS. You can't tell visually. One is going to need to go into microbial testing and using new methodologies, as opposed to the standard organoleptic techniques. This is where we come back to the HACCP concept in that we need to place these responsibilities upon industry. We need to have industry develop appropriate procedures and control points so that we can try to limit this pathogen, both coming into the plant and also during the slaughter process.

Again, there are a number of new innovative technologies which are coming now, which will enable the plants to reduce the degree of fecal contamination on the product, and which in turn hopefully will be able to reduce the levels of *Campylobacter*.

Mr. GUTKNECHT. Would any other members of the panel like to talk a little bit about the consequences and what we can do about it?

Dr. SATCHER. The only thing that I would want to just highlight from Dr. Morris' statement was that a major part of the active food

borne surveillance program that we have going will be looking more closely at *Campylobacter* to try to better understand the sources of the microorganisms and the consequences. So these programs are able to look at the sources of infection, but also what happens to a population of people. We estimate that there are about 2 million cases a year of *Campylobacter* infection, and we can learn much more about those infections in these emerging infection programs. One of course is in Minnesota, as you know. It is one of the four States with these programs.

Mr. SHANK. I think it has been adequately covered. Thank you.

Mr. GUTKNECHT. I am joined now by my colleague, Mr. Souder from Indiana. Did you have any questions or comments?

Mr. SOUDER. No. I will come in and I will listen for a while and then see if I develop some. I know Mr. Towns is right behind me coming over from the vote, so he should be here, very shortly here, too.

Mr. GUTKNECHT. I also understand you were asked about food irradiation. I missed the response, and I was just curious from a health perspective, and for my edification, if not for the record, I mean do you believe it is safe and effective and should we be doing more about it, and what about labeling?

Dr. SATCHER. Well, both CDC and FDA responded. From CDC's perspective, it is both safe and effective. And we think the major barriers to its use probably relate to better public education. And I think we have a lot of that to do.

I just reminded the panel that that is not new to a new public health intervention. We have gone through similar things with immunizations and some of the other interventions, where until the public is comfortable and knowledgeable about it, then they have reasons to be suspicious and concerned.

Mr. SHANK. I spoke unequivocally that I think that irradiation is safe, and also addressed the labeling issue. I would use the issue of strawberries to demonstrate the point.

Where you have irradiated strawberries and a delay in the maturation of strawberries and therefore extend the shelf life, this would be information that the consumer needs to know. I mean, those strawberries will undoubtedly be treated differently than the ones that are not irradiated. However, as you take the strawberries and make jam out of them, the irradiation is not going to have any effect on that jam; therefore, it is not appropriate for it to be—wouldn't be necessary to be labeled and we would not require it.

So there are certain situations where labeling is of a benefit to the consumer and needs to be provided for reasons other than strictly safety.

Mr. GUTKNECHT. How long will it extend the shelf life of things like strawberries? Again, for my benefit.

Mr. SHANK. The period is significant, but I don't have that data before me right now. But that is one of irradiation's primary advantages when you are talking about fresh produce.

Dr. MORRIS. I didn't say anything last time, so I will toss in my 2 cents worth here.

From the USDA perspective, irradiation for poultry and pork is approved, and again, obviously, irradiation is an effective methodology for reducing microbial loads. Our perspective is that it is

clearly something which can be included as part of a HACCP plan, but again, from a conceptual approach, where we are moving with HACCP is to say that the responsibility for food safety rests with the industry, and so we are not in a command and control situation where we say you have to do this or you have to do that. Irradiation is one component, it is one modality which can be used by the industry to produce a safer product, and so if the industry elects to use it, they are perfectly welcome to do so. There is nothing standing in their way.

But again, they need to develop a HACCP plan which looks overall at producing a safer product, and irradiation may be plugged in as a component of that.

Mr. GUTKNECHT. It would seem to me, though, that it would be helpful to the industry and to consumers as well if, particularly if CDC would sort of take up the job of helping to educate consumers, because I think there is undue alarm among a lot of consumers about what the potential health consequences of irradiated food are. So I would encourage you to, at least, consider that and talk about it.

Dr. SATCHER. We are, in fact, considering that.

Mr. GUTKNECHT. I am joined by my colleague, Mr. Towns, and my 5 minutes has more than expired. Any questions or comments?

Mr. TOWNS. Thank you very much.

Let me just sort of direct this to you, Dr. Shank. Microbial testing of seafood products, you don't have any requirements for testing seafood. Is there a reason for that?

Mr. SHANK. I am not quite sure of your question. I would point out that——

Mr. TOWNS. Does FDA, the HACCP Program include requirements for microbial testing of seafood products?

Mr. SHANK. OK, in the context of the HACCP Program, let me say that our program is designed primarily—among other hazards, to address microbial problems. There will be microbial testing required to establish an effective program. In other words, we need to know where the microbes are coming and what the critical control points are in order to get rid of the microbes, to make the food safe.

As far as the HACCP Program per se, and are we requiring end-product testing, the answer to that is no. Of course, end-product testing will be used as a verification that the overall program is working and it will be important in that regard.

Mr. TOWNS. I think, let's go a little further. Why not?

Mr. SHANK. If we are dealing with a ready-to-eat product, it is—we need to determine what the critical control points are and make sure that we are producing a product that has no pathogens when it is—leaves the production plant and made available to the consumer.

The whole concept of—an important concept of HACCP is to design a system whereby you produce a safe product. The inspection system we have today is dependent upon end-product testing, and that is only as good as the products that you actually subject to the test.

So what we are doing is designing a program, implementing one that has greater assurances that you are going to achieve your goal

of having no pathogens in the ready-to-eat product once it is made available.

Mr. TOWNS. Let me switch to Dr. Morris.

Dr. Morris, first of all, when will USDA publish the final rule implementing HACCP?

Dr. MORRIS. I wish I knew. The final rule has cleared the department, and it is undergoing final OMB review. We are hopeful that within a matter of weeks the final rule will be published. Obviously, again, since it is not yet published, I am somewhat constrained about what I can say about it. Nonetheless, we are optimistic that we are on the home stretch and that we will, indeed, have a final HACCP rule within the very near future.

Mr. TOWNS. Well, let me ask you, how—well, I guess, maybe I will just sort of skip that because of the fact that you indicated that you are having some problems talking about it, so I won't pursue it any further. I will respect that.

But I am concerned that we have the proper kind of coordination here to be able to address these problems in a very organized fashion, and that is really, you know, my concern.

Dr. MORRIS. I think I can reassure you on that. Again, I think what has happened over the last several years is that there has been very much the development of a team approach between FDA, CDC, and us in terms of dealing with food borne disease problems. It is reflected, as I said, the model is the sentinel site—five-State, sentinel-site system which for the first time gives us active surveillance. Those are critical data which is an input into what we are doing in terms of developing a HACCP system in which we will need to monitor the outcomes of what we are doing in terms of HACCP. There is constant communication between the agencies. CDC has played a key role in terms of the various conferences we have had and the work we have done on the development of HACCP. Dr. Potter, we have borrowed from CDC, I think he sort of lives in Washington here, for some of the work he has been doing in terms of working with us.

So across the board, I think we are doing this. Again, I think this is a new age. We really have a major new regulatory approach to food safety between the HACCP programs being developed by FDA and the HACCP programs being developed by USDA.

Mr. TOWNS. I am not trying to pick a fight or start a fight, but Dr. Satcher and Dr. Shank, do you agree with what Dr. Morris just said, and you too, Dr. Potter?

Mr. SHANK. Well, I certainly think that we are improving upon our collective efforts for the three agencies that are represented here today, and the reason we are doing it is primarily the reason that you all are having this hearing, because of our increased concern about food borne diseases and the fact that we need to do a better job.

And yes, we do—we will work with USDA and continue to work as the two agencies implement this new form of regulatory system for our food supply.

Dr. SATCHER. I would agree, too. And I will ask Dr. Potter if he wants to comment. He has worked very closely with USDA.

But I think the whole attitude and strategy of our approach to this whole thing is more coordination and collaboration. We very

seldom develop plans now that we don't develop jointly with our colleagues. And as I said, the fact that they are willing to fund programs with CDC and to place people there virtually full time to assure better coordination and collaboration, I think it is a major step forward.

Do you want to comment?

Mr. POTTER. I think in the last 5 years there has been an unprecedented level of coordination and communication among the Federal agencies so that we can go out to the public as a single Federal Government responding to food safety and foodborne disease prevention issues. Some of our changes in the way we are doing surveillance in response to the emerging infectious disease plan fit nicely into the need for more population-based quantitative data for decisionmaking on the part of the regulatory agencies.

Mr. TOWNS. Thank you very much. Mr. Chairman, I yield back.

Mr. GUTKNECHT. Thank you. Mr. Souder, any questions?

Mr. SOUDER. No. I have been trying to go through the testimony and catch up, and it is pretty detailed, so I think I will just listen a little bit more before I ask any questions.

Mr. GUTKNECHT. I want to thank the witnesses. I am particularly delighted to hear terms like collaboration, cooperation between the agencies and in the Government itself, because I think Americans have every right to expect that our food supply is safe, and I think if we all work together we can move in that direction. So again, thank you so much for sharing your testimony this morning.

We will call up the next panel. This committee and subcommittee has a rule that before you can testify, you must rise and raise your right hands.

[Witnesses sworn.]

Mr. GUTKNECHT. Please note for the record that the witnesses answered in the affirmative. We know who Mr. Robinson is. Would the other witness please identify himself?

Mr. ZADJURA. My name is Edward Zadjura, and I am the Assistant Director of——

Mr. GUTKNECHT. Can we bring the microphone a little closer?

Mr. ZADJURA. Ed Zadjura, Assistant Director at GAO.

Mr. GUTKNECHT. Which one of you wants to start? Mr. Robinson.

STATEMENT OF ROBERT A. ROBINSON, DIRECTOR, FOOD AND AGRICULTURE ISSUES AREA, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY EDWARD M. ZADJURA, ASSISTANT DIRECTOR, GENERAL ACCOUNTING OFFICE

Mr. ROBINSON. We are pleased to be here to report on our recent report on foodborne illnesses and to revisit the findings of many of our previous reports on problems in the Nation's food safety system. You have just met Ed Zadjura. He has been in this area for more than a decade now and is the principal author of those reports that I just referred to.

I do, of course, have a written statement for the record, but let me just confine my oral remarks to just a couple of highlights. Specifically, I want to first provide a quick overview of the foodborne illness situation. Second, point out weaknesses and available illness data that limit its use on this in devising control strategies,

and, third, discuss structural weaknesses that we believe hinder our food safety system's effectiveness and reduce its efficiency.

Starting with the problem, estimates of the number of foodborne illnesses that occur each year range widely, as we have heard from some of the statements from the members. The best available data, however, indicates that the number of illnesses traceable to contaminated foods each year is in the millions, ranging from 6.5 million on the—according to the estimate on the low side, and to 81 million on the high end. The most frequently identified cause of foodborne illness is microbial.

In addition, of course, public health experts believe the risk is increasing for a variety of reasons. We have heard about the issue of the distribution and food production systems. Adding to that, however, is the risk—adding to the risk is the increasing population of individuals such as the elderly that are at greater risk of contracting foodborne illnesses.

While most foodborne illnesses cause mild temporary digestive track disorders, some experts believe that about 2 to 3 percent lead to serious medical consequences, including kidney failure, meningitis, GBS, and some, perhaps 9,000 a year, result in death. The overall annual cost of foodborne illnesses is unknown, but estimates from USDA's Economic Research Service range from $5.6 to $22 billion annually from the major pathogens that they tracked alone.

In considering this statistical information, it is important to recognize that there are weaknesses in the system used to collect foodborne illness data. These weaknesses probably result in foodborne illnesses being undercounted. Also, the data are not sufficiently detailed, particularly as to the source of the illness, to permit regulatory agencies to develop the most informed control strategies or assess effectiveness of those strategies.

CDC has, as you have learned, no authority to mandate State reporting of foodborne illness cases, and existing reporting is therefore voluntary and uneven. To help address this situation, you have just learned about the five-States sentinel study to more aggressively track two major pathogens that cause foodborne illnesses, namely *E. coli* O157:H7 and *salmonella* in five areas of the country.

In contrast to the more passive data collection approach that normally characterizes the system, in this case the agencies are making a more proactive effort to determine the incidence of disease and, importantly, the source of the illness.

Finally, Mr. Chairman, I just want to turn for a moment to the structural problems that we believe will continue to hamper the performance of the food safety system, even in the presence of much improved data. As we have frequently reported, the U.S. food safety system is not the result of a rational plan. Rather, it is defined by a patchwork of inconsistent approaches that subjects food products posing essentially the same risk to widely differing rules. Inefficiently deployed limited inspection resources necessitates extensive coordination activities among the various regulatory bureaucracies, and these coordination activities, as we have reported, have not always worked.

These problems ultimately mean that our food safety system is not as effective as it could be in controlling foodborne pathogens. Earlier in the decade these structural problems hindered the Federal Government's efforts to control *salmonella* X. More recently, this problem is re-emerging in the form of differing HACCP requirements for meat and poultry as proposed by FSIS and seafood as proposed by FDA.

Prospectively, similar problems of split jurisdiction may affect potential Federal efforts to control BSG should such efforts become necessary. In this case, FSIS is responsible for ensuring responsibility for the safety of meat products sold to the public, but is not responsible for preventing cattle from being given feeds that could adversely affect it.

We continue to believe that establishment of a uniform, scientific, risk-based food safety system is the best way to reduce the incidence of foodborne illnesses and improve the safety of the Nation's food supply.

With that, I will stop my comments, and I will be happy to try to address any questions.

Mr. GUTKNECHT. Thank you, Mr. Robinson.

I think we will go and take the rest of the testimony and then have questions.

Mr. ROBINSON. I speak for both of us. We are finished.

[The prepared statement of Mr. Robinson follows:]

Statement of Robert A. Robinson, Director
Food and Agriculture Issues,
Resources, Community, and Economic Development Division

We are pleased to be here today to participate in this hearing on foodborne pathogens and their impact on public health. In previous reports and testimonies, we have discussed many aspects of food safety, including inspection and coordination activities and efforts to protect against unsafe chemical residues and microbiological hazards. Today, as you requested, we will focus on what is and is not known about the scope, severity, and cost of foodborne illnesses in the United States. We will also summarize our prior work on the structural problems that limit the federal government's ability to ensure food safety.

In summary, in our May 1996 report on foodborne illnesses,[1] we reported that existing data, although incomplete, indicate that foodborne illnesses are widespread and costly. Specifically, the best available data on foodborne illnesses demonstrate the following:

- Millions of illnesses and thousands of deaths in the United States each year can be traced to contaminated food. Moreover, the actual incidence may be much higher because public health experts believe that most cases are not reported. These experts also believe that the risk of foodborne illnesses has been increasing over the last 20 years.

- Foodborne illnesses generally cause temporary disorders of the digestive tract, but they can also lead to serious, long-term health consequences. Recent estimates of the cost of foodborne illnesses range from over $5 billion to over $22 billion annually. For example, the cost of medical treatment and lost productivity related to foodborne illnesses from seven of the most harmful bacteria ranged from $5.6 billion to $9.4 billion in 1993.

While providing useful indicators concerning the extent of foodborne illnesses, existing data have limitations. Public health and food safety experts believe that current data on foodborne illnesses do not provide a complete picture of the risk level and do not depict the sources of contamination and the populations most at risk in sufficient detail. More uniform and comprehensive data on the number and causes of foodborne illnesses could enable the development of more effective control strategies. While federal and state agencies have begun to collect such data in five areas across the country, federal officials expressed some concern about whether they would be able to continue funding this discretionary effort.

Providing more comprehensive data would help federal food safety officials develop better control strategies but would not address the structural problems with the food

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[1]Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

safety system. As we have previously reported,[2] the system evolved over many years in response to specific health threats and new technological developments, resulting in a patchwork of inconsistent approaches that weaken its effectiveness. Food products with similar risks are subject to different rules, limited inspection resources are not efficiently used, and agencies must engage in extensive and often unsuccessful coordination activities in an attempt to address food safety activities.

BACKGROUND

The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services is the federal agency primarily responsible for monitoring the incidence of foodborne illness in the United States. In collaboration with state and local health departments and other federal agencies, CDC investigates outbreaks of foodborne illnesses and supports disease surveillance, research, prevention efforts, and training related to foodborne illnesses. CDC coordinates its activities concerning the safety of the food supply with the Food and Drug Administration (FDA), which is also in the Department of Health and Human Services. With respect to the safety of meat, poultry, and eggs, CDC coordinates with the Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA).

CDC monitors individual cases of illness from harmful bacteria, viruses, chemicals, and parasites (hereafter referred to collectively as pathogens) that are known to be transmitted by foods, as well as foodborne outbreaks, through voluntary reports from state and local health departments, FDA, and FSIS. In practice, because CDC does not have the authority to require states to report data on foodborne illnesses, each state determines which diseases it will report to CDC. In addition, state laboratories voluntarily report the number of positive test results for several diseases that CDC has chosen to monitor. However, these reports do not identify the source of infection and are not limited to cases of foodborne illness. CDC also investigates a limited number of more severe or unusual outbreaks when state authorities request assistance.

At least 30 pathogens are associated with foodborne illnesses. For reporting purposes, CDC categorizes the causes of outbreaks of foodborne illnesses as bacterial, chemical, viral, parasitic, or unknown pathogens. Although many people associate foodborne illnesses primarily with meat, poultry, eggs, and seafood products, many other foods--including milk, cheese, ice cream, orange and apple juices, cantaloupes, and vegetables--have also been involved in outbreaks during the last decade.

Bacterial pathogens are the most commonly identified cause of outbreaks of foodborne illnesses. Bacterial pathogens can be easily transmitted and can multiply rapidly in food,

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[2]Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

making them difficult to control. CDC has targeted four of them–E. coli O157:H7, Salmonella Enteritidis, Listeria monocytogenes, and Campylobacter jejuni–as being of greatest concern.

FOODBORNE ILLNESSES ARE BELIEVED TO BE A SIGNIFICANT AND GROWING PROBLEM

The existing data on foodborne illnesses have weaknesses and may not fully depict the extent of the problem. In particular, public health experts believe that the majority of cases of foodborne illness are not reported because the initial symptoms of most foodborne illnesses are not severe enough to warrant medical attention, the medical facility or state does not report such cases, or the illness is not recognized as foodborne. However, according to the best available estimates, based largely on CDC's data, millions of people become sick from contaminated food each year, and several thousand die. In addition, public health and food safety officials believe that the risk of foodborne illnesses is increasing for several reasons.

Between 6.5 million and 81 million cases of foodborne illness and as many as 9,100 related deaths occur each year, according to the estimates provided by several studies conducted over the past 10 years. The wide range in the estimated number of foodborne illnesses and related deaths is due primarily to the considerable uncertainty about the number of cases that are never reported to CDC. For example, CDC officials believe that many intestinal illnesses that are commonly referred to as the stomach flu are caused by foodborne pathogens. People do not usually associate these illnesses with food because the onset of symptoms occurs 2 or more days after the contaminated food was eaten.

Furthermore, most physicians and health professionals treat patients who have diarrhea without ever identifying the specific cause of the illness. In severe or persistent cases, a laboratory test may be ordered to identify the responsible pathogen.

Finally, physicians may not associate the symptoms they observe with a pathogen that they are required to report to the state or local health authorities. For example, a CDC official cited a Nevada outbreak in which no illnesses from E. coli O157:H7 had been reported to health officials, despite a requirement that physicians report such cases to the state health department. Nevertheless, 58 illnesses from this outbreak were subsequently identified. In the absence of more complete reporting, researchers can only broadly estimate the number of illnesses and related deaths.

Food safety and public health officials believe that several factors are contributing to an increased risk of foodborne illnesses. First, the food supply is changing in ways that can promote foodborne illnesses. For example, as a result of modern animal husbandry techniques, such as crowding a large number of animals together, the pathogens that can cause foodborne illnesses in humans can spread throughout the herd. Also, because of broad distribution, contaminated food products can reach more people in more locations.

Subsequent mishandling can further compound the problem. For example, leaving perishable food at room temperature increases the likelihood of bacterial growth and undercooking reduces the likelihood that bacteria will be killed. Knowledgeable experts believe that although illnesses and deaths often result from improper handling and preparation, the pathogens were, in many cases, already present at the processing stage.

Second, because of demographic changes, more people are at greater risk of contracting a foodborne illness. In particular, certain populations are at greater risk for these illnesses: people with suppressed immune systems, children in group settings like daycare, and the elderly.

Third, three of the four pathogens CDC considers the most important were unrecognized as causes of foodborne illness 20 years ago–Campylobacter, Listeria, and E. coli O157:H7.

Fourth, bacteria already recognized as sources of foodborne illnesses have found new modes of transmission. While many illnesses from E. coli O157:H7 occur from eating insufficiently cooked hamburger, these bacteria have also been found more recently in other foods, such as salami, raw milk, apple cider, and lettuce.

Fifth, some pathogens are far more resistant than expected to long-standing food-processing and storage techniques previously believed to provide some protection against the growth of bacteria. For example, some bacterial pathogens (such as Yersinia and Listeria) can continue to grow in food under refrigeration.

Finally, according to CDC officials, virulent strains of well-known bacteria have continued to emerge. For example, one such pathogen, E. coli O104:H21, is another potentially deadly strain of E. coli. In 1994, CDC found this new strain in milk from a Montana dairy.

FOODBORNE ILLNESSES CAN BE DEBILITATING AND COSTLY

While foodborne illnesses are often temporary, they can also result in more serious illnesses requiring hospitalization, long-term disability, and death. Although the overall cost of foodborne illnesses is not known, two recent USDA estimates place some of the costs in the range of $5.6 billion to more than $22 billion per year. The first estimate, covering only the portion related to the medical costs and productivity losses of seven specific pathogens, places the costs in the range of $5.6 billion to $9.4 billion. The second, covering only the value of avoiding deaths from five specific pathogens, places the costs in the range of $6.6 billion to $22 billion.

Although often mild, foodborne illnesses can lead to more serious illnesses and death. For example, in a small percentage of cases, foodborne infections can spread through the bloodstream to other organs, resulting in serious long-term disability or death. Serious complications can also result when diarrhetic infections resulting from foodborne pathogens act as a triggering mechanism in susceptible individuals, causing an illness

such as reactive arthritis to flare up. In other cases, no immediate symptoms may appear, but serious consequences may eventually develop. The likelihood of serious complications is unknown, but some experts estimate that about 2 to 3 percent of all cases of foodborne illness lead to serious consequences. For example:

- E. coli O157:H7 can cause kidney failure in young children and infants and is most commonly transmitted to humans through the consumption of undercooked ground beef. The largest reported outbreak in North America occurred in 1993 and affected over 700 people, including many children who ate undercooked hamburgers at a fast food restaurant chain. Fifty-five patients, including four children who died, developed a severe disease, Hemolytic Uremic Syndrome, which is characterized by kidney failure.

- Salmonella can lead to reactive arthritis, serious infections, and deaths. In recent years, outbreaks have been caused by the consumption of many different foods of animal origin, including beef, poultry, eggs, milk and dairy products, and pork. The largest outbreak, occurring in the Chicago area in 1985, involved over 16,000 laboratory-confirmed cases and an estimated 200,000 total cases. Some of these cases resulted in reactive arthritis. For example, one institution that treated 565 patients from this outbreak confirmed that 13 patients had developed reactive arthritis after consuming contaminated milk. In addition, 14 deaths may have been associated with this outbreak.

- Listeria can cause meningitis and stillbirths and is fatal in 20 to 40 percent of cases. All foods may contain these bacteria, particularly poultry and dairy products. Illnesses from this pathogen occur mostly in single cases rather than in outbreaks. The largest outbreak in North America occurred in 1985 in Los Angeles, largely in pregnant women and their fetuses. More than 140 cases of illness were reported, including at least 13 cases of meningitis. At least 48 deaths, including 20 stillbirths or miscarriages, were attributed to the outbreak. Soft cheese produced in a contaminated factory was confirmed as the source.

- Campylobacter may be the most common precipitating factor for Guillain-Barre syndrome, which is now one of the leading causes of paralysis from disease in the United States. Campylobacter infections occur in all age groups, with the greatest incidence in children under 1 year of age. The vast majority of cases occur individually, primarily from poultry, not during outbreaks. Researchers estimate that 4,250 cases of Guillain-Barre syndrome occur each year and that about 425 to 1,275 of these cases are preceded by Campylobacter infections.

While the overall annual cost of foodborne illnesses is unknown, the studies we reviewed estimate that it is in the billions of dollars. The range of estimates among the studies is wide, however, principally because of uncertainty about the number of cases of foodborne illness and related deaths. Other differences stem from the differences in the

analytical approach used to prepare the estimate. Some economists attempt to estimate the costs related to medical treatment and lost wages (the cost-of-illness method); others attempt to estimate the value of reducing the incidence of illness or loss of life (the willingness-to-pay method). Two recent estimates demonstrate these differences in analytical approach.

In the first, USDA's Economic Research Service (ERS) used the cost-of-illness approach to estimate that the 1993 medical costs and losses in productivity resulting from seven major foodborne pathogens ranged between $5.6 billion and $9.4 billion. Of these costs, $2.3 billion to $4.3 billion were the estimated medical costs for the treatment of acute and chronic illnesses, and $3.3 billion to $5.1 billion were the productivity losses from the long-term effects of foodborne illnesses.

CDC, FDA, and ERS economists stated that these estimates may be low for several reasons. First, the cost-of-illness approach generates low values for reducing health risks to children and the elderly because these groups have low earnings and hence low productivity losses. Second, this approach does not recognize the value that individuals may place on (and pay for) feeling healthy, avoiding pain, or using their free time. In addition, not all of the 30 pathogens associated with foodborne illnesses were included.

In the second analysis, ERS used the willingness-to-pay method to estimate the value of preventing deaths for five of the seven major pathogens (included in the first analysis) at $6.6 billion to $22 billion in 1992. The estimate's range reflected the range in the estimated number of deaths, 1,646 to 3,144, and the range in the estimated value of preventing a death, $4 million to $7 million. Although these estimated values were higher than those resulting from the first approach, they may have also understated the economic cost of foodborne illnesses because they did not include an estimate of the value of preventing nonfatal illnesses and included only five of the seven major pathogens examined in the first analysis.

BETTER DATA COULD LEAD TO MORE EFFECTIVE CONTROL STRATEGIES

The federal food safety system has evolved over the years as changes were made to address specific health threats and respond to new technological developments. Often such changes occurred in reaction to a major outbreak of foodborne illness when consumers, industry, regulatory agencies, and the Congress agreed that actions needed to be taken. The system has been slow to respond to changing health risks, for a variety of reasons, including a lack of comprehensive data on the levels of risk and the sources of contamination.

While current data indicate that the risk of foodborne illnesses is significant, public health and food safety officials believe that these data do not identify the level of risk, the sources of contamination, and the populations most at risk in sufficient detail. According

to these experts, the current voluntary reporting system does not provide sufficient data on the prevalence and sources of foodborne illnesses. There are no specific national requirements for reporting on foodborne pathogens. According to CDC, states do not (1) report on all pathogens of concern, (2) usually identify whether food was the source of the illness, or (3) identify many of the outbreaks or individual cases of foodborne illness that occur.

Consequently, according to CDC, FDA, and FSIS, public health officials cannot precisely determine the level of risk from known pathogens or be certain that they can detect the existence and spread of new pathogens in a timely manner. They also cannot identify all factors that put the public at risk or all types of food or situations in which microbial contamination is likely to occur. Finally, without better data, regulators cannot assess the effectiveness of their efforts to control the level of pathogens in food.

More uniform and comprehensive data on the number and causes of foodborne illnesses could form the basis of more effective control strategies. A better system for monitoring the extent of foodborne illnesses would actively seek out specific cases and would include outreach to physicians and clinical laboratories. CDC demonstrated the effectiveness of such an outreach effort when it conducted a long-term study, initiated in 1986, to determine the number of cases of illness caused by Listeria. This study showed that a lower rate of illness caused by Listeria occurred between 1989 and 1993 during the implementation of food safety programs designed to reduce the prevalence of Listeria in food.

In July 1995, CDC, FDA, and FSIS began a comprehensive effort to track the major bacterial pathogens that cause foodborne illnesses. These agencies are collaborating with the state health departments in five areas across the country to better determine the incidence of infection with Salmonella, E. coli O157:H7, and other foodborne bacteria and to identify the sources of diarrheal illness from Salmonella and E. coli O157:H7.[3] Initially, FDA provided $378,000 and FSIS provided $500,000 through CDC to the five locations for 6 months. For fiscal year 1996, FSIS is providing $1 million and FDA is providing $300,000. CDC provides overall management and coordination and facilitates the development of technical expertise at the sites through its established relationships with the state health departments.

CDC and the five sites will use the information to identify emerging foodborne pathogens and monitor the incidence of foodborne illness. FSIS will use the data to evaluate the effectiveness of new food safety programs and regulations to reduce foodborne pathogens in meat and poultry and assist in future program development. FDA will use the data to

[3]The areas are (1) the greater metropolitan area of Atlanta, (2) an area that is comprised of two northern California counties, (3) an area that is comprised of two Connecticut counties, (4) the state of Minnesota, and (5) the state of Oregon.

evaluate its efforts to reduce foodborne pathogens in seafood, dairy products, fruit, and vegetables.

The agencies believe that this effort should be a permanent part of a sound public health system. According to CDC, FDA, and FSIS officials, such projects must collect data over a number of years to identify national trends and evaluate the effectiveness of strategies to control pathogens in food. Funding was decreased (on an annualized basis) for this project in 1996, and these officials are concerned about the continuing availability of funding, in this era of budget constraints, to conduct this discretionary effort over the longer term.

STRUCTURAL PROBLEMS LIMIT THE FEDERAL GOVERNMENT'S ABILITY TO ENSURE FOOD SAFETY

While providing more comprehensive data would help federal food safety officials develop better control strategies, it would not address the structural problems that adversely affect the federal food safety system. As we previously testified to this Committee, the current system was not developed under any rational plan but evolved over many years to address specific health threats from particular food products and has not responded to changing health risks.[4] As a result, the food safety system is a patchwork of inconsistent approaches that weaken its effectiveness. For example, as we reported in June 1992, food products posing the same risk are subject to different rules, limited inspection resources are inefficiently used, and agencies must engage in extensive and often unsuccessful coordination activities in an attempt to address food safety issues.

While federal agencies have made progress in moving towards a scientific, risk-based inspection system, foods posing similar health risks, such as seafood, meat, and poultry, are still treated differently because of underlying differences in regulatory approach. For example, FDA's hazard analysis critical control point (HACCP) requirement for seafood processors differs from FSIS' proposed HACCP program for meat and poultry processors.[5] Under FSIS' proposal, meat and poultry plants would be required to conduct microbiological tests to verify the overall effectiveness of their critical controls and processing systems.[6] In comparison, FDA's HACCP program for seafood products has no testing requirement. Furthermore, because the frequency of inspection is based on the

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[4]Food Safety: A Unified, Risk-Based Food Safety System Needed, (GAO/T-RCED-94-223, May 25, 1994).

[5]Food Safety: New Initiatives Would Fundamentally Alter the Existing System (GAO/RCED-96-81, Mar. 27, 1996).

[6]Meat and Poultry Inspection: Impact of USDA's Food Safety Proposal on State Agencies and Small Plants (GAO/RCED-95-228, June 30, 1995) and Analysis of HACCP Costs and Benefits (GAO/RCED-96-62R, Feb. 29, 1996).

agencies' regulatory approach, some foods may be receiving too much attention, while other foods may not be receiving enough. FSIS will conduct oversight of industries that use HACCP programs on a daily basis and will continue to inspect every meat and poultry carcass. Conversely, FDA will inspect seafood plants about once every 2 years and will only inspect other food plants under its jurisdiction an average of about once every 8 years. As we stated in our June 1992 report, such widely differing inspection frequencies for products posing similar risk is an inefficient use of limited federal inspection resources.

Moreover, federal agencies are often slow to address emerging food safety concerns because of fragmented jurisdictions and responsibilities. For example, in April 1992, we reported that jurisdictional questions, disagreement about corrective actions, and poor coordination between FDA and USDA had hindered the federal government's efforts to control Salmonella in eggs for over 5 years.[7] At that time, we stated that the continuing nature of such problems indicated that the food safety structure--with federal agencies having split and concurrent jurisdictions--had a systemic problem. The system's fragmented structure limited the government's ability to deal effectively with a major outbreak of foodborne disease, especially when such an outbreak required joint agency action.

Today, federal agencies are concerned with the potential impact on public health posed by Bovine Spongiform Encephalopathy (the so-called mad cow disease), which was the subject of your May 10, 1996, hearing. Because there is still no single, uniform food safety system, jurisdiction remains split between agencies. Ironically, FSIS is responsible for the safety of meat products sold to the public, but is not responsible for preventing cattle from being given feeds that could endanger public health. FDA is responsible.

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Mr. Chairman, this concludes my prepared remarks, we would be happy to respond to any questions you may have.

(150642)

[7]Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination, (GAO/RCED-92-69, Apr. 21, 1992).

Mr. GUTKNECHT. Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

With the economic costs of foodborne disease ranging from, as you indicated, from $5 to $22 billion, we don't even know how much, would you say that the cost of benefit ratio favors full deployment of the program?

Mr. ROBINSON. I am sorry, what program?

Mr. TOWNS. The surveillance program.

Mr. ROBINSON. I think we are very positive about the enhanced, more active surveillance program that is now being initiated and believe it will be a far superior system to the more passive surveillance that has been going on in the past, and will provide regulators with the informational tools to take more informed action to address pathogenetic risk.

Mr. TOWNS. I think you were here earlier when I asked the question should there be specific national reporting requirements? Should we have national reporting requirements?

Mr. ROBINSON. I don't know that we have the basis to suggest such a mandate. Again, I would come back to this more active approach that is being used in five locations that has been talked about frequently this morning, should provide a much improved basis to generate needed and actionable illness data. Moving into mandates of that gets into the whole issue of unfunded mandates and a whole host of other issues that I am not sure is absolutely necessary.

Mr. TOWNS. I am not sure we do, because what happens is that when you look at the amount of money, $22 billion, if we analyze it, maybe we might save money. We don't know, and nobody has been able to answer that question to me to my satisfaction.

Mr. ROBINSON. That is certainly true. The existing data does not enable a precise quantification. That $22 billion only reflects 7 pathogens of the 30 or more that exist. So it could be even higher than that, of course.

We are just optimistic, and I think based on the work that we just concluded and have very positive feelings about the capability of the active surveillance effort that is being put in place should provide the kind of data, or put the agencies in a much better position to have the kind of data to act upon it and develop control strategies. I guess I am just not willing to be—I don't have the capability to say that a mandated reporting strategy on the part of all 50 States is necessary.

Ed, do you have some comments?

Mr. ZADJURA. We are sort of like a sports broadcasting team. I am sort of the color commentator that comes in with stuff from time to time.

As Bob said——

Mr. TOWNS. As really a former player.

Mr. ZADJURA. As Bob said we don't really have a good basis to make any such recommendation and have no idea what the cost would be, because you have to look at the bigger context of the communicable diseases reporting system.

There are actually 49 diseases that have been recommended by the Consular of State and Territorial Epidemiologists to the States to report. Certainly if we were to attempt to mandate reporting of

all 49 of those diseases, it would get very expensive. To date, only really two of the diseases that are of interest for foodborne are being reported: *Salmonella* and *E. coli* O157:H7. Better reporting would certainly give us the opportunity to develop better programs, better control strategies, but better, even perfect reporting would not solve the problem. We already know there are a lot of illnesses out there and we need to do something. What we really are looking for today is to devise the best control strategy, and we can probably do that without mandatory reporting.

Mr. TOWNS. Let me ask you two quick ones, Mr. Chairman, and then I will be out of the way.

In your view, why does FSIS and FDA have different procedures for the inspection of production facilities? Why is that?

Mr. ROBINSON. It goes back to their basic, almost core approaches. FSIS, of course, through their legislative and statutory requirements, has a preapproval structure. FDA, of course, relies more on postmarket surveillance. The result, of course, is widely differing inspection approaches and techniques. Vastly different for similarly risked items that, frankly, make little sense.

Mr. TOWNS. Let me put another one to you, and then I am going to be out of the way, Mr. Chairman.

What should Congress do to assist the development and deployment of an effective Federal food safety strategy? You have gotten a lot of information now.

Mr. ROBINSON. We have been writing on this subject for about 10 years, and to many of you it is probably starting to sound like a broken record. But having a uniform risk-based system under the responsibility of a single entity seems to be the approach that makes the most sense to us. It would avoid all the coordination issues and the coordination problems that exist; it would apply the same level of testing to similarly risk-posing issues, and potentially, and it could even be, could even be a cost-saving step.

Right now of course, if you are a plant that gets inspected by FDA, you have the likelihood, on average, of being inspected once every 8 years. If you are a plant that is under FSIS jurisdiction, you are inspected at least daily, if not on every—if you have multiple shifts, every shift.

The soup case is the classic example. If you have a little bit more than 2 or 3 percent meat in the soup, you get inspected every day. If you have less than that meat content, you have the likelihood of getting inspected once every year or more by FDA, even though it is the canning process that presents the risk, not the content of the ingredients in that can.

It doesn't make any sense, and it goes back to a—you know, probably the statutory structures that are in place, the regulatory structures that are in place and the vastly different approaches in funding levels that are in place.

Mr. TOWNS. Are you prepared to make a recommendation?

Mr. ROBINSON. We have made that recommendation frequently and would continue to stand by it.

Mr. TOWNS. Tell me which one, because I want to help you. Which entity, which one——

Mr. ROBINSON. Oh, which Federal agency it should be placed in. That obviously—that is a different kettle of fish.

Mr. TOWNS. Let's go to the color commentator.

Mr. ROBINSON. I am afraid our answer might be more colorful that you might want, or certainly more colorful than I might want.

But what we have said is that a single independent agency is the one that makes the most sense. Obviously that creates difficulties, and there are difficulties in creating new, new Federal entities. But the alternatives both have weaknesses, placing all the responsibility under FSIS, of course, press the classic conflict of interest problem that the same agency built to sort of promote. An industry would also be the regulatory body, some problems there. FDA, of course, has limited—limitations in its inspection authorities and certainly in its resources to assume that.

What we have said is that—and this is where the shuffling really begins, Mr. Towns. Whatever——

Mr. TOWNS. You are doing well.

Mr. ZADJURA. He is going to get better.

Mr. ROBINSON. Whatever agency it is, it needs to operate under a uniform set of rules that are risk-based and scientifically applied. With that, beyond that, it ceases to become an analytically based decision. It gets into a whole host of other issues that I am not sure analysis or facts can really mandate a solution.

Mr. TOWNS. Thank you very much. Thank you, Mr. Chairman, for your generosity.

Mr. GUTKNECHT. Thank you, Mr. Towns. Mr. Souder.

Mr. SOUDER. I think one of the fundamental opening questions is, given the fact that you have testified, GAO has, before this committee, 1993 and 1994, saying that we had these problems of coordination, are we better? Have we improved? And if so, where and how much farther do we have to go, or have we not progressed at all?

Mr. ROBINSON. I think you heard many examples this morning of some real improvements, particularly on the data collection end and pretty clear cooperation on that front.

I would have to say that the last time we really did an intensive analysis of the coordination issue among the 12 Federal agencies that have some sort of food safety regulatory responsibility, at that time we were looking at 25 separate cooperative agreements that were in place, and lots of problems with failure to notify and refer cases where agency one might be in the plant, sees a problem, doesn't refer it to agency two, so they don't have the capability and the use of that knowledge. We have not gone back and done any kind of, any kind of wholesale assessment of that issue.

I have to say, though, that the situation with the differing HACCP rules does not speak to a vastly improved situation. FSIS's HACCP is considerably different than FDA's HACCP. So for similarly risked items, meat and poultry on the one hand, seafood on the other hand, it doesn't speak to—I guess it does suggest that there is a way to go yet, and it also—again, it comes back to a single agency would solve all of those—solve those problems.

Mr. SOUDER. Can you explain to me in simple Hoosier-oriented language, as somebody who isn't up on all of the different consonants that you are putting together at different times here, what fundamentally led to having different standards for the same type of products, or what fundamentally led to the idea of the canning

process as the problem? Why does the meat content drive the analysis?

Mr. ZADJURA. A lot of it is historical. You have to look at the fact of when the legislation was enacted, and why it was enacted. The Meat Act goes back to the turn of the century. It gave USDA jurisdiction for meat products and mandated what is called continuous and carcass-by-carcass inspection. That means they inspect every single cattle carcass, every single pork carcass. For processing plants, they go in at least daily. At least daily can be 15 minutes, or it can be 5. FSIS inspectors are there all day long.

The Poultry Act was subsequently introduced and passed in I think, about 1957, as I recall the year, when it became evident that there was some problems with poultry and poultry was becoming a big consumer product, more than it had ever been before. The Poultry Act is similar to the Meat Act.

The Food and Drug Act is more generic, and it gives them wide and broad jurisdiction, but did not mandate any of this continuous or the same thing as carcass by carcass. That historical development and the response to individual crises and trying to fix them, as we said, it wasn't developed under any rational plan, it tended to be to fix a crisis or a problem. So as a result, you have an agency that preapproves everything. I mean, the USDA technically can approve the plant, where the drains are in the plans, you know, how you do this, compared to an agency that sort of has to catch you after the fact if you have done something wrong, and that really is the reason why everything ends up being done in different ways and different manners.

Mr. ROBINSON. If this were airline safety, for example, it would almost be as if one agency is responsible for planes that land on grass strips and one that lands on water, and one agency is responsible for planes that travel more than 200 miles—I mean, it is a crazy structure.

Mr. SOUDER. I understand. And I want to pursue in a minute the risk-based, and getting a more logical process, but if I can continue off this hypothetical can of soup to try to further elaborate.

Mr. ROBINSON. OK.

Mr. SOUDER. You are not really proposing, I don't think, that they relax the meat and poultry standards, are you?

Mr. ROBINSON. No. What we would be proposing is that all inspections be risk-based, that the level of oversight and the level of monitoring and the level of surveillance and the level of checking should be proportionate to the risk posed. Items that pose little risk would get relatively little inspection, items that pose high risk would get higher. It is strictly logical.

Mr. SOUDER. And so beef and poultry, would they have a different risk factor in the early stages than they would when they hit the can of soup? Is that what you said?

Mr. ROBINSON. No; with soup it is the canning process itself that poses the risk of botulism, not so much the contents of it. So whatever the kind, whether it is vegetable soup with two little flecks of chicken in it really doesn't make much difference to the risk and hence, you would expect that with equal risk you would have equal or a roughly equal inspection and checking.

Mr. SOUDER. And in the—if I can——

Mr. ROBINSON. It gets crazier than that, too, if you want to get into it.

Mr. SOUDER. I think that is enough.

It is clear that there needs to be a logical risk-based system and that I assume that part of what I understood you to say, that they are based on historical factors, because when there is a risk factor, these things can damage an industry overnight if they don't have the graded and protected system with it, so it is not like Government against the producers, because the producers need the protection as well, and you know, I am trying to figure out how you do that balanced risk factor given the fact that historically there were things that scared consumers.

Mr. ZADJURA. Can we clarify something on risk, too? To say, for example, that meat and poultry and maybe even seafood, the major protein-type products, have the same potential for causing problems because of the type of product they are, they can get microbial contamination and stuff like that. That does not say that our existing system, including the current meat and poultry inspection system, is effective. Whether we relax it or not, it is not really relevant given that most of what inspectors do today will not catch or prevent microbial contamination.

So essentially, what GAO has said in the past is that we need to fundamentally change that, base it on risk, and then do things that are relative to preventing that risk.

Mr. TOWNS. Will the gentleman yield just for a second?

Mr. SOUDER. Sure.

Mr. TOWNS. Will microbial testing, will that do it?

Mr. ZADJURA. In the sense of what is being proposed by FSIS, and we need to be careful here in the sense that GAO is not advocating and has never advocated piece-by-piece end-product testing that is prohibitively expensive, and we have testified to that before. But GAO has testified that part of the HACCP system should include microbial testing, because under the circumstances that is the only reasonable way to make sure that your HACCP Program is working, that your control points are working.

So in the sense of a test, whether it is daily or periodically during the day or some other frequency, to determine that your system is operating as planned and is reducing the microbes, yes. In the sense of, is it a system to say, this chicken wing is now approved, no. So it is a different level of testing, but yes, microbial testing.

Mr. TOWNS. So when they see that stamp saying "Government-inspected", it really doesn't mean a lot, does it?

Mr. ROBINSON. It doesn't mean anything with respect to microbial contamination.

Mr. TOWNS. You should eat this at your own risk.

Mr. ROBINSON. No. That might go a little too far. It doesn't mean very much with respect to microbial contamination. It certainly means that flecks of fecal material have been removed and——

Mr. ZADJURA. Obviously, as you well know, Mr. Towns, because we have testified twice before you when you chaired this commit that the fact that the hamburger was inspected more than one that was involved in the Jack-in-the-Box incident shows that the current level of testing does not necessarily prevent microbial con-

tamination. It essentially doesn't even look at it other than on an almost coincidental basis.

Mr. SOUDER. When you propose risk-based, are you proposing that there would also be some sort of balancing of the severity of what kind of combinations you put in the risk? In other words, there is a little bit of difference between diarrhea and, say, dying. Would you weigh those different things proportionately? Would you make sure that it was balanced at all levels from the food handling and to the actual product?

Mr. ROBINSON. Sure. Those would all be components to assessing the risk, obviously, yes.

Mr. SOUDER. And is that possible to clearly do in a—would you do it by subcategory? Because now you also have process questions in addition to product questions.

Mr. ZADJURA. We can do better than what we are doing, and we know some of the risk factors. For example, as I think FDA testified, animal feeds at different points in time have been identified as problems, so we now have programs that require the industry to develop feeds that are essentially free of *salmonella*, because that has been a factor in infecting the animals, so we can do a better job in that area.

As to the point of whether it causes diarrhea or death, that is almost unpredictable. Every one of these pathogens has the capability of, given the right individual, the right circumstances, of causing a fatality, of killing somebody.

Mr. SOUDER. But you are certainly not—I mean the testimony of the first panel that I read through and your testimony does suggest that in most cases one leads to this, and I think one of the 50 percent death rate whereas another had only a small—I mean there are differences and would you weigh those?

Mr. ROBINSON. Mr. Souder, I think the issue of *Campylobacter* and *listeria* are probably instructive here. *Campylobacter* is a much more widely prevalent event, *Campylobacter* illness. It has a very, very minuscule chance of leading to death. I think in our numbers about 0.03 percent chance. But because the numbers of illnesses are so much larger, the total number of absolute—I mean the absolute number of total deaths might be such as high as *listeria*, a much lower incidence, but you know, 20 to 40 percent chance of killing you if you get it.

Mr. SOUDER. I would still argue that it is not the percentage of deaths, it is the number of deaths. There is a difference between kidney failure in a child, and there needs to be some logic based with that as well.

Mr. ROBINSON. Absolutely. I couldn't agree more.

Mr. SOUDER. Could I ask one other type of question, and that is one of the most delicate things in this is how you balance the—you proposed—I think you had three different things about pathogens of concern, identify whether the food was the source of the illness, and identify many of the outbreaks in individual cases of foodborne illnesses that occur, and I don't think anybody would oppose that. Those are obvious things that we need better data on.

How do we balance the risk of reporting that may or may not in its initial stages or even in its final stages have pinpointed at the right place and the absolute devastation that can occur to an indi-

vidual retailer, a food category, a warehouse company, that is all of a sudden out of business and we find out later that it was misidentified. How would you go about balancing those two risks which are employment in one hand and health risk in the other?

Mr. ROBINSON. Well, to a degree you almost have to depend upon the professionalism of the agencies involved. I don't think that we have any evidence that there is a pattern of anybody trying to be—any of the agencies responsible trying to be alarmists or act without the best possible data.

What we are talking about, and what this five-location study is aimed at doing, is to providing much better quality data upon which to act. Right now, to a degree, the data that has historically been available has a lot more guesswork involved because you are not absolutely certain what the source of the illness was, you are not exactly sure, you know, of the level of—you are not nearly as sure of the prevalence as you would be with this much more active effort. But beyond getting the best possible data, I think you have to depend upon the professionalism of the folks involved to act responsibly with that data. I am not sure I can be more definitive than that.

Mr. SOUDER. You mean part of it is when it gets in the press. I mean as a parent I would like to know as soon as possible what information is out, for example, that a certain place had a product or a brand name that had a product, and I may, if the information leaks out, which is a big danger, react permanently against—to take something that is not directly related, like Tylenol in a case where people got scared and panicked the whole brand, which was an overreaction. But as a parent when you hear anything, you are more protective of your children than risk-free, and yet we have to figure out in our society how to balance those things, because we definitely need more information. But the more detailed information we are going to get, we may be possibly up blind alleys whether it was at the food handler level, when actually the food handler didn't have plastic gloves on.

Mr. ROBINSON. I understand your concern. I just don't think——

Mr. ZADJURA. Also, I think that GAO and others have advocated that the system should not be only at particular levels, but what has become the terminology of farm-to-table, because as you say, in some cases it is the feed that goes in, or what you do after it comes out, and the most dependable, most reliable program that hopefully some day we will get to is one that controls—identifies and controls those risks at all levels, including, you know, education for food handlers and consumers so that they don't compound the problem.

Mr. SOUDER. Thank you.

Mr. GUTKNECHT. I just had a couple of quick questions. First, you said that your estimates were between $5 billion and $22 billion. I mean even by Federal Government standards, that $17 billion swing is a pretty big swing. How do you arrive at those numbers?

Mr. ROBINSON. Those were ERS numbers, as I mentioned, based on two separate and two different approaches. One estimated the cost of the illnesses and the lost productivity. Those are the numbers that start with the $5 billion. Alternatively—and of course

those numbers have weaknesses, because a lot of people that get sick are the very young and the elderly, and the value of their productivity, of course, gets diminished in those kind of conditions.

Alternatively, they looked at it from a, what they call a willingness-to-pay basis or the value of avoiding death, if you will. In those cases what they did was take the estimated number of deaths based on the number of illness occurrences, and then multiply that by a ranging value of the like involved, essentially. Of course, that has weaknesses, too, and it doesn't account for the cost of illnesses that make you sick, but don't kill you.

All of those, of course, have weaknesses. The first study I talked about, it was seven pathogens. In the first approach they looked at seven pathogens, the next approach looked at five pathogens, so therefore, you are not dealing with all of the 30-plus or more pathogens involved. But that is essentially the way they were computed. You can see there is a lot of wiggle room in those numbers. I don't know that anyone would run to the bank with those numbers, being definitive.

Mr. ZADJURA. The other thing that is, of course, included is because of the data system, you are working with estimated numbers of illnesses and estimated deaths, which is a large range, OK? I mean you are projecting relatively weak data to the population. As a result, they use a range. I mean they don't say there is 2 million *salmonella* illnesses. They say there is 2 to 4 million. So automatically, whatever value you come up with, the productivity loss or the cost of illness, you are multiplying 2 times 4 million, so it expands the range on the other end.

Mr. ROBINSON. And that is why the active data collection effort seems so superior and will put people in a better position to develop strategies.

Mr. GUTKNECHT. But in the end, the consumer, I believe—and maybe you can share with us what the numbers are.

How much of the foodborne contamination occurs after it leaves the stream of Federal inspections at one level or the other? I mean cross-contamination, or undercooked, or people leave the potato salad out in the sun too long or whatever.

Mr. ROBINSON. The contamination can occur from anywhere along the stream. You know, consumers can attempt to deal with that contamination. I am not sure that they can create the contamination. The contamination was likely there to begin with, and they may have magnified it by not taking steps to prevent the number of bacteria from increasing.

But clearly the bacteria had to be there in the first place. And that bacteria could have entered the stream in an infinite number of ways, and that gets back to the HACCP where it is not enough just to control the entrance of pathogens at a plant when they may have entered the process much sooner than that, and the plant would have no capability of controlling pathogens that entered before or after. So that is why that approach has drawn so much attention.

Mr. GUTKNECHT. Well, listen. We thank you. We are going to call up the next panel.

Dr. Allos and Dr. Kobayashi, will you please rise.

[Witnesses sworn.]

Mr. GUTKNECHT. Please let the record show that they answered in the affirmative.

We welcome you to the subcommittee. Who wants to go first?

STATEMENTS OF BAN MISHU ALLOS, M.D., VANDERBILT UNIVERSITY SCHOOL OF MEDICINE, DIVISION OF INFECTIOUS DISEASES, DEPARTMENT OF MEDICINE; AND JOHN KOBAYASHI, M.D., M.P.H., SENIOR EPIDEMIOLOGIST, WASHINGTON STATE DEPARTMENT OF HEALTH

Dr. ALLOS. Thank you. Good morning—good afternoon. My name is Ban Mishu Allos and I am an internist and an infectious diseases physician at the Vanderbilt University School of Medicine in Nashville, TN. Today I will discuss the evidence that *Campylobacter jejuni*, a common foodborne bacterial infection in humans, causes Guillain-Barre syndrome, an acute paralytic disease.

First, let's just talk a little bit about *Campylobacter*. They are bacteria that typically produce gastroenteritis and diarrhea, which can be either watery or bloody. It is one of the most common bacterial causes of diarrhea worldwide. In the United States, *Campylobacter* is the most common bacterial cause of diarrhea, occurring more commonly than *salmonella* and *shigella* infections combined. The CDC estimates that 1 percent of the U.S. population is infected with *Campylobacter* every year.

In developed countries such as ours, the principal way people acquire this infection is through eating chicken. Although *Campylobacter* may occasionally be transmitted to people in other ways, several studies have shown that more than 70 percent of human *Campylobacter* infections are associated with the preparation and consumption of chicken.

Guillain-Barre syndrome, which I will also call GBS, has been recognized as a complication of *Campylobacter* infection for about 10 years, but the link has become a lot more solid in the last 4 years. Before I describe to you the evidence that suggests that *Campylobacter* infection is an important trigger of Guillain-Barre syndrome, let me tell you a little bit about what this syndrome is.

GBS typically causes an ascending paralysis. It starts with weakness in the feet and ankles, and then affects the legs, trunk, arms and muscles of respiration and can eventually cause a person to become completely paralyzed and to stop breathing altogether.

Since the eradication of polio, GBS has become the most common cause of acute neuromuscular paralysis in the United States. About 9,000 people in the United States are diagnosed with GBS every year.

What happens to people who get GBS? Twenty percent of them will require mechanical ventilation because of paralyzed muscles of breathing. That is, they are on a respirator or breathing machine. Patients require weeks or months of acute hospital care, followed by an even longer period of recovery in a rehabilitation center or a nursing home.

About 25 percent are never able to return to work. Because of advances in ICU care, the mortality of GBS has been reduced. Now only about 5 percent of patients die. However, another 20 percent are left with permanent debilitating neurologic deficits and the re-

mainder will recover totally or with only minimal neurologic damage.

GBS occurs because myelin, the insulating material surrounding our nerves, becomes stripped away by the body's immune system. Because it takes weeks or months for this myelin to grow back, people with GBS may be paralyzed for many months. If the immune attack is particularly severe, then the nerve itself, not just the myelin insulation, may be injured. When this happens, the paralysis is irreversible.

But how did we first learn of an association between GBS and *Campylobacter* infection? Like so many things in medical science, it started with an anecdotal report. In 1982, there were two English physicians who wrote a letter to the British Medical Journal describing a patient that they had seen who developed GBS 10 days after a *Campylobacter* infection. Almost immediately there was a flurry of responses from all over the world from other physicians saying, hey, we have seen this, too. We have patients with GBS who had had *Campylobacter* infection just 1 to 3 weeks before.

Well, these reports are very interesting, but good medical scientists understand that anecdotal reports are not the same thing as proof. But how could you prove that *Campylobacter* is an important cause of GBS? At Vanderbilt we had studied this by testing the blood of 116 patients with GBS for antibodies to *Campylobacter* and comparing this to blood from 105 controls, people who didn't have GBS. The patients and the controls were people who lived in Maryland, New Jersey or Missouri.

We found that GBS patients were five times more likely than controls to have *Campylobacter* antibodies. The presence of *Campylobacter* antibodies in blood means that the person was recently infected with *Campylobacter*. We were able to estimate that at a minimum 30 percent and possibly even more than 50 percent of GBS patients had had preceding Campylobacter infections.

Investigators all over the world have also documented this association. Some studies have shown that more than 40 percent of GBS patients have *Campylobacter* in their stools at the time of onset of their neurologic symptoms. This cannot be attributed to mere coincidence. As less than 1 percent of healthy, asymptomatic adults will have this bacteria cultured from their stools.

GBS is a devastating disease that probably has many triggers, but it is now clear that the most important trigger is *Campylobacter* infection causing 40 percent or more of GBS cases. The following six suggestions may help to reduce the incidence of *Campylobacter*-triggered Guillain-Barre. First, because most human *Campylobacter* infection is acquired from chicken, control of *Campylobacter* infections of poultry flocks is critical.

Second, even if *Campylobacter* cannot be completely eliminated from food supplies, the burden of infection should be lowered. Reducing cross-contamination in poultry plants may be one way to combat the problem. Perhaps another way to accomplish the goal is for public health agencies such as CDC to conduct studies that identify specific food products that are associated with *Campylobacter* infection. Then the CDC, FDA or other agencies could work with the USDA to implement control measures based upon these findings.

Third, to reduce the risk of being infected with *Campylobacter*, consumers should be educated about proper kitchen hygiene. They should especially understand the importance of cooking poultry products thoroughly. It is not sufficient to barbecue chicken until it is black on the outside and still pink near the bone.

Fourth, to increase our understanding of how and why *Campylobacter* triggers GBS, increased NIH funding for study of foodborne diseases, their pathogenesis as well as mechanisms of prevention should be encouraged.

Fifth, to enable physicians and public health authorities to predict which *Campylobacter* infections are most likely to trigger Guillain-Barre, improved *Campylobacter* typing methods are needed. The current zero typing mechanisms are crude, expensive and labor-intensive. Perhaps if we knew which *Campylobacters* are most dangerous to humans, we could look for these bacteria on our farms and in our food supplies and stop them before they end up on our dinner plate.

Sixth, we still don't know so much about the epidemiology of these infections. Who gets them? Why? What are the risk factors? Can we control it? How? All of these questions need answers. The CDC has excellent surveillance mechanisms described earlier by the earlier panel established under the names, "Emerging Infection Sites." Expanding these sites and utilizing them to identify causes of *Campylobacter*-induced Guillain-Barre, to collect clinical histories on patients as well as cultures and serum specimens could be the most useful way to combat this problem.

In closing, recently we have come to learn that the impact of infectious diseases, especially foodborne inefficiencies diseases goes way beyond the effects of the immediate acute infection. It is not just the diarrhea. Hemolytic uremic syndrome may follow *E. coli* infection. Arthritis may follow *salmonella* and *Campylobacter* infection may trigger GBS. Future studies of these and other infectious agents will show us how to prevent them and perhaps reduce the burden of human suffering caused by these diseases.

Thank you.

[The prepared statement of Dr. Allos follows:]

INTRODUCTION

Good morning. My name is Dr. Ban Mishu Allos and I am an Internist and Infectious Diseases Specialist at the Vanderbilt University School of Medicine in Nashville, Tennessee. My title is Assistant Professor of Medicine. I am the principal investigator of a National Institute of Health (NIH) research grant proposal entitled "The molecular basis of *Campylobacter jejuni*-triggered Guillain-Barre syndrome". Today, I will discuss the evidence that *Campylobacter jejuni*, a common food-borne bacterial infection in humans, causes Guillain-Barre syndrome, an acute paralytic disease. First I'll talk about what *Campylobacter* infection is, how frequently it occurs, and how it is transmitted. Then I'll tell you about Guillain-Barre syndrome, and why we believe *Campylobacter* infection is an important cause of this disease. And finally I'll give some suggestions about where we should go from here.

PART I -- *Campylobacter*

WHAT IS *Campylobacter* INFECTION AND HOW COMMON IS IT?

Campylobacter jejuni are bacteria that typically produce gastroenteritis -- fever, abdominal cramps, and diarrhea which can be either bloody or watery. *Campylobacter* is one of the most common bacterial causes of diarrhea world-wide. In the U.S., *Campylobacter* infections occur more commonly than *Salmonella* and *Shigella* infections combined. The U.S. Centers for Disease Control estimates that 1% of the U.S. population is infected with *Campylobacter* every year.

HOW DO PEOPLE GET IT?

In developed countries such as ours, the principal way humans acquire this infection is through eating chicken. Although *Campylobacter* may occasionally be transmitted to people from dogs and cats and from other foods of animal origin (such as pork, beef, or unpasteurized milk) several studies show that more than 70% of *Campylobacter* infections are associated with preparation and consumption of chicken. Except for rare occasions, *Campylobacter* infection does not occur as a result of person-to-person transmission, nor do food handlers cause *Campylobacter* outbreaks. Outbreaks have not been described in day-care centers or institutions for the mentally retarded.

WHAT HAPPENS TO PEOPLE WITH *Campylobacter* INFECTION?

Symptoms caused by *Campylobacter* infection can range from none -- completely asymptomatic -- to severe illness, and to death which is quite rare. Most people develop a self-limited diarrheal illness and get better within one week. GBS has been recognized as a complication of *Campylobacter* infection for the past 10 years but the link has become more solid in the last 4 years.

PART II -- GBS

Before I describe to you the evidence that suggests that *Campylobacter* infection may be an important trigger of Guillain-Barre syndrome, let me tell you a little bit about this syndrome.

WHAT IS GBS?

GBS typically causes an ascending paralysis -- it starts with weakness in the feet and ankles, then affects the legs, trunk, arms, and muscles of respiration and can eventually cause a person to stop breathing altogether.

HOW FREQUENT IS GBS?

Since the eradication of polio, GBS has become the most common cause of acute neuromuscular paralysis in the United States. This disease affects about 2 of every 100,000 people in the U.S. each year. Data from the National Center for Health Statistics Hospital Discharge Survey showed that between 1979 and 1993, an average of 9,575 cases of GBS were diagnosed each year. GBS can affect people of all ages.

WHAT HAPPENS TO PEOPLE WHO GET GBS?

About 20% of patients require mechanical ventilation because of paralyzed muscles of breathing. Patients with GBS may require weeks or months of acute hospital care followed by an even longer period of recovery in a rehabilitation center or nursing home. About 25% will never return to the work force. Because of improved ICU and critical care medicine, the mortality of GBS has been substantially reduced. Only 5% of GBS patients die. Another 20% are left with permanent debilitating neurologic deficits. The remainder recover totally or with only minimal neurologic damage.

WHAT CAUSES GBS?

GBS occurs because myelin, the insulating material surrounding our nerves, gets stripped away by the body's immune system. Because it takes weeks to months for this myelin to regenerate, people with GBS may be paralyzed for months. If the immune attack is particularly severe, then the nerve itself (not just the myelin coat) may be injured. When this happens, paralysis becomes irreversible.

GBS frequently occurs after an acute infectious illness, such as an acute upper respiratory or gastrointestinal infection. This was recognized more than 100 years ago when the syndrome was called "acute post-infectious polyneuritis". However the first reports of an association between GBS and *Campylobacter* did not appear until the 1980s.

PART III -- *Campylobacter* AND GBS

WHEN AND HOW DID WE LEARN OF AN ASSOCIATION BETWEEN GBS AND *Campylobacter* INFECTION?

In 1982, 2 English physicians wrote a letter to the British Medical Journal describing a patient who developed GBS 10 days after a documented *Campylobacter* infection. Almost immediately there was a flurry of responses from physicians all over the world who had also seen patients who developed GBS 1 to 3 weeks after infection with *Campylobacter*. For several years afterwards, there were reports of this association published in various medical journals.

HOW CERTAIN ARE WE THAT *Campylobacter* IS ASSOCIATED WITH GBS?

These reports were interesting but good medical scientists understand that anecdotal reports are not the same as proof. But how could we prove that *Campylobacter* was an important cause of GBS? And how would you determine how many GBS cases are preceded by *Campylobacter* infection? At Vanderbilt University we have studied this by testing the blood of 116 patients with GBS for antibodies to *Campylobacter* and comparing this to blood from 105 controls -- people who didn't have GBS. The patients and the controls were people who lived in Maryland, New Jersey, or Missouri. We found that GBS patients were 5 times more likely than the controls to have *Campylobacter* antibodies. The presence of *Campylobacter* antibodies in blood means that the person was recently infected with *Campylobacter*. We were able to estimate that a minimum of 30% of GBS patients had had preceding *Campylobacter* infection.

Investigators all over the world have also documented this association. In Japan, evidence of *Campylobacter* infection was found in more than 40% of GBS patients. Fully 30% of GBS patients still had the bacteria present in their stools at the time of onset of their neurologic symptoms. Similarly in England, 26% of GBS patients had *Campylobacter* isolated from their stools. The finding of *Campylobacter* in stools of these patients cannot be attributed to mere coincidence. Less than 1% of healthy, asymptomatic adults will have this bacteria cultured from their stools.

HOW DOES A BACTERIA THAT CAUSES DIARRHEA CAUSE PEOPLE TO BE PARALYZED?

The mechanism by which *Campylobacter* triggers the Guillain-Barre syndrome is not yet clear. We believe that the antibodies which our bodies make to fight against the bacteria in some cases may attack myelin leading to GBS. We have learned that certain strains of *Campylobacter* (serotype O:19) are more likely to trigger GBS. We also know that some patients may develop GBS after being infected with campylobacters that may only cause a simple diarrheal illness in another patient. We are just beginning to understand this disease process but there is still much to learn.

PART IV -- WHAT SHOULD WE DO?

The following suggestions may reduce the incidence of *Campylobacter*-triggered GBS:

1. Because most human *Campylobacter* infection is acquired from chicken, control of *Campylobacter* infections of poultry flocks is critical. But the best ways to achieve this goal have yet to be determined. Infected flocks must be identified and appropriate treatment or vaccination programs or other strategies devised.
2. Even if it cannot be completely eliminated, the burden of *Campylobacter* infection in foods should be lowered. Reducing cross-contamination in poultry plants may be effective. Perhaps another way to accomplish this goal is for public health agencies such as the U.S. Centers for Disease Control and Prevention to conduct studies that identify specific food products that are associated with *Campylobacter*

infection. Then CDC, FDA, or other agencies could work with USDA to implement control measures based on these findings.

3. To reduce the risk of being infected with *Campylobacter*, consumers should be educated about proper kitchen hygiene. They should especially understand the importance of cooking poultry products thoroughly. It is not sufficient to barbecue chicken until it is black on the outside but still pink near the bone. To avoid cross-contamination, utensils and plates which are used to handle raw meat should be washed before using them on uncooked foods such as salads. People should know not to place their thoroughly cooked chicken on the same plate that held the raw chicken and still has raw chicken juice on it -- unless the plate is first washed.
4. To increase our understanding of how and why *Campylobacter* triggers GBS, increased NIH funding for study of food-borne diseases -- their pathogenesis as well as mechanisms of prevention should be encouraged.
5. To enable physicians to predict which *Campylobacter* infections are most likely to trigger GBS, improved *Campylobacter* typing methods are needed. Current serotyping mechanisms are crude, expensive, and labor intensive. Perhaps if we knew which *Campylobacter*s are most dangerous to humans, we could look for them on our farms and in our food supplies and stop them before they end up on our dinner tables.
6. We still don't know so much about the epidemiology of these infections. Who gets them? Why? What are the risk factors? Can we control it? How? The U.S. Centers for Disease Control has excellent surveillance mechanisms currently

established under the name "Emerging Infection Sites". Expanding these sites and utilizing them to identify cases of *Campylobacter*-induced GBS, collect clinical histories on patients as well as cultures and serum specimens, could be the most useful way to combat this problem.

PART V -- CLOSING

In recent years we have come to learn that the impact of infectious diseases, especially food-borne infectious diseases, goes way beyond the effects of the immediate acute infection. Hemolytic uremic Syndrome may follow infection with *E. coli* O:157 infection acquired from eating ground beef. Arthritis may follow *Salmonella* infections transmitted to humans from eating eggs. And *Campylobacter* infection may trigger Guillain-Barre syndrome. Future studies of these and other infectious agents will show us how to prevent them and perhaps reduce the burden of human suffering caused by these diseases.

Thank you

Mr. SOUDER. Dr. Kobayashi.

Dr. KOBAYASHI. My name is John Kobayashi. I am in charge of the Communicable Disease Epidemiology Section in the Washington State Department of Health. We perform surveillance and investigation of infectious diseases. Our most notable outbreak in Washington State was the 1993 *E. coli* O157:H7 epidemic caused by contaminated hamburgers from a fast food chain.

In less than a week after our first notification, we identified the outbreak source. Over 60 percent of the contaminated meat was recalled, or over one quarter million hamburgers. About 600 people were confirmed or probable cases. While this was an infectious disease disaster, it could have been many times worse if our investigation were delayed only a few days.

It is important to note that the rapid response in this instance was not accidental or developed overnight. In Washington State, work on *E. coli* O157:H7 began in 1984. In 1987, we were the first State to declare a reportable disease. These activities were performed without Federal categorical funding for foodborne disease. However, we received significant noncategorical Federal support for decades, which developed our response to *E. coli* O157:H7 and other foodborne pathogens.

This was through epidemiologists, EIS officers from the CDC who worked full time with us in Washington State. Since 1984, CDC epidemiologists, under my supervision, documented that *E. coli* O157:H7 was a significant disease. They identified outbreaks and helped change the Washington State regulations to require its reporting. Were it not for these EIS officers, our rapid response to the 1993 outbreak would not have occurred.

Other Federal funds to improve our foodborne disease surveillance include the following: The USDA has provided funds to two universities in Washington State for research on *E. coli* O157:H7. We are receiving CDC funds to develop DNA fingerprinting studies of disease-causing bacteria at the State laboratory, and to publish a monograph for physicians on the diagnosis of foodborne disease.

We have received FDA funds to perform a shellfish and meat consumption survey. While not specifically for foodborne diseases, CDC funds are being used to develop computerized communication networks between State, county, and Federal agencies.

For future Federal support, I recommend the following: Additional categorical support such as through the CDC Emerging Pathogens Program is indeed welcome, and I will be happy to talk about details, if you wish. However, it is also important to support general activities such as the CDC EIS program. From the local and State perspective, we are initially faced with outbreaks of disease of unknown cause, not necessarily those classified as foodborne, waterborne or otherwise.

What we need are people with general epidemiologic expertise such as those in the EIS program, who can respond to the unexpected. The unmet need for epidemiologists in States is great. In the last EIS conference, States sought 33 EIS officers. Only 13 positions were filled.

In the long run, such general support will reap great benefits in foodborne disease control, as shown by the Washington State experience.

I urge that funding be consistent over many years. It takes years of sustained work to establish a strong surveillance system.

Finally, epidemiology should be considered as a tool to evaluate regulatory measures.

I thank you for the opportunity to speak. I will be happy to answer any further questions that I can.

[The prepared statement of Dr. Kobayashi follows:]

My name is John Kobayashi. I am a senior epidemiologist with the Washington State Department of Health. For the past fourteen years, I have been in charge of the Communicable Disease Epidemiology Section, which performs surveillance and investigation of infectious diseases, including foodborne outbreaks.

Foodborne Diseases in Washington State:

In Washington State, over 100 foodborne disease outbreaks are reported each year. In each, investigations are performed, and corrective measures made to prevent bigger disasters in the future.

Our most notable outbreak in Washington State was the 1993 *E. coli* O157:H7 epidemic, caused by contaminated hamburgers from a fast food chain.[1] In less than one week after our first notification, we identified the outbreak source. Over 60 percent of the contaminated meat was recalled, or over one quarter million hamburgers.

About 600 people were confirmed or probable cases. Of these, 151 were hospitalized, 45 had hemolytic uremic syndrome, 28 required kidney dialysis, and three died. While this was an infectious disease disaster, it would have been many times worse if our investigation were delayed only a few days.

Lessons Learned:

It is important to note that the rapid response in this instance was not accidental or developed overnight. In Washington State, work on *E. coli* O157:H7 began in 1984, only two years after it was known to cause human illness. In 1987, we were the first state to declare it a reportable disease.

While reporting requirements do not prevent epidemics, they improve the speed and accuracy in which outbreaks are identified. If physicians are not aware of *E. coli* O157:H7 and laboratories do not test for it, it will not be found. Over the years, the reporting regulation increased awareness and testing in Washington State. Since the 1993 outbreak, required reporting for *E coli* O157:H7 has improved nationwide, from only 11 states before 1993 to 38 states at the present time.

Past Federal Support:

Until recently, the Washington State Department of Health did not receive categorical federal funding for foodborne diseases. However, we received significant non-categorical federal support for decades which developed our response to *E. coli* O157:H7 and other foodborne pathogens. This was through epidemiologists -- Epidemic Intelligence Service (EIS) Officers from the CDC who worked full time with us in Washington State.

Since 1984, CDC funded epidemiologists under my supervision documented that *E. coli* O157:H7 was a significant disease. They identified outbreaks and helped change the Washington State regulations to require its reporting. Were it not for these EIS officers, our rapid response to the 1993 outbreak would not have occurred.

Other federal funds to improve our foodborne disease surveillance include the following:

- We are receiving CDC funds to develop "DNA fingerprinting" methods for disease causing bacteria at the State Laboratory. This will allow more accurate and rapid identification of outbreaks.

- We received CDC funds to develop and publish a monograph for physicians and health care providers on the diagnosis of foodborne diseases. Physicians are a key link in the reporting system, but receive little training about foodborne illness.

- We received FDA funds to perform a shellfish and meat consumption survey in Washington State. This information will be used to guide public education efforts and provide baseline data to identify foodborne outbreaks.

- The USDA has provided funds to the Washington State University to study the frequency and risk factors for cattle carriage of *E. coli* O157:H7, and to the Children's

Hospital and Medical Center on the molecular mechanisms used by this bacteria to infect cattle.

- While not specifically for foodborne diseases, CDC funds are being used to develop computerized communications between state, county, and federal agencies. This includes the establishing a statewide network with local health departments. With CDC funds, we are also developing electronic disease reporting from local health departments and laboratories. Such communications networks should improve the speed and accuracy of disease surveillance and investigations.

Recommendations:

- Additional categorical support to improve foodborne disease control, such as through the CDC Emerging Pathogens Program is indeed welcome.

- However, it is also important to support general programs, such as the CDC EIS program. and the projects to establish statewide communications networks.

From the local and state perspective, we are initially faced with outbreaks of disease of unknown cause, not necessarily those classified as foodborne, waterborne or otherwise. What we need are people with general epidemiologic expertise, such as those in the EIS program who can respond to the unexpected. The unmet need for epidemiologists in

states is great. In the last EIS conference, states sought 33 EIS officers. Only 13 positions were filled.

In the long run, such general support will reap great benefits in foodborne disease control, as shown by the Washington State experience. Our accomplishments in *E. coli* O157:H7 surveillance were in large part possible because Washington State sucessfully recruited EIS officers for at least 18 continuous years. However, as the number of unfilled positions this year indicates, many other states have not been so fortunate.

- I urge that funding be consistent over many years. It takes years of sustained work to establish a strong surveillance system. Surveillance data is of much greater value if it is collected in a consistent manner from year to year and from place to place. A crash program which generates data and then disappears because of insufficient funding is frequently worse than no program at all.

- Finally, epidemiology should be considered as a tool to evaluate regulatory measures.

For example, we were able to compare restaurant inspection results in the Seattle area with the subsequent risk of foodborne outbreaks.[2] We found a clear relationship between violating certain items, such as handwashing and temperature control and the risk of foodborne disease. Other violations had no relationship to the risk of disease.

While these findings were generally consistent with opinions of knowledgeable food scientists, our study was the first to document the relationship of inspections to disease prevention. A large amount of time and money is spent on restaurant inspections. In the Seattle area alone, about 20,000 inspections in 6,000 restaurants have been performed every year. Any study which can document the need for inspections or make them more effective is of value.

Clearly, epidemiology cannot provide answers to every program evaluation or policy question. In this situation, however, computerized restaurant inspection data was available, foodborne disease data was excellent, and an EIS officer was present to analyze the data. I suspect there are many other circumstances such as this where epidemiology can provide program management information at minimal cost.

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A Multistate Outbreak of *Escherichia coli* O157:H7–Associated Bloody Diarrhea and Hemolytic Uremic Syndrome From Hamburgers

The Washington Experience

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Objective.—To determine the source of and describe a large outbreak of *Escherichia coli* O157:H7 infections in Washington State.

Design.—Case-control study; environmental investigation; provider-based surveillance for *E coli* O157:H7 infections.

Setting.—Chain of fast-food restaurants, hospitals, physician offices, local laboratories, and local health departments.

Participants.—Patients with diarrhea and neighborhood controls. A case was defined as diarrhea with culture-confirmed *E coli* O157:H7 infection or postdiarrheal hemolytic uremic syndrome (HUS) occurring from December 1, 1992, through February 28, 1993, in a Washington State resident. Controls were age- and neighborhood-matched friends of the first 16 case patients.

Interventions.—Announcement to the public; recall of implicated hamburger lots.

Main Outcome Measure.—Abatement of outbreak due to *E coli* O157:H7.

Results.—Infection was associated with eating at a fast-food chain (chain A) in the 10 days before symptoms began. Twelve (75%) of 16 case patients but no controls had eaten at chain A (matched odds ratio undefined; lower 95% confidence interval, 3.5; $P<.001$). In total, 501 cases were reported, including 151 hospitalizations (31%), 45 cases of HUS (9%), and three deaths. Forty-eight patients (10%) had secondary infections. Of the remaining 453 patients (90%), 398 (86%) reported eating at a Washington chain A restaurant; 92% of them reported eating a regular hamburger. The pulsed-field gel electrophoresis pattern of the *E coli* O157:H7 strains isolated from all regular hamburger lots of a single production date shipped to Washington was identical to that of the strains isolated from patients. Ten (63%) of 16 regular hamburgers cooked according to chain A policy had internal temperatures below 60°C. Public health action removed more than 250 000 potentially contaminated hamburgers, preventing an estimated 800 cases.

Conclusions.—This *E coli* O157:H7 outbreak, the largest reported, resulted from errors in meat processing and cooking. Public health surveillance through state-mandated reporting of *E coli* O157:H7 infection as is carried out in Washington State was critical for prompt outbreak recognition and control. Measures should be developed to reduce meat contamination. Consumers and food service workers should be educated about cooking hamburger meat thoroughly.

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SINCE its identification as a pathogen in the early 1980s, *Escherichia coli* O157:H7 has come to be recognized as an important cause of hemorrhagic colitis and the hemolytic uremic syndrome (HUS).[1-3] Infection has most commonly been linked to consumption of foods derived from cattle, such as undercooked ground beef and unpasteurized milk.[3-5]

On January 12, 1993, a pediatric gastroenterologist notified the Washington Department of Health of an increase in emergency department visits for bloody diarrhea and the hospitalization of three children with HUS at the Children's

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Hospital and Medical Center in Seattle. We report herein the results of the investigation that implicated hamburgers from a fast-food chain (chain A) and the epidemiologic characteristics of the Washington outbreak.[7]

MATERIALS AND METHODS

Since *E coli* O157:H7 is a notifiable disease in Washington, health care providers reported cases to the local health departments as required by law. On January 15, 1993, we began active surveillance for bloody diarrhea and *E coli* O157:H7 infection through hospital emergency departments, infection control practitioners, and laboratories in the three counties forming the greater Seattle area. Following a public announcement on January 18 and subsequent widespread publicity, patients also reported illness to local health departments. We conducted hypothesis-generating interviews with patients or their parents, asking about foods eaten during the 10 days before symptom onset, restaurants visited, travel, pets, and other possible exposures, as well as cooking and shopping practices.

A case was defined as diarrhea with a stool culture positive for *E coli* O157:H7 or postdiarrheal HUS occurring from December 1, 1992, through February 28, 1993, in a resident of Washington State. Postdiarrheal HUS was defined by the triad of microangiopathic hemolytic anemia (hematocrit <0.30 with microscopic evidence of intravascular erythrocyte destruction), thrombocytopenia (platelet count $<150\times10^9$/L), and renal abnormalities (serum urea nitrogen >7.15 mmol/L of urea [>20 mg/dL] and cylindruria). Patients were considered to have primary cases if illness began within 10 days after eating at a chain A restaurant. Patients were considered to have secondary cases if they became ill within 10 days of household or other close contact with another patient and had not eaten at chain A during that time. Patients were defined as having primary and secondary cases after the initial hypothesis was tested.

A case-control study was conducted on January 16 and 17 to test the hypothesis that infection was associated with eating at a chain A restaurant. Each of the first 20 patients interviewed or the patient's parents were asked to name one neighborhood friend of the patient to serve as a control. Controls were further matched for age (within 2 years for children younger than 16 years and within 5 years for adults). Potential controls were excluded if they had a history of diarrhea in the 2 weeks before the case patient's illness began. Controls were questioned concerning foods eaten and restaurants visited in the 10 days before the matched case patient's symptom onset date.

The χ^2 test, Student *t* test, and Pearson correlation coefficients were used to examine relationships between demographic and other variables. For data that were not normally distributed, the Kruskal-Wallis test for two groups was used. For the case-control study, matched odds ratios and 95% confidence intervals were calculated according to the method of Martin and Austin.[8]

Environmental Investigation

On January 17, 1993, 10 chain A restaurants were visited by health department sanitarians, raw hamburger patties were collected for culture, cooking practices were examined, and internal temperatures of cooked hamburgers were measured with metal stem thermometers. On January 18 and 19, internal temperatures of cooked hamburgers were measured at four points in each hamburger by using thermocouple thermometers (model 51 with 80-PK-1 bead probe, John Fluke Manufacturing, Everett, Wash).

The hamburger patty production dates, lot numbers, restaurant-specific attack rates, shipping and holding procedures, and the quantity originally shipped and subsequently returned to Washington in the meat recall were determined using information supplied by chain A's parent company and by inspecting boxes of recalled meat in the chain A warehouse in Washington. The restaurant-specific attack rate was calculated as the number of case patients who ate at a particular chain A restaurant between January 1 and January 17, 1993, divided by the approximate number of regular hamburgers sold at that restaurant during that time.

Laboratory Investigation

Stool samples were submitted to local laboratories, tested for *Salmonella*, *Shigella*, and *Campylobacter*, and inoculated onto sorbitol-MacConkey (SMAC) agar to test for *E coli* O157:H7. In some laboratories, colonies that did not ferment sorbitol at 24 hours were sent to the Washington State Public Heath Laboratory (PHL). Other local laboratories also performed serotyping. All presumptive *E coli* O157:H7 isolates were sent to the PHL for confirmation. The PHL confirmed the O157 antigen by using the Oxoid O157 latex test kit (Oxoid Diagnostic Reagents, Basingstoke, England) or the O157 direct fluorescent antibody conjugate of Kirkegaard and Perry (Kirkegaard and Perry Laboratories Inc, Gaithersburg, Md) and the H7 antigen by using H7 antiserum (Centers for Disease Control and Prevention, Atlanta, Ga, or Difco Laboratories, Detroit, Mich). The presence of Shigalike toxin types I and II was determined using oligonucleotide probes.[9]

Regular hamburger patties from the eight lots produced on November 19, 1992, that were shipped to Washington were cultured at the PHL (five lots), at the US Department of Agriculture (eight lots), and at the University of Georgia (eight lots). The following methods, using a procedure developed by one of us (P.I.T.), were used by the PHL. Hamburger samples were incubated in a modified trypticase soy broth[10] containing vancomycin (40 mg/mL) instead of novobiocin. Dilutions of this enriched culture were spread evenly on SMAC or MacConkey agar. Sorbitol-nonfermenting colonies were plated onto MacConkey agar, and lactose-fermenting colonies were plated onto SMAC agar. Candidate *E coli* O157:H7 colonies (ie, sorbitol nonfermenting, lactose fermenting) were tested for indole positivity and reactivity in a O157 latex particle agglutination test (Unipath, Basingstoke, England). Isolates that caused agglutination were tested for the H7 antigen by using H7 antiserum (Difco).

Pulsed-field gel electrophoresis (PFGE) was used to compare *E coli* O157:H7 isolates. Bacterial DNA was prepared in agarose plugs and digested with *Xba* I (Boehringer Mannheim Biochemicals, Indianapolis, Ind) by previously described methods.[11] Fragments of DNA were separated by electrophoresis through 1% PFGE agarose (Boehringer) on a CHEF DR II system (BioRad Laboratories, Hercules, Calif) at 200 V for 20 hours with a ramped pulse time of 5 to 50 seconds. Isolates with PFGE patterns differing from the outbreak strain by fewer than three bands were further analyzed by using additional restriction enzymes (*Asp* II and *Not* I, New England Biolabs, Beverly, Mass).

RESULTS

Case-Control Study and Environmental Investigation

Initially, our investigation focused on patients with bloody diarrhea or postdiarrheal HUS beginning after January 1, 1993. By January 17, we had conducted hypothesis-generating interviews with 37 patients, of whom 27 (73%) reported having eaten at a chain A restaurant in the 10 days before illness began; all reported eating a regular hamburger. Patients mentioned many chain A restaurants; no clustering of illness was associated with a particular restaurant.

The case-control study was conducted on January 16 and 17 by using the first 16 patients identified who could name an eligible control, and their matched controls (Table). Seventy-five percent of case-patients but no controls had eaten at a chain A restaurant in the 10 days before symptom onset (matched odds ratio undefined; lower 95% confidence interval, 3.5; $P<.001$). All case patients had eaten regular hamburgers. No other exposure was a risk factor for illness. The case-control study was concluded because the association with chain A was confirmed and continuing interviews with newly reported possible case patients supported the findings of the case-control study. Also, in light of the subsequent public announcement, an ongoing case-control study would likely have been subject to bias.

The chain A menu included two sizes of hamburger patties. Regular patties, weighing 45 g, were sold individually and as part of the children's menu. Jumbo patties, weighing 114 g, were sold under a variety of names. All chain A restaurants reportedly followed the same routine cooking practices. Frozen regular hamburger patties were cooked for 1 minute on each side on a 191°C grill with timers programmed at chain A headquarters. We cooked 16 regular hamburgers according to chain A policy on grills in four restaurants. After being cooked for 1 minute on each side, all had at least one internal temperature measurement below 68.3°C (range, 41.7°C to 81.1°C), the cooking temperature required by Washington State law. Ten (63%) had a measurement below 60°C, the temperature recommended at that time by the Food and Drug Administration model food service code.[12]

On January 18, the state health department made a public announcement identifying chain A hamburgers as the cause of the outbreak, and the company voluntarily recalled all hamburger meat from its restaurants in Washington.

Characteristics of Cases and Attack Rates

In total, 501 cases were reported. Three hundred ninety-eight (79%) met the definition of a primary case, 48 (10%) were secondary cases, and 55 (11%) could not be classified as primary or secondary. Illness peaked during the week of January 17, when 243 patients became ill (Figure).

Four hundred eighty-six patients (97%) reported abdominal cramping, 451 (90%) reported bloody diarrhea, 316 (63%) reported subjective fever, and 271 (54%) reported vomiting. One hundred fifty-one patients (31%) were hospitalized for a median of 4 days (range, 1 to 118 days). Forty-five patients (9%) developed HUS, and three died of complications of HUS.

Frequency of Selected Exposures Among Cases and Controls, Washington, January 1993

Exposure	No. of Cases/ Total (%)	No. of Controls/ Total (%)	Matched Odds Ratio (95% Confidence Interval)
Chain A	12/16 (75)	0/16 (0)	Undefined (3.5-?)*†
Chain B	3/15 (20)	3/15 (20)	1.0 (0.2-5.8)
Chain C	2/14 (21)	4/14 (29)	0.5 (0.1-2.8)
Pork	1/9 (11)	7/9 (79)	0.0 (0.0-0.6)†
Chicken	11/14 (79)	11/14 (79)	1.0 (0.2-5.8)
Hot dogs	8/12 (67)	5/12 (42)	4.0 (0.4-99.0)

*The matched odds ratio and upper bound of the 95% confidence interval are undefined because there were no pairs in which the control ate at chain A but the patient did not.
†$P<.05$.

The median age of all case patients was 8 years (range, 4 months to 88 years); 75% were younger than 18 years. Forty-nine percent were female. Patients with HUS were younger than the 456 patients without HUS (median age, 5 years; mean, 8 years; range, 1 to 68 years vs median age, 9 years; mean, 15 years; range, 4 months to 88 years; $P<.01$); 60% were female patients with HUS.

Thirty-two (67%) of the 48 secondary case patients lived in the same household as a primary case patient; the others were playmates of or attended the same child day-care center as a primary case patient. Secondary case patients were younger than primary ones (median age, 3 years; mean, 8.6 years; range, 4 months to 60 years vs median age, 9 years; mean, 15.1 years; range, 1 to 88 years; $P<.001$) and less likely to have bloody diarrhea (78%; rate ratio, 0.9; 95% confidence interval, 0.7 to 1.0). Three secondary case patients (6%), including two of those who died, developed HUS.

Of the 398 patients with primary cases, 374 (94%) had eaten at chain A only once in the previous 10 days and were able to recall what they ate. The median incubation period was 3 days (mean, 3.7 days). Three hundred forty-four (92%) reported eating a regular hamburger. Of the 55 patients who could not be classified as having primary or secondary cases, seven (13%) had both eaten at chain A and been exposed to a case within the household in the 10 days before symptoms began, and five (9%) reported eating at chain A more than 10 days before they became ill (range, 11 to 20 days). The remaining 43 unclassified patients (78%), including four children with HUS, could not be linked to chain A. All but six patients who reported eating at chain A had eaten on or before the date meat was recalled. Sixty-seven patients ate at chain A restaurants on January 16, the day of peak exposure.

At least one case was reported from 58 (91%) of the 64 chain A restaurants in Washington. The median number of cases per restaurant was four (range, zero to 18). Available data for the 51 company-owned restaurants indicate that the median restaurant-specific attack rate was 3.5 cases per 1000 regular hamburgers sold from January 1 through January 17 (range, zero to 10). Higher attack rates were associated with a longer time from the date the first patient ate at the restaurant to the recall date ($r^2=0.28$; $P<.01$).

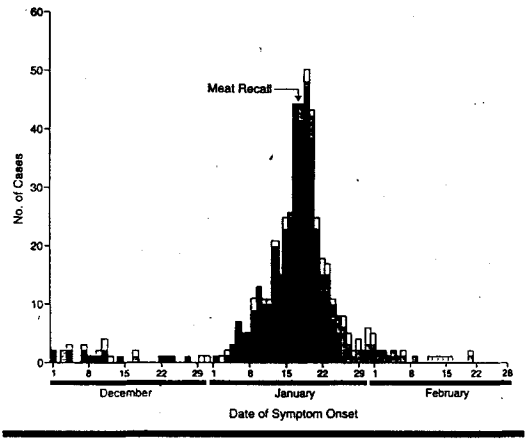
Recalled Meat

Hamburger patties for all chain A restaurants were prepared at a single patty-making plant in California. For each production day, the hamburger patties produced in each hour formed a lot. Soon after production, boxes of frozen hamburger patties were shipped from the plant to a central chain A warehouse in Washington. According to chain A personnel, the warehouse received one or two such shipments each month, held each shipment for 3 to 4 weeks, and then distributed it to chain A restaurants as needed. Each restaurant received approximately two deliveries a week of regular hamburgers and generally began using them a few days after delivery. Thus, chain A staff estimated that restaurants generally began serving regular hamburger patties from a particular production date no sooner than 4 weeks after production.

Approximately 90% (255 000 patties) of the regular hamburgers recalled from chain A restaurants in Washington had been produced on November 19, 1992. These recalled patties represented 43% of all regular hamburgers produced for chain A on that day and 62% of the shipment of this day's production that had been sent to Washington.

Patient Isolates

We tested a convenience sample of 25 isolates from primary case patients, one isolate from a secondary case patient, and all 18 available isolates from unclassified case patients who became ill during the outbreak period, as well as isolates from more than 100 Washington residents with *E coli* O157:H7 in-



Date of onset of culture-confirmed *Escherichia coli* O157:H7 infections and hemolytic uremic syndrome cases, December 1, 1992, through February 28, 1993, Washington State. Black bars indicate primary cases; shaded bars, secondary cases; and white bars, unclassified cases.

fection in the 6 months before December 1992. All primary case isolates, the secondary case isolate, and 11 (61%) of the 18 unclassified case isolates possessed the genes for Shigalike toxin types I and II and had identical PFGE patterns (outbreak strain). The patterns of each of the seven isolates that did not match the outbreak strain were distinct. Among the 18 unclassified case patients, those in whom the PFGE pattern of the isolate did not match the outbreak strain developed illness later in the outbreak period ($P<.01$ for the difference between the mean onset date of patients whose isolates matched the outbreak strain compared with those whose isolates did not match). One of the 100 isolates obtained before December 1992 matched this strain, but this isolate was a different phage type and showed a different pattern when another enzyme (*Avr* II) was used. The PFGE pattern of two other isolates differed from the outbreak strain by a single band, but the use of additional enzymes (*Avr* II and *Not* I) revealed multiple differences.

Hamburger Meat Cultures

Eight regular hamburger patty lots produced on November 19, 1992, were shipped to Washington State and returned in the meat recall (Washington lots). The Washington State PHL isolated *E coli* O157:H7 from two of the most widely distributed Washington lots, and other laboratories isolated the organism from these lots and all other Washington lots produced on November 19, 1992 (Michael Doyle, PhD, Food Safety and Quality Enhancement Laboratory, University of Georgia, written communication, April 1994; Ann Marie McNamara, ScD, Food Safety and Inspection Service, US Department of Agriculture, written communication, May 1994; Jessica Tuttle, MD, and Tom Gomez, DVM, Centers for Disease Control and Prevention, written communication, April 1994). The PFGE patterns of the strains isolated from all these lots were identical to the outbreak strain.

COMMENT

This outbreak of *E coli* O157:H7 infections, linked to hamburgers distributed by a single chain of fast-food restaurants, resulted from errors in meat processing and cooking. It illustrates the potential for large food-borne outbreaks in fast-food chains, where many restaurants receive shipments of meat from a single source and use a uniform cooking technique.

A large portion of 1 day's production of hamburger patties was contaminated with a single strain of *E coli* O157:H7, as evidenced by our PFGE results and bacteriophage λ restriction fragment length polymorphism analysis as reported by Samadpour et al.[13] Culture surveys of US dairy farms (some linked to human illnesses), a stockyard, and a packinghouse in two northern states showed an overall fecal isolation rate for *E coli* O157:H7 of 0.15% from cows and 2.8% from heifers and calves.[14] Beef may become contaminated if intestinal contents contact the meat during slaughter or processing. Bacteria present on the surface are distributed throughout the meat by grinding.

As demonstrated by our cooking tests, most regular hamburgers cooked according to chain A policy did not achieve Washington State's required internal temperature of 68.3°C. This temperature is sufficient to kill more than 99% of organisms and to produce a "well-done" hamburger.[15]

Our experience illustrates the value of making *E coli* O157:H7 a notifiable disease. In Washington, where infection with the organism has been notifiable since 1987, 150 to 300 cases are reported yearly.[16] Because health care providers, laboratories, and health departments in Washington are relatively familiar with the organism, we were able to identify patients with bloody diarrhea rapidly and confirm that they had *E coli* O157:H7 infection. This facilitated determining the source of the outbreak and allowed for prompt intervention. In fact, applying the median restaurant-specific attack rate to the 255 000 recalled regular hamburgers suggests that approximately 800 primary cases were prevented by the meat recall in Washington.

Nonetheless, the outbreak also illustrates the limitations of routine passive surveillance. Cases of chain A–associated infection had occurred before mid January, when the outbreak investigation was conducted (Figure). Delays in reporting, lapses in patient recall, and the insensitivity of routine case follow-up may have hampered earlier detection of the outbreak. As others have argued, improved clinical laboratory capabilities and better surveillance for food-borne disease are needed.[17-19]

Because we used a strict case definition, the reported number of cases probably underestimates the actual size of the outbreak. We received reports of an additional 130 patients with bloody diarrhea during the outbreak period who did not have a positive culture, raising the number of persons reported ill to 631. Moreover, in *E coli* O157:H7 outbreaks in which the entire exposed population could be ascertained, the proportion of ill persons with bloody diarrhea was generally lower than the 90% we observed.[3,20-22] Thus, many persons with *E coli* O157:H7 infection may not have had bloody diarrhea and did not seek medical attention.

Further evidence of unrecognized in-

fection is provided by the similarity by PFGE of the *E coli* O157:H7 isolates from many patients with no known exposure source to those of patients who ate at chain A. Presumably, many patients whose source of exposure could not be determined represent cases of secondary infection after exposure to an individual with undiagnosed infection.

Few other studies have reported secondary attack rates; the 10% secondary attack rate we observed is lower than that reported in some studies of outbreaks in child day-care centers.[17,23] However, the characteristics of secondary cases we observed are similar to those in previous reports: fewer secondary than primary case patients reported bloody diarrhea, and secondary case patients were younger.[3] Similarly, studies of shigellosis transmission have reported a higher secondary attack rate among younger children.[24,25]

It is unclear how patients who became ill after eating at chain A in early December acquired their infection. These patients were similar demographically to patients who became ill later in the outbreak period, and the PFGE patterns of their strains were identical. However, according to chain A personnel, hamburgers from the implicated production day would not have reached Washington chain A restaurants by early December. Cultures of some lots of regular hamburger patties from three earlier production dates, likely to have been served in early December, were negative for the outbreak strain of *E coli* O157:H7 (Ann Marie McNamara, ScD, US Department of Agriculture, written communication, May 1994; Michael Doyle, PhD, University of Georgia, written communication, April 1994). However, the contaminated patties from these earlier production dates may have already been used. Although patties from earlier lots may have contained the outbreak strain, it is also possible that some restaurants may have received contaminated hamburgers from the November 19, 1992, shipment earlier than usual.

In the absence of records of dates when lots were supplied to restaurants, we could not determine when individual restaurants received the contaminated lots of meat and thus could not calculate accurate restaurant-specific attack rates. That the length of time restaurants served the contaminated lots of meat was a determinant of the attack rate is suggested by the fact that restaurants where the first reported case patients ate early in January had higher overall attack rates. This attack rate underestimated the actual rate by a varying degree, as different amounts of uncontaminated meat were included in the denominator we used (regular hamburger sales from January 1 to January 17), depending on when the contaminated lots reached each restaurant. Nonetheless, the median attack rate was higher than the 0.6 to 1.0 case per 1000 patties reported in the 1982 fast-food hamburger–associated *E coli* O157:H7 outbreak.[5] Better records of dates and lot numbers of products supplied to restaurants would have facilitated this and other disease cluster investigations.

This is the largest outbreak of *E coli* O157:H7 infections yet reported. It illustrates that ongoing public health surveillance is essential for the prompt recognition and control of outbreaks. The magnitude and severity of the disease underscore the importance of preventing infection. To avert human illness caused by this potentially lethal pathogen, measures should be developed to reduce meat contamination. Consumers and the food service industry should be educated about the importance of thoroughly cooking hamburger meat. Restaurants should ensure that meat cooking procedures result in complete cooking.

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Results of Routine Restaurant Inspections Can Predict Outbreaks of Foodborne Illness: The Seattle-King County Experience

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Abstract: To analyze the association between the results of routine inspections and foodborne outbreaks in restaurants, we conducted a matched case-control study using available data from Seattle-King County, Washington. Case restaurants were facilities with a reported foodborne outbreak between January 1, 1986 and March 31, 1987 (N=28). Two control restaurants with no reported outbreaks during this period were matched to each case restaurant on county health district and date of routine inspection (N=56). Data from the routine inspection that preceded the outbreak (for case restaurants) or the date-matched routine inspection (for control restaurants) were abstracted from computerized inspection records. Case restaurants had a significantly lower mean inspection score (83.8 on a 0 to 100 point scale) than control restaurants (90.9). Restaurants with poor inspection scores and violations of proper temperature controls of potentially hazardous foods were, respectively, five and ten times more likely to have outbreaks than restaurants with better results. Although this study demonstrates that Seattle-King County's routine inspection form can successfully identify restaurants at increased risk of foodborne outbreaks, it also illustrates that more emphasis on regulation and education is needed to prevent outbreaks in restaurants with poor inspection results. (*Am J Public Health* 1989; 79:586–590.)

Introduction

Routine inspection of restaurants to prevent foodborne disease is mandated by food sanitation codes throughout the United States[1] and is recommended by the Model Standards for Community Health Practice of the US Public Health Service.[2] Although common sense dictates that the results of routine inspections should predict outbreaks of foodborne illness, this relation has never been studied in food service facilities other than cruise ships.[3] We therefore conducted a case-control study to determine whether routine inspection results and other characteristics were associated with reported foodborne outbreaks in restaurants using available data from Seattle-King County, Washington.

Restaurant Permit Program

For several decades, the Seattle-King County Department of Public Health has issued annual permits for permanent restaurants. Since January 1, 1986, when 3,076 restaurants had such permits,* characteristics noted on the permit have been entered into a computerized permit file.[4]

Restaurant Inspection Program

Sanitarians in five health districts use a standard reporting form developed by the Seattle-King County Department of Public Health for all routine inspections.[5] Data from the current form have been entered into a computerized inspection file since the form was adopted on January 1, 1986. The form identifies 42 types of violations classified as "critical" or "noncritical." Critical violations are thought to have a direct impact on foodborne disease, e.g., the temperature of potentially hazardous foods, food handling practices, the health status of food handlers (Table 1). Noncritical items are thought to play a minor role in foodborne illness, e.g., the cleanliness of nonfood contact surfaces, walls, and ceilings. A critical violation incurs a debit of 4-5 points from a perfect inspection score of 100, whereas a noncritical violation incurs a debit of 1-2 points. Violations are also classified as to type (food, food protection, personnel). After tallying all debit points, sanitarians assign a final score from 0 to 100 and a result category, which is largely a function of the final score. A score of 86 to 100 indicates a "satisfactory" result. A score of 70 to 85 or a violation of any critical item indicates an "unsatisfactory" result, requiring timely correction of violations. A score of less than 70 points indicates a "suspend permit" result, warranting permit suspension and restaurant closure. These score cutoffs were based on a county-wide study that simultaneously scored restaurants with the old 298-point inspection form and the new 100-point form; restaurants closed on the basis of the old form typically received scores of less than 70 on the new form.*

Foodborne Illness Investigations

Epidemiologists in the Seattle-King County Department of Public Health receive about 700 complaints of suspected foodborne illness each year.[7] All suspected outbreaks of foodborne illness are investigated to determine the number of affected persons, the symptoms of illness, the suspected vehicle, the food source, and the preparation, storage, or handling of food. A reported outbreak of foodborne illness is defined as an incident in which two or more persons have the same disease, have similar symptoms, or excrete the same pathogen after eating a common food or beverage. Poisoning by botulism or by a toxic chemical requires only one ill individual.[8]

Methods

Restaurants

Case restaurants were permanent restaurants with an active food permit in March 1987 and with a reported foodborne outbreak between January 1, 1986 and March 31, 1987. Although 36 restaurants were associated with an outbreak during this period, only 28 were permanent facilities with an active permit and therefore eligible for further analyses. Control restaurants were permanent restaurants with an active food permit in March 1987 and with no reported foodborne outbreak between January 1, 1986 and March 31, 1987. Two controls were randomly selected from eligible controls that had been matched to each case on health

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*Unpublished data, Food Protection Program, Seattle-King County Department of Public Health.

TABLE 1—Risk of Foodborne Outbreaks Associated with Routine Restaurant Inspection Results, by Individual Violation, Seattle-King County, Washington, January 1, 1986–March 31, 1987

Number	Violation Type†	Debit Point Value	Odds Ratio	(95% CI)
Food Violations				
1.	Foods from approved source, sound condition, not adulterated: no spoilage, no home canned foods†	5	3.2	(0.3, 36.6)
2.	Original container, properly labeled	1	1.0	(0.1, 16.9)
	Any food violation		2.1	(0.3, 13.1)
Food Protection Violations				
3.	Potentially hazardous foods at safe temperatures during storage, display, service, transport, hot and cold holding (45° or below or 140°F or above)†	5	10.1	(2.2, 45.7)
4.	Potentially hazardous foods properly cooked to 140°F, except pork to 150°F, poultry to 165°F, and rare roast beef to 130°F†	4		(1.2,)*
5.	Potentially hazardous foods properly cooled, 4" food depth cooled to 70°F within 2 hrs to 45°F within 4 hrs; salads made with prechilled ingredients†	5	1.4	(0.4, 5.2)
6.	Potentially hazardous foods properly reheated to 165°F†	4	1.0	(0.1, 11.0)
7.	Enough facilities to maintain proper hot and cold temperatures, properly designed, maintained, operated. Potentially hazardous foods kept under temperature control except during necessary preparation procedures†	4	8.6	(1.0, 74.9)
8.	Thermometers provided and conspicuous	1	2.0	(0.7, 5.4)
9.	Potentially hazardous foods properly thawed	1	6.0	(0.6, 57.7)
10.	General food protection during storage, preparation, display, transportation, service; no double stacking; sneeze guards	2	2.4	(0.8, 7.2)
11.	Foods protected from cross-contamination during preparation and refrigerated storage. Foods not re-served†	4	1.7	(0.4, 7.0)
12.	Handling of food (ice) minimized; proper use of utensils	2	3.9	(0.4, 39.5)
13.	In-use food (ice) dispensing utensils properly stored	1	2.1	(0.5, 9.5)
	Any food protection violation		15.8	(2.0, 124.1)
Personnel Violations				
14.	Personnel with infections or illness restricted†	5		(0.1)*
15.	Hands washed and clean; wash hands after using the restroom; after coughing, sneezing, smoking, eating, drinking; between handling raw and cooked; or otherwise contaminating hands. Good hygienic practices†	5		(0.6)*
16.	Clean clothes, hair restraints	1	NA	
17.	Food and Beverage Workers' Permits current for all personnel	1	1.8	(0.3, 12.0)
	Any personnel violation		3.3	(0.6, 18.0)*
Food Equipment, Utensils Violations				
18.	Food (ice) contact surfaces: designed, constructed, maintained, installed, located	2	1.5	(0.4, 5.0)
19.	Nonfood contact surfaces: designed, constructed, maintained, installed, located	1	0.2	(0.04, 1.1)
20.	Food contact surfaces of equipment and utensils clean	2	1.8	(0.6, 5.4)
21.	Nonfood contact surfaces of equipment and utensils clean	1	0.6	(0.2, 2.2)
22.	Proper storage and handling of clean, sanitized equipment and utensils	1	14.9	(2.6, 85.4)
23.	Single-service articles properly stored and dispensed. No reuse of single-service articles	1	1.7	(0.2, 12.2)
	Any food equipment or utensils violation		1.8	(0.6, 5.8)
Cleaning, Washing, Sanitizing Violations				
24.	Dishwashing facilities designed, constructed, maintained, located, operated (accurate thermometers, chemical test kits provided)	2	4.2	(0.8, 21.9)
25.	Equipment and utensils preflushed, scraped, soaked. Wash and rinse water clean, proper temperature	1		(0.03,)*
26.	Sanitization rinse: clean, proper temperature, concentration, exposure time. Equipment, utensils sanitized†	4	1.9	(0.6, 6.5)
27.	Wiping cloths clean, use restricted, stored in sanitizer	1	0.7	(0.2, 2.3)
	Any "cleaning, washing, sanitizing" violation		1.2	(0.5, 3.1)
Water				
28.	Approved water source, hot and cold, under pressure; safe†	5	NA	
Sewage, Plumbing Violations				
29.	Sewage and waste water disposed sanitarily. No cross-connection, back siphonage, backflow†	5	2.0	(0.1, 32.0)
30.	Plumbing installed, maintained	1	2.0	(0.4, 9.9)
	Any sewage and plumbing violation		1.5	(0.3, 6.7)
Toilet, Hand-Washing Facilities Violations				
31.	Number, convenient, accessible, designed, installed†	4	3.6	(0.7, 18.9)
32.	Toilet rooms enclosed, self-closing doors, fixtures in good repair, clean; hand cleanser, sanitary towels/hand-drying devices provided, proper waste receptables	2	1.5	(0.5, 4.1)
	Any toilet and hand-washing facilities violation		1.6	(0.6, 4.2)
Garbage, Refuse Disposal Violations				
33.	Containers/receptacles covered, adequate number, insect and rodent proof, pick-up frequency, clean	1	0.7	(0.1, 6.4)
34.	Outside storage area enclosures properly constructed, clean	1	4.0	(0.4, 44.1)
	Any garbage and refuse disposal violation		1.0	(0.2, 5.5)
Insect, Rodent, Animal Control Violations				
35.	Presence of insects/rodents. No birds, turtles, or other animals†	4	6.5	(0.8, 51.1)
36.	Outer openings protected from flying insects/rodent proof	1	3.9	(0.4, 39.5)
	Any insect, rodent, animal control violation		3.8	(0.9, 16.1)
Floors, Walls, Ceilings Violations				
37.	Floors constructed, clean, good repair, covered	1	1.5	(0.5, 4.6)
38.	Walls, ceiling, attached equipment: constructed, good repair, clean, smooth	1	2.0	(0.6, 6.8)
	Any floors, walls, ceilings violation		1.1	(0.4, 3.2)

(continued)

TABLE 1—Continued

Number	Violation Type†	Debit Point Value	Odds Ratio	(95% CI)
Lighting, Ventilation				
39.	Lighting provided as required, fixtures shielded. Rooms and equipment vented as required	1	1.2	(0.3, 5.0)
Other Operations				
40.	Toxic items properly stored, labeled, used†	4	1.9	(0.5, 7.4)
41.	Premises maintained free of litter, unnecessary articles; living/sleeping quarters separate; authorized personnel; dressing rooms, lockers	1	0.8	(0.2, 3.0)
42.	Clean, soiled linen properly stored	1		(0.1,)*
Any "Critical" Violation†			6.3	(1.8, 22.5)

*Odds ratio was indeterminate in matched and unmatched analyses; only the lower 95% confidence interval could be calculated in the matched analysis.
†"Critical" violations are numbers 1, 3–7, 11, 14, 15, 26, 28, 29, 31, 35, 40
NA—No restaurants had this violation

district and routine inspection date (±30 days), yielding 56 control restaurants for analysis.

Data

Data on each outbreak were collected from the Seattle-King County investigation files, including number of affected persons; implicated agent, vehicle, and contributory cause; and laboratory test results. We analyzed two variables from the permit file: type of ownership (corporate versus noncorporate) and seating capacity. All case and control restaurants had known values for at least one of these variables and were included in these analyses. Using the inspection file, we compared the routine inspection that preceded the outbreak for case restaurants with the date-matched inspection for control restaurants. We analyzed overall score, result category, specific violations, classes of violations, and inspection duration. One case and one control restaurant were excluded from the analyses because of incomplete inspection data.

In June 1987, managers of the 28 case and 56 control restaurants were telephoned to collect additional risk factor data. After obtaining informed consent, a trained interviewer questioned the restaurant manager on duty at the time of the call about restaurant characteristics, food preparation practices, employee turnover, training in food sanitation, and attitudes on food poisoning. After exclusions for non-response and interview refusal, 25 case and 48 control restaurants remained for analysis.

Mean scores, t tests, and confidence intervals (CI) were calculated using methods described by Ury.[9] Odds ratios and 95% CI for matched case-control analyses were calculated using PECAN.[10,11] Although we planned to match two control restaurants per case restaurant, exclusions during analysis necessitated a variable matching ratio. When sparse data made odds ratios in the matched analysis indeterminate, but at least one case restaurant and one control restaurant were exposed to a given factor, we calculated unmatched odds ratios and 95% CI.[12] When this was not possible, we applied exact methods to the matched data to calculate the lower 95% CI.[13]

Results

As shown in Table 2, the foodborne outbreaks affected from one to six persons with a mean of 2.9 persons. The implicated pathogen was unknown for most outbreaks; poultry was the most commonly implicated vehicle. The implicated contributory cause for most outbreaks was improper temperature control of food during cooking, cooling, reheating, holding, or storage. The interval between index inspection and outbreak ranged from 2.0 to 14.1 months, with a mean interval of 3.7 months. This interval is less than the four-month inspection interval recommended for all restaurants by the Seattle-King County Public Health Department.[14]

Case restaurants had a significantly lower mean inspec-

TABLE 2—Characteristics of Reported Foodborne Outbreaks in 28 Seattle-King County, Washington Restaurants, January 1, 1986–March 31, 1987

Characteristics	N
Number Persons Ill	
1	1
2	15
3–4	7
5–6	5
Total	28
Implicated Agent	
Unknown	22
Clostridium perfringens	2
Salmonella heidelberg	1
Shigella flexneri	1
Copper	1
Alkaline cleaner	1
Total	28
Implicated Vehicle	
Poultry	8
Rice	5
Fish	5
Beef	4
Pork	3
Beans	3
Other	4
Unknown	4
Total	36*
Implicated Contributory Cause	
Improper temperature control of potentially hazardous foods	25
Unsafe food source	5
Improper storage of toxic chemical	1
Cross-contamination	1
Poor food handler hygiene	1
Total	33*
Restaurant/Cuisine Type	
American	9
Chinese	7
Mexican	7
Seafood	2
French	1
Japanese	1
Moroccan	1
Total	28

*Totals do not add up to 28 because in some outbreaks more than one vehicle or contributory cause was implicated.

TABLE 3—Factors Associated with Foodborne Outbreaks in Restaurants, Seattle-King County, Washington, January 1, 1986–March 31, 1987

Factors	Factor Present Cases/Controls*	Factor Absent Cases/Controls*	Odds Ratio	(95% CI)
Any improper food protection practice (violations 3–13)	25/31	2/22	15.8	(2.0, 124.1)
Improper storage or handling of equipment and utensils (violation 22)	6/1	21/52	14.9	(2.6, 85.4)
Potentially hazardous foods at unsafe temperature (violation 3)	15/10	12/43	10.1	(2.2, 45.7)
Any "critical" violation	22/24	5/29	6.3	(1.8, 22.5)
Inspection lasting ≥37 minutes	13/22	4/27	5.6	(1.1, 26.9)
Score ≤86 points	13/10	14/43	5.4	(1.5, 19.8)
Corporate owner	21/28	5/17	5.3	(1.1, 24.4)
"Unsatisfactory" or "Suspend Permit" result	20/22	7/31	3.9	(1.4, 11.0)
Restaurant size ≥150 seats	12/11	16/45	3.4	(1.1, 9.9)
Potentially hazardous food not cooked to proper temperature (violation 4)	3/0	24/53	†	(1.2, —)†
American cuisine specialty	9/32	16/16	0.2	(0.1, 0.7)

*Presented for unmatched data only.
†Odds ratio was indeterminate in unmatched analysis; only the lower 95% confidence interval could be calculated in the matched analysis.

tion score (83.8) than control restaurants (90.9) (difference = 7.1, 95% CI = −13.3, −2.18). Restaurants with an overall score of less than 86 were about five times more likely to have an outbreak than those with better scores. Restaurants that received an inspection result of "unsatisfactory" or "suspend permit" were about three times more likely to have an outbreak than those with "satisfactory" results (Table 3). Several specific violations significantly increased the risk of an outbreak, including any improper food protection practice (violations 3–13), especially improper temperature control of potentially hazardous foods (violations 3 and 4), improper storage and handling of equipment (violation 22), and any "critical" violation. Several other individual violations related to improper food protection practices had odds ratios of 2.0 but the confidence intervals included 1.0 (Table 1). Restaurants with inspections lasting longer than 36 minutes, with corporate owners, or with 150 or more seats were also more likely to have outbreaks than restaurants without these characteristics (Table 3). Two factors identified through telephone interviews were positively associated with outbreaks: Chinese cuisine specialty (OR=5.0, 95% CI=1.0, 25.8), and any Asian cuisine specialty (OR=4.0, 95% CI=1.0, 15.6). One factor, American cuisine specialty, had a clearly negative association with outbreaks (OR=0.2, 95% 0.1, 0.7) (Table 3).

Discussion

This study demonstrates that restaurants with poor routine inspection results were at increased risk of foodborne outbreaks. Key risk factors included a low score (less than 86 points), an inspection result warranting follow-up inspection or permit suspension, and violations of recommended food protection measures.

Our study was based on the inspection form used in Seattle-King County which differs from forms used by other locales and the US Food and Drug Administration[13] by assigning greater weight to violations of proper temperature controls of potentially hazardous foods. Most outbreaks in this series were probably caused by improper heating, cooling, cooking, holding, or storage of food—a finding consistent with a nationwide series of outbreaks reported to the Centers for Disease Control.[1] Inspection forms that give less weight to these temperature control factors may be less predictive.

It is widely believed that inspection results vary according to the sanitarian who performs an inspection.[14] We were unable to directly evaluate the quality of inspection data used in this study because Seattle-King County does not routinely require more than one sanitarian to do the same inspection. A recent evaluation in one district of the county where several sanitarians inspected the same restaurant at the same time suggested that the sanitarians were fairly consistent in identifying violations of proper temperature controls and cross-contamination but less consistent on overall score or the combination of violations accounting for that score.*

The strong association between outbreaks and improper storage and handling of equipment (violation 22) is difficult to explain on a biologic basis, and may be spurious because it is based on extremely sparse data. Conceivably, certain equipment violations, such as improper storage or handling of meat slicers, could be hazardous. Alternatively, improper use of equipment may reflect food-handling techniques more directly related to foodborne illness, a consideration if sanitarians do not use standard techniques for identifying violations.

Inspections lasting 37 minutes or more may have been associated with foodborne outbreaks because more time is needed to identify and record multiple violations. Large restaurant size may represent a risk factor simply because such restaurants serve numerous patrons, thus increasing the likelihood of finding two ill persons needed to identify an outbreak. Alternatively, large restaurants may be more likely to have an outbreak because of poor control of food temper-

*Unpublished data, Food Protection Program, Seattle-King County Department of Public Health.

atures, greater food volume, more complex menus, or less closely supervised food handlers. The association of the outbreaks with corporate ownership largely reflects the association of outbreaks with restaurant size. Compared with small noncorporate restaurants, large noncorporate restaurants were more likely (OR=5.0, 95% CI 0.5, 47.1) than small corporate restaurants (OR=2.5, 95% CI 0.6, 10.4) to have an outbreak.

We cannot rule out chance as an explanation for the positive associations with Asian or Chinese restaurants because the lower confidence bounds were 1.0, but these positive associations are plausible because certain food preparation practices in Cantonese-style restaurants have been found to be hazardous.[16] On the other hand, reporting bias could also explain these associations if Seattle-King County residents were more likely to report foodborne illness after eating in Asian restaurants than in other restaurants. Similarly, the apparent "protective" effect of American cuisine specialty could reflect less hazardous food preparation and sanitation practices or less intensive reporting of foodborne illness from American-style restaurants.

Poor inspection results should trigger appropriate education and regulatory action, such as follow-up inspection or permit suspension, which in turn should prevent outbreaks. Because our study illustrates that restaurants with poor inspection results are *more* likely to have outbreaks, it appears that the resulting regulatory action and education were not sufficient to prevent these outbreaks or that the restaurants did not adopt the recommended improvements on a long-term basis. Although we did not directly address this issue in our study, it probably reflects several problems. Restaurants with suspended permits are typically closed for less than 24 hours, a reprimand which might have little impact on a restaurant's profits or reputation. In addition, some restaurant managers complained during the telephone interviews that the education offered by sanitarians at the time of routine inspection is cursory or inconsistent. Finally, sanitarians in Seattle-King County and other locales[17] often report that food sanitation procedures taught at routine inspection have been abandoned by the next inspection.

Although this study demonstrates that the Seattle-King County inspection form can successfully identify restaurants at increased risk of foodborne outbreaks, it also illustrates that more emphasis is needed on regulation and education to prevent outbreaks in restaurants with poor inspection results. Permit suspension and timely follow-up inspections are clearly warranted when low scores or critical violations are noted. Detailed education to food handlers and their supervisors on the risks associated with specific violations is also needed. The risk estimates in Table 1 provide a simple instruction tool: for example, a sanitarian who notes unsafe storage temperatures of potentially hazardous foods (violation 3) could explain that this increases the risk of an outbreak ten-fold. Food protection programs should also assure that sanitarians use appropriate inspection techniques and that food handlers are certified in proper food preparation techniques. Finally, investigation of all complaints of foodborne illness will also help to monitor restaurants that pose an unusual public health risk.

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Mr. SOUDER. For Congress to find anything consistently or logically over an extended period of time, don't hold your breath. But we will do the best we can.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Earlier, we talked about mandatory reporting. We talked about in terms of uniform reporting. What are your views on that?

Dr. KOBAYASHI. Well, to my knowledge, there is not a State in this country that does not require foodborne disease outbreak reporting. Forty-one of the States in the United States currently are requiring reporting of *E. coli* O157. That increased from about 11 States before the 1993 outbreak.

So I think that there is a certain amount of uniformity with regard to the requirement of foodborne outbreak reporting. There is variability, of course, with regard to how complete that reporting is.

Mr. TOWNS. So do you think we should have—the Government should say in terms of what has to be reported and how it should be reported? Are you saying that that is not necessary?

Dr. KOBAYASHI. Well, whether it should be in law or not is beyond my level of comprehension. The Conference of State and Territorial Epidemiologists, for example, has a list which is considered to be nationally reportable diseases. It does not require that every State have them, but it is the gold standard to which States adhere to.

Whether that should be codified into an actual Federal law, I don't pretend to understand. But I think that there is a process of consensus-building on what is acceptable practice in terms of public health reporting requirements. The reporting requirements themselves are legally present in each State.

Mr. TOWNS. But my problem is, and I am not here to sort of push and push, I am not doing that today. But my problem is that if there is inconsistency in reporting, you know, even in terms of the time that it comes in, you know, sometimes that can create a problem and could—and if we had the information, we could save lives. That is my concern. And until we have some uniform kind of way to deal with these kinds—with this situation, you know, I am not sure, you know, that we will be able to do the kind of job that needs to be done.

Now, I know in terms of maybe, you know, legislation might not be the way to go. I don't know. But the point is that I just think that we need to have a little better handle on it than we have now, because right today, you indicated that all States don't even report. I mean that within itself tells me something.

Dr. KOBAYASHI. All States are not requiring reporting of *E. coli* O157. So far as I know, they are all requiring reporting of foodborne outbreaks. But I completely agree with your comments that there is lack of uniformity of reporting and a great deal could be done to improve that.

For example, several years ago, a survey was performed among various States as to exactly what they defined as various illnesses. It is not only have a reporting requirement, but then what do you consider to be a reportable case of *E. coli*? Do you have to have a culture, or what sorts of tests are required? And there were—it was

found that there was a great deal of variation, even among widely reported diseases, as to exactly how the reporting occurred.

The CDC and the Conference of State and Territorial Epidemiologists did a lot of work on establishing a standard case definition set, which is, to my knowledge, used widely around the country. We use it in Washington State. And I think that that helps. But there is still a lot of work to be done to improve uniformity of reporting on a national basis.

Mr. TOWNS. Yes, Doctor.

Dr. ALLOS. Well, with *Campylobacter,* I believe 49 out of 50 States require reporting of *Campylobacter* infections. I think one of the things about reporting is you can only report a culture that is positive, and there are many laboratories, many hospitals that don't culture for *Campylobacter,* and there are many more, I am sure, that don't culture for *E. coli* O157. And there are many things—you know, my interest is Guillain-Barre syndrome and *Campylobacter.* You are not going to be able to detect those from a reporting system. You are going to need to do specific studies, case control studies, active sorts of surveillance work, to ferret those kinds of issues out.

So although I think reporting is useful and it is important, I don't think it is going to solve the problems.

Mr. TOWNS. Let me put it this way. Let's switch roles. What should we do, then? What should the Congress do to be able to get the kind of information out there that decisions can be made and be made quickly? What should we do on this end, on this side? I mean what role should we play? I mean evidently something is wrong.

I know in the State of Washington, the serious problem that you had a few years ago, and you described so eloquently here. What can we do to sort of cut down on the possibility of something like that happening again?

Dr. ALLOS. Well, I think the situation you are talking about, the Jack-in-the-Box outbreak of *E. coli* O157, it seems to me that that was a situation that was handled admirably. Reporting did take place, and as a result of that reporting, the public health agencies at both the State and the Federal level were able to take the actions needed to impound contaminated lots of beef and prevent the further spread of infection, so that the reporting mechanism was in place and worked there.

The reporting mechanism could not have stopped the outbreak. The way you would stop the outbreak would have something to do with what you would do at the level of the farm or the beef industry, the cattle industry, the restaurants. That is how you could stop it from occurring to begin with.

The reporting helps you track it and helps you prevent further spread, but it can't—by definition, if there is a report, there is already disease. It already took place.

Mr. TOWNS. What about the States that are not even reporting it? That is my concern. Every State is not even reporting it? Even *Campylobacter,* you are saying that all of the States are not reporting?

Dr. ALLOS. Again, I will probably let Dr. Kobayashi talk about this since we are talking about *E. coli* O157, but 10 years ago there were hardly——

Mr. TOWNS. Any. We just happened to pick on that one because we are all familiar with what happened in the State of Washington. I am talking about any pathogen. I am trying to get some information, some direction from you, and I appreciate you coming and you gave an eloquent testimony, both of you. And I am now trying to tap into your experience to see what we can do from a legislative standpoint to be able to protect the lives of people.

I am not trying to put you on the spot, because that is not my intention at all. I want to just say that right up front. But what I am trying to find out is if there is anything from this standpoint as a Member of the U.S. Congress that is concerned about what is going on, as to what we might be able to do to curtail and to be able to eliminate these kinds of problems. That is really where I am coming from. So if either of you have any information, maybe if you feel comfortable, why don't you take my seat for a few minutes and then tell me what I should be doing.

Dr. ALLOS. Well, I agree with you that reporting is crucial. It is important. All I am saying is that it is only part of the solution, it is not all of the solution.

Dr. KOBAYASHI. I guess my general suggestions fall into the general categories of education, surveillance, and evaluation. On the education front, I don't think there is a State in this country that is more aware of the risk of *E. coli* O157:H7 and poorly cooked hamburger meat. Yet on a survey that we recently performed among citizens in Washington State, we found that still to this day, 10 percent of the people in Washington State are still eating poorly cooked hamburger. Hopefully, that is not poorly cooked hamburger in restaurants, but it is poorly cooked hamburgers that they may be preparing themselves.

Now, I can't tell you what that percentage was before 1993. Chances are it was a lot higher than that. I can't tell you what that percentage is in other parts of the country that haven't been affected. But at least to me, that means that we have a long way to go to really educate the public with regard to the risks of foodborne disease. And that is just one food, one agent, and a lot of foodborne disease prevention is related to the food handling and preparation methods that individual people make in their own homes.

Similarly, there is a continual effort that needs to be made on educating food handlers and food inspectors and public health workers and doctors and so on and so on. And that is not something that you do one time and then feel you have accomplished your goals and then go on to do something else. You have to continue to work on that. The turnover in food handlers is enormous, and there has to be ongoing educational efforts. We try to do that in Washington State, and I am sure most other States do. But additional help on having the resources to really educate people at every level would be highly useful.

With regards to surveillance, I think a lot has been discussed in previous presentations. I think this issue of surveillance sites is a great idea. In Washington State, for hepatitis we have had one of our counties involved in a CDC surveillance site ever since the

1970's, and I think a great deal of useful information comes out of those special studies.

I urge that the efforts that occurred after the 1993 outbreak with regards to epidemiologic support at the USDA, as well as what I have mentioned already from the CDC and FDA continue. The difference between the epidemiologic support we get through the USDA now as compared to before the 1993 outbreak is night and day, and it would be a great shame to lose that expertise.

With regards to evaluation, as I mentioned, I think that there is a role for epidemiology to play in terms of evaluations of regulatory measures. In the written testimony I detailed a study that we did in the Seattle area comparing risk of outbreaks to risk of occurrence of violations of certain items on restaurant inspections. And there was a very clear relationship that was established, a fifteenfold increase in risk if certain items were violated upon the inspections, which were occurring before the outbreaks occurred.

We are able to do that because we had computerized records of inspections in Kent County and we had an excellent foodborne disease surveillance program in that county during that time. But it is interesting that to my knowledge, besides one study that the CDC did years ago, this was the only study that I am aware of that actually looked at the outcome of restaurant inspections. I don't think that epidemiology can answer every policy question, every evaluation question, but I think that there is a role for epidemiology to perform in areas like this as new regulations become developed.

Finally, I think that further work needs to be done on helping us identify good economic measures of the economic impact of foodborne disease. One of the frustrating things we have dealt with following the *E. coli* outbreak and other outbreaks has been difficulty in really determining what the economic impact is with regards to these diseases. We know that these diseases are very costly, but exactly how costly is difficult for us to determine. I think in part because we are physicians and epidemiologists and not economists.

So those are some general areas where I think increased Federal support would be greatly appreciated.

Mr. TOWNS. Well, I thank you very much, both of you. I really appreciate your statements. I sort of want to add that I think if we really look at this very closely that we might, by putting additional resources into it, even save this money. And I know for a fact we will save some lives, and that is a fact.

So on that note, I am prepared to do what I have to do on this side to get additional resources out there, to be able to get some answers to these questions. I think for the community to hear that it costs between $5 billion and $22 billion, I mean that is B as in "boy." That is a lot of money, and we don't know the difference. I mean $17 billion and questions still unanswered. I just think that we have come too far to have those kind of questions unanswered.

This is the same country that you can put a man and a woman on the Moon over the weekend and can't answer—I mean I just have difficulty.

Mr. Chairman, I yield back. I have used way over my time. I yield back.

Mr. SOUDER. Well, one additional thing that I learned is that I have always had my meat well done. I started to moderate to medium well; I think I will go back to well done. No pink.

One of the things that we heard you say is that physicians are key in this link, and yet we all the time hear that health costs are too high. Part of the reason health costs are high is because of all of the different tests that—and the doctors with more and more information and technical knowledge, it is becoming particularly hard for family practitioners, yet we need to see these things at the early stages. We can't have the data that we need.

Without the reporting, we need to have the doctors involved. How would you get the doctors more involved in this? How would you have them get additional knowledge on how to report the illnesses and identify the illnesses?

Dr. KOBAYASHI. Well, ironically, I am not sure about the costs for testing for *Campylobacter,* but the difference in cost for testing for *E. coli* O157:H7 and not doing it on a still test are a matter of only a few pennies, and it is more awareness among laboratories and people in general that this is a disease that should be looked for.

And what we found in Washington State was that if we obtained, even before the reporting requirement occurred, if we obtained information and investigated outbreaks and reported them back to the physicians and the public at large, that generated more reporting, and more reporting generated more information, and so on and so on. I think in general, even in these times of desires for reduced regulation, people are willing to participate if they think that you are doing something with the information.

Mr. SOUDER. Did you in Washington State have—is there a simple list of trigger signals to look for, if you see this, it is not a very expensive test, do the test?

Dr. KOBAYASHI. Yes, in so many words, and there are various modes of reporting through newsletters and bulletins and so forth. In particular, the MMWR that the CDC produces to feed back information to the practicing public as well as the public at large.

Mr. SOUDER. I wanted to move to Dr. Allos for a minute.

I had a couple of kind of technical questions on your testimony. Where you had the—you were talking about the risk factor in the study where you had a control group, I believe, of 103 and 115. What were the actual numbers of the people who got the disease where you said it was five times higher than the control group.

Dr. ALLOS. About—it was about 45 percent of the GBS patients had evidence of *Campylobacter* in their serum, indicating they had had recent infection.

Mr. SOUDER. And only about, maybe about 9 percent of the others?

Dr. ALLOS. Well, it gets a little bit more complicated than that, because when you are talking about—when you are looking for antibodies, it is kind of a level and you can define a positive as being above a certain level or below a certain level, and so you end up making estimates, and that is why I said a minimum of 30 percent were infected, and it could have been more than 50 percent.

So it gets to be a little bit more complicated when you are talking about various levels with serologic testing.

I think the better data comes from people who actually culture stools of patients with Guillain-Barre and are finding *Campylobacter* there in about 40 percent or more, and that is very dramatic and very telling information.

Mr. SOUDER. Were any other things as high of predictors as this?

Dr. ALLOS. A predictor of getting GBS.

Mr. SOUDER. Right.

Dr. ALLOS. Nothing. They have looked at so many other bacteria, so many other viruses, drugs, immunizations, surgical procedures, nothing even approaches this. This is significantly and dramatically the most important trigger of Guillain-Barre syndrome.

Mr. SOUDER. In the second page of your testimony, you have that it—the infection does not occur as a result of person-to-person transmission nor do food handlers cause *Campylobacter* outbreaks. Outbreaks have not been described in day care centers or institutions for the mentally retarded. That statement kind of jumped out at me. Is that because of the food handlers question or where did that statement pop in?

Dr. ALLOS. No; the reason is that *Campylobacter* comes from food. There are some infections like hepatitis A or shigella which occur as a result of fecal-oral contamination, and an infected food handler can cause everybody who ate at that restaurant to become sick. You can get a lot of transmission from one person to the next in a day care center where diapers are being changed or where people aren't washing their hands properly.

Campylobacter comes from food. It is like *salmonella*. It comes from a food source. And so although it is possible to transmit it from one person to another, it is not the typical and usual way it occurs. So if you look at the epidemiology of *Campylobacter,* you will see outbreaks that occur because all of the people ate one particular food which was contaminated to begin with, not because a food handler handled that—who was infected handled that food.

Mr. SOUDER. And you used the day care and the institution for mentally retarded because they have a high incidence, the potential——

Dr. ALLOS. A lot of other bacteria, fecal orally contaminated bacterid diseases are transmitted at a high rate in day care centers, institutions for the mentally retarded, nursing homes, other places like that.

Mr. SOUDER. Could that be a reporting factor as opposed to it is not there?

Dr. ALLOS. No; I don't think it is just a reporting factor. I think those diseases actually occur at a higher rate in those populations. It is just that when you have infants crawling around on the ground, everything goes into their mouth, there is a lot of opportunities for becoming infected in that age group and in that setting, than, let's say, college students, who wouldn't have the same risk.

Mr. SOUDER. And what would—in your suggestions of what we should do related to yours, you had a number of basic goals. What do you think the biggest need is at our level?

Dr. ALLOS. Well, it is not that easy to pinpoint into one particular thing. We don't know enough—if I could tell you that it is this particular *Campylobacter* strain that is causing all of the trouble and it is causing the trouble in this population of people right here,

then we could come in with legislation and fix that problem, but we don't know that yet. And so most of my recommendations have to do with getting the information.

The CDC's emerging infections program is a great way to collect epidemiologic data to help us figure out who is getting these infections, why, what are the risk factors, and also to look at the strains, try and type them, figure out which strains are the ones that are presenting the greatest risk, NIH funding so that it can be studied at a basic science level, educating consumers, trying to reduce the risk of *Campylobacter* in poultry plants. All of those things together could help the problem. I can't tie it up in a nice neat package, because we are just not that far advanced in our knowledge of this connection yet. We are still basically at the trying-to-figure-it-all-out stage.

Mr. SOUDER. Dr. Kobayashi, in one of the similar questions, what Mr. Towns was asking, because I don't fully understand it, and I apologize for being relatively ignorant, which is kind-to-me statement in these areas.

I understand that the Washington system worked well comparatively because by getting 60 percent of it, you could have had more deaths and more severe illnesses. But was there not a way to catch it before it got to that point? Are things being done in Washington State before the restaurant level as well as a result of what happened?

Dr. KOBAYASHI. Well, reporting requirements and outbreak investigations aren't going to keep outbreaks from happening, and I think that that is—yes, this is the big $64 question, or $64 million question, I guess, with regards to looking back on the *E. coli* outbreak is what could have been done to prevent it. We now know that when those restaurants were inspected, in fact, there was inadequate cooking of that hamburger, that no matter by whose temperature requirements you go by, by the FDA's, the State of Washington's, et cetera, at that time, there was a significant amount of undercooking of hamburger at that facility.

The problem is that there are many, many restaurants that need to be inspected, and you can't identify all violations all the time.

Looking back on our old data with the DNA fingerprinting methods, we found that in fact there were a small number of cases that were occurring before we knew about it by about 4 weeks or so. It is hard to know what would happen today if we were using the technology that we are using today to identify outbreaks what would have happened back in 1993. But it is entirely possible that we may have had a small outbreak or perhaps no outbreak at all.

So it is difficult to know what could have been done completely.

Mr. SOUDER. Do you have any further questions?

Mr. TOWNS. I just want to make certain I understand this very clearly. We are talking about reporting, and I am not sure what you are saying? It is my understanding that if you are reporting and you find that there is some information coming in that might be a signal that there is a problem, is there some kind of way that that information could be used to sort of encourage you to look further to begin to put out some signals to alert people of the fact that there might be a problem?

Isn't there some way this could be done? This issue in the State of Washington, which I think you are very familiar with, of course, that if you are giving—information is coming out which signals that, wait a minute, here is something unusual that has happened, then wouldn't you be in a position to—from a point of saying, wait a minute, I think we better examine this a little closer and maybe the information should get out to the people. Wouldn't that be something that we could do to save lives?

Dr. KOBAYASHI. I believe what you have described is the essence of reporting and surveillance and investigation. In fact, at the State level, or at least in the area that I work in, that type of process occurs all the time. And in Washington State, we report about over 100 outbreaks of foodborne disease every year. And most of those are very, very small outbreaks where problems are identified, deficiencies are corrected, and the outbreak is reported, and no publicity or any sort of general alarm is created. It is less frequent that we have the big outbreaks that generate national attention like the 1993 outbreak.

Mr. TOWNS. On that note, I think that in the State of Washington you seem to have made a lot of progress after the crisis that occurred. But I think my concern, doctor, is that you have several States that are not reporting. I mean that is a concern. And then it is my understanding that you have other States that are not reporting with great consistency. So my question that I asked you earlier, do you feel that we should mandate this from this side?

I know you felt uncomfortable in answering it, and that is the reason why I have these concerns, because it appears to me that the State of Washington might have a model that the Nation could follow, and evidently you have put a lot of resources into it after the crisis, I mean after the situation that developed, that a lot of attention was paid to it and that a lot of people got involved, and you put additional resources into it, you reorganize, which was like some of the—maybe we should do it in other places, you know, to try and get consistency in the data. I mean that is the point I am talking about. And I am not sure I am asking the question in the fashion that it should be, because, you know, it is just coming out of my concern, you know, when I hear that even in terms of *Campylobacter,* there are States that don't even report it. I mean a State, I should say, that doesn't even report it. That bothers me. And then to look at *E. coli,* I mean, what can we do, you know, is the question to prevent what happened in Washington from happening in other places.

Now, I think somewhere along the line that information could be helpful. That is the point I am making, and I am sure, you know, I am making myself clear. But I really feel that there is more that can be done, and that is all I am saying. And I think that your State might be a State that we could use as a model.

Dr. KOBAYASHI. Well, I guess my feeling is that there is a line or lines that need to be drawn somewhere with regards to where the requirements are laid and then where participation is voluntary, and it is difficult to know exactly where to draw that line.

For example, even if a State requires reporting, say, we require reporting of *E. coli* O157:H7, frankly, we are still dependent upon the voluntary participation of health care providers, hospitals, lab-

oratories, and so forth. And you know, the penalties and the fines and so forth for nonparticipation are just not feasible to enforce with regards to those. And so I think—I completely agree with you that there is a great need for reporting requirements, but where to draw the line is the difficult question, and frankly, I am not prepared to answer that, reporting requirements on the national level. But certainly a possible consideration would be to take the nationally reportable disease list that the CSTE has and have that as a national standard and as a legal requirement.

Mr. TOWNS. Thank you very much. You have been very, very helpful.

Mr. SOUDER. We appreciate both of your commitments to the advancement of science and to knowledge, and that we realize that you are scientists, not the politicians, and we have to make some of the political decisions. It doesn't keep us from asking you questions to see if you have suggestions on what we should do.

I found that you illustrate today another point that we are concerned about in our society. One is that you couldn't find the number of people needed at the State level to do this type of thing. At the conference we were talking about the shortage, and we need to encourage more people dedicated to science, as you have been, and we need the general public to understand as we get the expertise that you all give us and that knowledge of the balance of the risks so they don't get overpanicked as they see the scientific evidence coming out, and all that speaks to your profession and the importance in our society of your profession. Thank you very much. The hearing is now adjourned.

[Whereupon, at 12:45 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

STATEMENT OF JOHN J. GUZEWICH, R.S., M.P.H. CHIEF
FOOD PROTECTION SECTION
BUREAU OF COMMUNITY SANITATION AND FOOD PROTECTION
CENTER FOR ENVIRONMENTAL HEALTH
NEW YORK STATE DEPARTMENT OF HEALTH

I would like to thank you for the opportunity to submit testimony on the need to revamp the Federal foodborne disease surveillance system. My reason for commenting is to provide insight into current foodborne disease threats and how data from a well-functioning foodborne disease surveillance network can provide a useful tool for identifying food safety threats and determining food safety priorities.

BACKGROUND

Systematic foodborne disease surveillance in New York State began in 1980 and is coordinated by the Department of Health's Bureau of Community Sanitation and Food Protection. The system consists of a network of state and local professionals, all focused on protecting the public's food supply. Depending on the type and location of an outbreak, teams from any of the 37 county and city health departments, nine state district health offices and three state regional health offices may be involved. Investigative teams include surveillance officers, public health physicians, nurses, sanitarians, and epidemiologists.

Other governmental agencies also are part of our surveillance network. The NYS Department of Agriculture and Markets (NYSDA&M) provides assistance in reporting, outbreak investigation and laboratory testing. The NYS Department of Environmental Conservation tracks sources of shellfish involved in outbreaks. New York State, in turn, is part of a larger national system, working with agencies in other states and reporting outbreaks to the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC). The state surveillance system also draws on investigation expertise and assistance for laboratory testing from these agencies.

Once an investigation has commenced, the Bureau coordinates information on a regular basis with the Department's Wadsworth Center Laboratories (Wadsworth), the Bureau of Communicable Disease Control, local surveillance program units, FDA, USDA, NYSDA&M, CDC, etc. Laboratory support is provided by Wadsworth for the majority of etiologic confirmation. In addition, many hospitals, local health departments, county, and private labs

contribute to the information gathered in an investigation.

Procedures for investigation of foodborne disease outbreaks in New York State follow the guidelines set up by the International Association of Milk, Food and Environmental Sanitarians, Inc.: "Procedures to Investigate Foodborne Illness," fourth edition (1987) and the Department's "Environmental Health Manual." Staff submit a final report to the Bureau for each investigation that identifies an association between food consumption and illness. The Bureau reviews all reports for accuracy, validity of conclusions and completeness of information with follow-up back to the investigators as necessary. Data are reported to CDC and are entered into the program's computer database after this review is completed.

Since its inception, analysis of the findings from our foodborne disease surveillance network has provided information to assist in setting program priorities. For example, our analysis convinced us that our traditional sanitation inspection approach emphasized the wrong factors; therefore, we revised our inspection protocol in 1985 to emphasize a system based on analyzing hazards and establishing control points known as Hazard Analysis Critical Control Point (HACCP). Our compilation of 15 years of data enables operators and local health department staff to prepare HACCP plans to address factors, including methods of preparation, significant ingredients and critical control points, identified as causing foodborne illness in New York State.

During the period 1980 through 1994, our foodborne disease surveillance system reported 1,807 outbreaks involving 39,214 cases of illness. An agent was identified in 1,252 or 69.3% of these outbreaks. Viral etiologies accounted for 24.6% of the outbreaks and 33.1% of the cases of illness. Our data are influenced by 219 molluscan shellfish outbreaks, most of which occurred in the period 1982-1984, with suspect enteric viruses as the etiology in most instances. Bacterial etiologies were reported in 32.9% of the outbreaks involving 43.1% of the cases. Salmonellosis accounted for 16.1% of the outbreaks and 23.6% of the cases.

Contributing factors were identified in 912 or 50.5% of the outbreaks. Food temperature problems (e.g., inadequate refrigeration, inadequate cooking, inadequate hot-holding and improper cooling) are among the ten most frequently reported contributing factors. Inadequate refrigeration is number four, reported in 21.9% of the outbreaks where factors were reported. An infected worker was the fifth most commonly reported contributing factor at 18.3%.

PROGRAM HIGHLIGHTS

Our foodborne disease surveillance program has identified many food safety problems over the years. Some examples include over 100 outbreaks between 1982 and 1984 of gastroenteritis associated with consumption of raw clams which led to stricter regulation of illegal shellfish harvesting in several states; Salmonella outbreaks associated with USDA inspected pre-cooked roast beef which led to closer supervision of that industry; botulism associated with commercially processed garlic in oil which led to closer FDA control over that category of foods; Salmonella enteritidis associated with raw eggs (we have had 86 outbreaks) which led to closer USDA

oversight, amendments to the FDA Food Code and industry-initiated improvements; and foodborne illness associated with ill food workers (we have had 167 outbreaks) which led New York to become the first state in the nation to prohibit bare hand contact with ready-to-eat food in restaurants and supermarkets.

Data from our foodborne disease surveillance system is shared through annual summaries and numerous special reports. The FDA has recognized the value of our system by funding three special projects: The first special project compiled our foodborne disease data for use in our regulatory program. A copy of the paper we published on that project "Use of Foodborne Disease Data for HACCP Risk Assessment" is appended to my testimony. The second project prepared in depth analysis of our seafood associated and Salmonella enteritidis data. A paper on the seafood data is in preparation and the Salmonella enteritidis findings will be presented at a scientific conference this summer. The third project supported the development of a computer program that we use to track ongoing outbreak investigations and to automatically compile data from our completed investigations. A copy of nine of the tables that this program automatically compiles is appended to my testimony. In addition, we have provided over 150 copies of our computer program to agencies throughout the U.S. as well as in several foreign countries.

HOW CAN COORDINATION BE STRENGTHENED?

I believe that the biggest food safety issue the federal government faces today is the lack of an effective national system that can detect food safety problems such as emerging pathogens and commercially distributed food that is causing illness. The Centers for Disease Control, in a 1994 report,"Addressing Emerging Infectious Disease Threats, a Prevention Strategy for the United States", described the weak condition of infectious disease surveillance in the U.S. CDC's foodborne disease surveillance program is a piece of that problem. According to CDC officials, they have so little confidence in the foodborne disease data that is submitted to them from the states that it frequently is not published. Many state and local agencies have poor foodborne disease surveillance programs or none at all. A 1992 survey by Dr. Mike Osterholm, Minnesota State Epidemiologist, found 12 states with no one responsible for foodborne or waterborne disease surveillance and 34 additional states with fewer than one person per million doing food and waterborne disease surveillance. Adding to the problem is the fact that the FDA and USDA have their own independent surveillance programs for the products they regulate. The protocols followed by FDA and USDA for conducting investigations do not include routine coordination or communication with state or local health authorities. This contributes to a haphazard system that limps from crisis to crisis. The federal food safety agencies only learn of crises like Escherichia coli O157:H7 in hamburgers in the northwest and Salmonella enteritidis in shell eggs in the northeast. They aren't as aware of the nation's broader foodborne disease problems.

To address this problem, three actions are needed. First, a coordinated national surveillance system for foodborne disease must be supported. This system could provide information to Congress and regulatory agencies which can be used as the basis for determining short-and-long

term priorities and for evaluating current food protection programs. For this system to be successful, the federal government must first create a single focal point for all foodborne disease reports at the national level. This central point should receive information through an electronic reporting system. All federal, state and local ongoing investigations should feed into the system. The data from this system should be constantly analyzed for patterns or trends that point to common contaminated products or emerging agent trends. Data from final reports should be compiled and summarized in a timely manner and shared with public health agencies at all levels, as well as with industry and the public. The most recent summary available from CDC is for the period 1982-1987.

Second, the federal government should provide support to state and local surveillance programs in the form of program funding, staff training, laboratory support and resources for community outreach, thereby strengthening the surveillance infrastructure. Federal agencies provide funding and staff for many other communicable disease programs, and they should do the same for foodborne surveillance. Until the nation has a coordinated, functional system, it will not be prepared to detect emerging problems or to anticipate and prevent problems before they get started.

Third, to strengthen foodborne disease surveillance, the federal government should sponsor periodic national conferences on foodborne disease surveillance. Such conferences are conducted annually on many disease problems. They provide opportunities for professionals in the field to network and learn of new techniques, as well as to learn of new agents, vehicles, contributing factors, etc. The federal government could co-sponsor such conferences with professional organizations such as the International Association of Milk Food and Environmental Sanitarians and the Conference of State and Territorial Epidemiologists.

WHAT DATA ARE NEEDED?

From my experience there is a severe lack of data and much of what is collected is of very poor quality. This is why I highlighted the need to strengthen the infrastructure of the surveillance system in my earlier comments. The quality of data will not improve unless government at all levels is willing to better fund surveillance and reporting. The data that is collected must be categorized in a way that makes it useful for food regulatory applications. The reporting form the CDC has used for collecting foodborne terms of data it asks for on the epidemiologic aspects of an outbreak. The data it elicits on the mode of transmission, how and where the vehicle became contaminated and what preparation errors occurred, is extremely misleading because it is too general and incomplete, and yet the information is quoted frequently. The system we use in New York was designed to make the step from epidemiologic findings to sound science based on information that we use daily in our regulatory program. CDC's new sentinel surveillance program will not provide this kind of information. It will identify relative risks associated with various foods, but, it will not identify how the food became contaminated and what contributing factors led to the illnesses. This kind of information is essential if regulatory agencies are to use the data to improve prevention

programs.

WHAT STEPS HAVE BEEN TAKEN IN RESPONSE TO INCREASED RISK?

The New York State Department of Health has been very proactive in responding to food safety threats identified by our surveillance program. When specific contaminated products are identified, we can embargo remaining contaminated food at that location. If the food is in wide distribution, we may alert other state/ federal agencies, issue statewide recalls, alert the public and industry, amend our regulations and procedures, when appropriate, and develop educational materials. We have worked with other state or federal agencies to modify their regulatory programs and also have worked with the industry to improve their quality control programs. We adopted the use of HACCP in our regulatory program in 1985, years ahead of most state and federal programs. We constantly strive to improve our surveillance program and the data it produces and we share our findings with government, industry and the public.

CONCLUSION

The existing federal foodborne disease surveillance system is divided along product or commodity lines at FDA and USDA and is passive at CDC. States should not have to struggle with multiple agency systems, each with different and sometimes conflicting protocols. We need a coordinated system where federal, state and local foodborne disease surveillance agencies have close and well established working relationships. For the system to work, the federal government should recognize state and local counterparts as equal partners on the team and provide monetary support for state and local foodborne disease surveillance programs.

Once again, thank you for this opportunity to submit testimony and I would be happy to answer any questions you have.

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