UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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# ATTRIBUTING ILLNESS TO FOOD

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George Mason University
Arlington Campus
3401 Fairfax Drive
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(8:30 a.m.)

DR. HOLT: I'm Kristin Holt, FSIS Liaison to the CDC in Atlanta, Georgia, and I will serve as your Moderator today.

Welcome to this public meeting on Attributing Illness to Food. I think you'll find here today the most comprehensive coverage and discussion of efforts to attribute illness to food. And I'd like to thank Dr. Raymond for having the novel idea of pulling together all these speakers and pulling together all these different people to talk about this important and call it cutting edge topic.

I'd like to quickly review our agenda with you. I think you should all have an agenda, and for people on the audio bridge, it is listed on the FSIS website. So we have an agenda, and I'll go through it quickly.

We'll start with opening comments where Dr. Raymond and Dr. Agwunobi will give us our charge for today, followed by a session of perspectives that will shed light on how we all define attribution and

use attribution. A little before 10:00, we'll break for 20 minutes, and then return for additional views on attribution, on definitions of attribution, and we'll have microphones available in this room, and we'll also check in with the audio bridge participants.

Our next session is on Current Methods and Activities to Develop Attribution Data, followed by time for additional views on methods. And again, we'll have microphones and check in on the phone.

Then we'll break for lunch from 12:15 to 1:15, and return for more discussion on methods, but this time led by a panel of questioners. Then we'll have a 15-minute afternoon break, and then hear about FSIS Next Steps followed by a discussion on next steps, and basically where do we go from here.

And at the end of the day, we'll have 20 minutes or so to make sure we've heard all comments, and then we'll have closing remarks with the goal of ending at 4:30 today. So we do have a very full agenda, and as Moderator, I ask everyone to help us keep us on track.

We do plan to post the transcripts from this meeting on the FSIS website and the presentations that we receive.

I need to talk just a minute about logistics, and as a morning coffee drinker, and probably many of you are coffee drinkers, too, you want to know where the restrooms are. So if you haven't found them already, you go out of the room and go to your right and make a hard right, and they're down at the end of the hall. If those restrooms are crowded at break, feel free to go up a level and they're basically oriented in the same location.

And for ideas about places to get lunch, you can talk with people at the registration desk.

Now I'll introduce Dr. Raymond and Dr. Agwunobi, who will speak about the importance of foodborne illness attribution data and provide the charge to participants.

Dr. Richard Raymond was appointed as Under Secretary for Agriculture for Food Safety on July 18, 2005. He is responsible for overseeing the policies and programs of the Food Safety and Inspection

Service, and he chairs the U.S. Codex Steering Committee, which provides guidance to the U.S. Delegation to the Codex Alimentarius Commission. Dr. Raymond has extensive experience in developing and implementing policies and programs designed to improve public health.

Prior to joining USDA, Dr. Raymond served as the Director of the Nebraska Department of Health and Human Services, Regulation and Licensure Division, where he oversaw regulatory programs involving health care and environmental issues. He also developed several anti-bioterrorism initiatives and a statewide healthcare alert. Dr. Raymond also played a major role in the development of local health districts to serve Nebraska's 93 districts.

And I guess I'll just move on and also introduce Dr. Agwunobi, who was confirmed by the U.S. Senate on December 17, 2005, to be Assistant Secretary for Health at the U.S. Department of Health and Human Services and an Admiral in the U.S. Public Health Commission Corps. He serves as the Secretary's primary advisor on matters involving the nation's

public health and science.

Admiral Agwunobi's responsibilities include disease prevention, health promotion, women's and minority health, the reduction of health disparities, fight against HIV Aids, pandemic influenza planning and vaccine preventable disease. He's actively involved in the push for improvements in research and enhanced access to quality healthcare.

He currently serves as the Department's Blood Safety Officer and the representative on the World Health Organization's Executive Board.

Prior to becoming the Assistant Secretary for Health, Dr. Agwunobi served as Florida's Secretary of Health where he led the state's public health and medical response to the unprecedented four major hurricanes that struck Florida in 2004.

Let me introduce Dr. Raymond.

DR. RAYMOND: Thank you, Kristin. We do appreciate your taking the time to come up to D.C. today to help moderate this important meeting and bring your expertise on this important topic to us.

Attributing foodborne illness to specific

vehicles of transmission has been one of the foremost priorities for researchers, risk assessment specialists and Government officials like myself and Dr. Agwunobi, who use that data to create policies and make the food supply safer. That focus is what has resulted in a lot of reports and a better understanding of what is possible with food attribution. We now need to use that information and translate it into action. I believe action is what public health needs right now, today.

However, before action can be taken, we must first agree on foodborne illness attribution, what it means to every stakeholder and how we can use it to improve public health protection. That's the purpose of this meeting, and that's why I'm joined by our partners in securing the safety of the food supply from the Department of Health and Human Services as well as our important food safety partners from all other arenas.

Everyone here today brings with them a great deal of knowledge and diversity of experience on this subject that we hope to share. I hope everyone will

forgive me for using the cliché, but I believe that this experience and special knowledge of each one of you coming together will create a product that is far greater than the sum of its parts. When people from varying backgrounds collaborate and communicate, you need perspectives that would otherwise be absent or brought together to achieve a common goal.

This discussion we've having today is not just the right thing to do. It's what we must do to achieve the best results as public servants.

Speaking only for the USDA's Office of Food Safety, I can tell you that the subject of this summit holds a particular interest to me and to us because of how it could be used to further enhance our plans for a more robust risk-based inspection system.

Many of you here today in the audience have repeatedly told me that improved attribution data would be a real benefit to this important initiative that we are moving on. So I assure you that as this discussion continues, I'm going to be paying very close attention to what is presented here today.

Additionally, it's my charge to everyone

here today that you focus much of the discussion today on the existing data gaps that we face when trying to make practical use of the current attribution data available and to other barriers that prevent us from working together in the best fashion. Identifying these barriers and these data gaps is an important step but as is my nature, as most of you know by now, I'm much more interested in hearing solutions than problems, and I'm interested in the next steps that the USDA and HHS can implement together to develop a better attribution data system.

And even as I give you this charge this morning, I hope that those in the audience realize that this is a jointly held meeting between USDA and HHS and our partners in food safety, the CDC and FDA under the auspices of HHS. This is not just about risk-based initiatives. I would hate to see an opportunity to agree on what attribution data is and how we can move forward in using it to improve public health protections be overshadowed by concerns that are not directly related and pertaining to the issue at hand today.

We will have a follow-up meeting on food attribution data and how it can best be applied to risk-based inspection systems. That will be a topic of a separate meeting in the future that we will be announcing.

I do want to keep my remarks short, so I can get to my good friend, Dr. Agwunobi. He's someone who I'm always excited to hear speak. He can kick off a meeting like no one I've ever heard before. He will give you a charge that will get you riveted and ready to work for the rest of the day.

But before I go, I want to leave everyone with something I've been thinking about this week, especially since Monday, especially since last Thursday. It's important that we are all careful today not to confuse excellence with perfection. After all, we can all reach for excellence, but I think perfection on the other hand is something that I would leave at least to a power that's much higher than the Federal Government, and I do not want to let perfection get in the way of being better.

Now with that said, the introduction,

Kristin, that you gave for Dr. Agwunobi, was very accurate, very complete and very detailed. I want to summarize it at a very high level. Dr. Agwunobi and I are almost exactly alike. We started as practicing physicians, and we made a decent living and we put some money away for a college, we put some money away for retirement, and then we got a calling to public service. And John went to Florida and I went to Nebraska, and we became state health officials at the same time, and we worked together collaboratively. And John would come to my conferences and I would go to his conferences. Then we both felt a calling to do a higher level, and we came to the Federal Government in our current positions, and we continue to be almost exactly alike.

John asked me to come to Denver to a conference that he had. I came. I asked John to come to Denver to a conference I had. He came. I asked John to come to this meeting. He came. There's a payback somewhere I know.

DR. AGWUNOBI: For sure.

UNIDENTIFIED SPEAKER: Alaska.

DR. RAYMOND: Alaska. Probably in December. So, John and I have had career paths that have been similar. We've acted alike. We look alike. We like each other, but when John came to a minority health conference in Nebraska, he told the audience that if he and I went to the emergency room with chest pain, even though we are a lot alike, we would not be treated alike in that emergency room. Now I know what you're thinking, but what John said was, Raymond is an old man. So therefore he won't get all the interventions that I will.

(Laughter.)

DR. RAYMOND: With that, Dr. Agwunobi.

(Applause.)

DR. AGWUNOBI: Thank you, Dick. I've got to tell you, he's being very kind, Dr. Raymond, and I say this with all sincerity. I'm of a young countenance, as you can see, and Dr. Raymond has served as a mentor and as a big brother for me for a large chunk of my public health career. And he continues to gently offer me advice almost every day.

I have to tell you, I am extremely

privileged to be here. As you can well imagine, I stand in front of you somewhat humbled by the expertise that I recognize is in the room. And although I won't be able to stay and learn an awful lot from you today, you and your colleagues inform me and educate me on a daily basis as I watch you in your work, as I receive reports and briefings of how you're doing and of the challenges that you're facing. And I think Dr. Raymond would be the first to agree that this nation is truly privileged and quite frankly fortunate to have this army of experts committed to this field.

Now I describe you as a single unit, a single army, regardless of which agency you come from, quite frankly, regardless of which level of government you come from, the Federal Government, the state government, or local, because in my travels through public health, I've come to realize that no one agency or level of government can do it on its own, that when all is said and done, it doesn't matter how we structure ourselves, we're going to have to do it collaboratively across a number of experts, across a

number of settings, across a number of states. It's the nature of our nation that when all is said and done, it's the nature of the challenge that when all is said and done, there will always be someone from the food industry at the table. There will always be someone from state government at the table. There will always be someone from the Federal Government at the table. There will always be a need for us to figure out not only how to do our jobs better, but there will always be a need for us to figure out how to help everyone else on that collaborative team do their jobs better if we hope to reach that excellence that Dr. Raymond described.

I'm humbled by science. I'm frequently proven wrong by nature, and you are today going to be discussing how to learn from science, and how to gather data from nature and beyond, and how to analyze and present and use that data to intervene and prevent future occurrences of disease associated with food.

I have the experience of -- I was made Secretary in Florida on September -- no, I was made the Acting Secretary for the Department of Health in

Florida, on September 7, 2001. The Buildings fell on the 11th, and the job changed. I was made the full Secretary on October 2nd, and on October 3rd, we had the first anthrax attack in Palm Beach, and things really began to heat up. And I was struck by the fact that as I watched the experts rush to the challenge of anthrax, as I watched many of us rush to the challenge of bioterrorism and buildings being blown up by planes and just all of the issues that followed, West Nile, SARS, and the many different challenges that public health has faced, I've always been struck by the fact that we approach each of these challenges with a set of data, a dogma as to how to approach the situation, but that dogma is always full with holes. There's always something we don't know, and we need to build systems and processes and collaborations to fill those data holes.

But I think we also have to realize that with each new challenge, we have to be willing to throw aside some of the dogma, some of the established thinking that we hold to be true. Each event teaches us something new, or at least it should. I'll give

you an example. I was told when we were approaching anthrax, and I know this isn't food related but allow me this. When we were approaching the anthrax challenge, I was told, you know, don't worry. Once the anthrax falls to the ground, it sticks. It can't be re-aerosolized. No one's going to inhale it once the initial attack's over. They were wrong. Very quickly we realized that it's quite easy to re-aerosolize anthrax.

I remember an *E. coli* O157:H7 outbreak in a petting farm, in which children were petting, touching animals and contracting *E. coli* and I remember that the dogma at the time was that *E. coli* can't persist in that farm setting for a prolonged period of time because it requires warm, moist feces to survive, and because it doesn't encapsulate and become in cysts, that it dies when the medium dries up. Well, two or three weeks later, we just happened to have somebody go up on the rafters of that petting zoo and swab on the rafters, meaning it was dust that blew up there. Live *E. coli* was found.

I know that in our food safety work, at our

pursuit of disease associated with food, we approach each of these circumstances with a pile of data and my pleas to you, my charge to you is to gather data constantly. Let it inform how you begin but don't let it knock out what you might learn as you go. It's important that we have better data and that we find better ways of using that data. It's important that we fill gaps in the data spectrum but it's also important that we improve our process for gathering data, so that in an event we have the flexible ability to change direction, to real time analyze how we are learning from what we're being presented with.

I'm beginning to sound a little bit like I'm preaching. So I will stop. I'll say this, however. I have three children, 12, 10 and 8, two girls and a boy. And I live in a suburban community not far from here on the other side of the river. And I've often been struck, I joined public health as Dick described around the same time as he did, perhaps a few years later, and I was told that it was kind of boring and bureaucratic, and that I was going to have a quiet time when I joined public health.

Man, were they wrong. It's been the most exciting time of my entire life. It's been the most fulfilling time of my entire life. And although as a pediatrician I treated babies for the most part, sitting on mother's knees with an ear infection or pneumonia, in some case sometimes something very severe, and I would be there, and I felt quite satisfied with my work.

The work that you do cures and prevents disease in thousands, millions of people. The work that you do is that gift that keeps on giving. It's not just about the people that are at risk today. It's about the people that are at risk 20 years from now, 30 years from now, 100 years from now, and not just in this nation. Your work is one of the primary sources of data and knowledge for the entire world. And when I was a pediatrician in that office treating that sick baby, I touched one person, one family, one life. And when I was at the state level, I like to think that I touched the people across the state, but your work is so much bigger than just the nation. It's not just about this generation of citizens living

in the United States. It's about this generation and all future, and it's about every other nation. You impact them in very real ways.

So I'll stop by saying, sometime during the course of the day, if you would, with a sense of gratitude, turn to someone from another part of this army and congratulate them for the work that they do, and recognize that we have to work together. We just have to. It doesn't matter how we structure ourselves. That will never go away. The need to collaborate will always be a required competency of this army, and it's not just about what you know inside your heart and your brain. It's about what everyone else can bring to the table. So I, with greatest respect, applaud you and thank Dick for this opportunity to come and preach before you. Thank you very much.

(Applause.)

DR. HOLT: Thank you, Dr. Raymond and Dr. Agwunobi. I think we have a clear direction for what we need to do today and in the future.

I'd like to shift us now to the session on

perspectives, on how do we all define and use attribution. For a Federal Agency Perspective, I'd like to introduce Dr. David Goldman with Food Safety and Inspection Service.

DR. GOLDMAN: Thanks, Kristin, and again thank all of you for coming to this meeting. It's really good for me personally to see very many of the colleagues that I've worked with over the past few years. I've just passed five years here in the Agency on foodborne illness and attribution in particular.

I want to share with you very briefly how FSIS views attribution and data generally, but I want you to hear not only from me, but appreciate throughout the day that attribution is not an easy topic. There is no magic button to push. There is no book on the shelf that has the attribution data, and I'm confident that at the end of the day if you're here to the end, you'll come to appreciate that.

If you'll bear with me, even though it says Federal Agency Perspective, I was a local health director for three and a half years. So I want to walk you through a quick timeline to give you an

appreciation for how difficult attribution can be. So imagine this past Monday you lived in Fredericksburg, Virginia, and you became sick with diarrhea. It was non-bloody diarrhea, you've had diarrhea before, you tolerate it for the day and you are confident you'll be well the next day.

So Tuesday, this past Tuesday, you still have diarrhea. It's still non-bloody but you decide to go see your healthcare provider. So on Tuesday you go see your healthcare provider and that healthcare provider in this instance decides to order a stool test or a stool culture and that test comes back on Wednesday. So the doctor gets the test back and it's confirmed, *Salmonella* Typhimurium on Wednesday. It's a little bit artificial because we probably wouldn't have the serotype. Let's just say you have *Salmonella* Typhimurium on Wednesday, which is yesterday.

So in this health department, that I managed for three and a half years, we would be waiting. We wouldn't know anything about this illness just yet. The hospital or the lab would put a lab slip in the mail. We still used the mail just a few years ago,

and would send that lab slip to the health department.

So today is Thursday, the lab slip's in the mail today. It arrives tomorrow, on Friday. So Friday, Ms. Berry, my communicable disease nurse who also does lots of other things in the health department, gets the lab slip amongst many other things, as she's preparing the maternity charts for Monday morning's clinic. So because she sees it's *Salmonella*, she might decide she can't get to it tomorrow, Friday. So it's next Monday that she gets to this lab report and at that point, she may call the patient.

So bear in mind you're now a week from the time you first had symptoms. So she's going to call you next Monday and ask you what you ate last weekend. So just imagine, if you will, trying to recall what you had to eat for the three days or so prior to the onset of your illness this past Monday, next Monday when she calls you. Now if it was *E. coli* O157:H7, she might call you on Friday afternoon because she knows that's a little bit more serious. So even so, she might call you tomorrow but again, your symptoms

started Monday. She's going to ask you about your food history for the previous days prior to the onset of illness.

So I hope you can see from that little illustration, which is hypothetical, but quite realistic, how difficult foodborne attribution can be. And we're talking right then about sporadic cases. Arguably, outbreak cases bring more resources to bear both at the local public health level as well as at the state level, but even so, CDC published a report last fall in which they reported on outbreak investigations over the previous several years and even in those cases, where outbreaks were investigated and to the extent they could be the ideology and the vehicle was defined, in those cases, only between 55 and 65 percent or so of the outbreaks could be attributed to a specific food vehicle. You can even see that in outbreak cases where there are more resources, attribution can be difficult.

Along the way investigating a foodborne illness, there are other issues that come to bear in addition to food histories. There are sometimes

delayed onset of illness and listeriosis would be a good example of that. There are issues with further processing of food products, repackaging. Sometimes foods come from restaurants where there are investigations to determine the contributing factors in those restaurants which might have led to illness. There are the issues of in-home food preparation and the difficulties that can occur in the home situation in terms of cross-contamination. So there are many factors which can be investigated which are difficult to investigate, that make foodborne attribution a difficult matter.

Having said all that, FSIS continues to use foodborne illness data to help us to develop policies and regulations and to inform and shape our consumer food safety education messages.

I'll give you a couple of quick examples. Everyone knows about the severe outbreak of *E. coli* O157:H7 in the northwest in the early nineties. After that, this Agency took several steps over a period of years to implement policies which would help work with the industry to drive down the levels of *E. coli*

O157:H7 in ground beef products. Just very recently, several years ago, we had an outbreak of listeriosis in turkey deli meat. From that experience, you will now find that when we go and divide a sampling scheme for our products, that we will go and look for turkey deli meats among other deli meats as well as franks, as to those products which are most likely to cause illness. So we developed policies which would help us direct our resources at those products, in this case, deli meats and franks, which are most likely to cause illness.

You'll also know that just in the past year or so, we found that there were some cases of salmonellosis that were attributable to frozen poultry products which appeared to be cooked but were, in fact, raw products. From that experience, we determined that there needed to be new cooking instructions provided to consumers as well as label changes for those products.

So you can see that FSIS has taken information from illnesses and made policy changes which we hope will have reduced the potential that

consumers will be exposed to pathogens causing illness.

I think you can appreciate from what I just said, that we've been able to take imprecise data in the past. This is not precise attribution data but these are instances in which we've taken data from illness investigations or outbreaks and made policy changes based on the best data we have available. And no less than the eminent epidemiologist, John Snow, said, and I'll paraphrase, good public health is to put preventative measures in place before knowing the exact cause, and I think we've been able to do that.

FSIS sees attribution data in at least one instance as a report card. It will help us to measure the effects more precisely than we can do now of the policies that we put into place. And, so FSIS continues to look forward to having better attribution data so that we can continue to assess the effects of our policies. After all, if we put a policy in place and don't know what its effect is, then arguably we should not spend the time developing that policy.

I think you can see from previous examples

we have used engaged our assessment function with our partners to find out about foodborne illnesses and made policy changes to lower the risk of exposure but we need to have better attribution data to assure ourselves and the public that we've been able to create good policies that will result in lower pathogen exposure and ultimately lower illnesses.

More precise data will make our decisions better, and we will continue to look forward to this better data in order to help us assess our policies.

We will hopefully use attribution data both for further development of our risk-based systems in general, and I mentioned the listeriosis sampling program which is a risk-based program. We also intend to develop a risk-based sampling program for *E. coli* O157:H7.

We also will look forward to using this data more specifically for risk-based inspection in processing which is the initiative that's on our front burner right at the moment. This data is important to our Agency and to our stakeholders, our public health partners, as well as to our sister agencies. We need

to take this data, develop and implement policies based on the information we have that's available to us today as well as continue to improve the data that we have available on which to make those policy decisions.

Thank you very much.

(Applause.)

DR. HOLT: I'd like to move on to our next Federal Agency Perspective that will be provided by Dr. Robert Tauxe with the Centers for Diseases Control and Prevention.

DR. TAUXE: While we're setting up here, let me just say, it's an honor and a pleasure to be here today, and I welcome this conference, this meeting, and everyone's participation in it. I think there's a set of issues that we're going to be talking about here that have been animating us for sometime in the group at the Centers for Disease Control and Prevention that grapples with foodborne and related diseases.

Back in 1999, we published a paper in which we established the burden of foodborne disease in

terms of number of illness, number of hospitalizations, number of deaths. And, the very day it was published, I mean obviously the very next question that came to people's minds, well, how much of that burden, how much of those illnesses, hospitalizations and deaths can we attribute to one particular food group or another particular food group. And the question ranged from into large categories of food, like seafood or meat to very specific categories of a particular type of product processed in a particular way. And it became clear that a lot of people thought about attribution, that kind of question, in different ways.

Actually surprisingly perhaps to some, it's not easy to answer these questions, and our answers have been evolving over time and are made possible by new data that we've been gathering and the new support for a number of food safety issues that has been applied over the last number of years. And today I'm going to discuss some of the approaches to these questions, that we consider really version 1.0 but an important step forward.

Now I'm going to present quickly a conceptual framework, which was how we started to try to think how to even categorize these questions we're trying to answer. Talk about attribution at multiple levels of food production, because different questions relate to different points along the food production chain, and it became clear to us that different data and different approaches actually are appropriate for the different levels.

The data that we principally used for these purposes and that we contribute to this discussion, come from three main data sources at CDC. There's the eFORS, the Electronic Foodborne Outbreak Reporting System, our national foodborne outbreak surveillance data. There is FoodNet, the active surveillance program, the collaborative program across 10 sites and 3 Federal agencies, conducting case control studies with specific pathogens and PulseNet, our molecular subtyping network that's used, can also be used to -- it's main purpose is to detect outbreaks, but it can also be used as a tool for attribution questions.

Now let's start with a conceptual model, and

this is coming out of our attempts to try to categorize the different questions that we feel are embodied in the question of attribution. One of the dimensions and, of course, this reflects that sort of scientific and medical microbiological background. One of the questions is, well, what pathogens are we talking about or which agent, which diseases are we talking about. A lot of different things can cause foodborne conditions. And so we can think of the ones we don't know at all or the bacteria, the viruses, parasites, the prions and toxins and there are undoubtedly other categories we could probably fit on this line.

There's the vehicle dimension, the food vehicle, and actually I've got a vehicle dimension here that could encompass all of public health beyond food. There's contact with animals like the petting zoo. There's contact with people, if we go further out to the left maybe. But then there are the foods that come from the land animals, the foods that come from the plants that we eat, the seafood. There's the drinking water, and there are a variety of different

ways that diseases can be transmitted and reach us.

And if we put those two together, we've got the pathogen vehicle plane and a whole lot of public health happens on this plane, and we can put some boundaries on it and I've circled land animals, plants and seafood as being sort of that's the boundary of really the foods that we eat. That's what we're going to be considering here and bacteria, viruses and parasites are the pathogens we're really considering in these discussions giving us that sort of bounded plane.

Now there's another important dimension. So, for example, we could be talking about the bacteria that are transmitted through seafood, viruses transmitted by eating plants or parasites that might be contaminants of the foods derived from land animals, and that sort of breaks down those kind of categories, but there's another really important dimension, of course, the food processing continuum starting with the farm, the orchard, the fishery. It might be we're talking about the issues that are happening there and attributing our problems to

whatever issues might be happening at that level. Or processing, slaughter plant, packing, cannery, again there may be a set of issues there, and what we deal with most of all in public health is, when people get sick, it's because of food that was prepared in the kitchen, and that may be the immediate focus. Did something happen in the kitchen or at least what was the state of the food as it left the kitchen before it reached the person and caused the illness or even death?

And if we put those three dimensions together, we get what we could call a food safety box and can think about these attribution questions now in this term.

Now mapping the boundaries of that box, I did several things there when I sort of clipped that out. First of all, how many infections were related to food as opposed to the petting zoos or other categories that are out there? And, we can provide answers to that by looking at, for example, a series of outbreak investigations for *E. coli* O157:H7. There might be some that are related to non-food and some

that are related to food, some to water.

For other infections, we have the case control studies of sporadic cases in FoodNet that help us determine those boundaries. And for a few, we can get it from individual case reports and if we have no other source of information, expert elicitation is a perfectly acceptable way of helping to bound us.

Another boundary that came up is whose food was it, and where did it come from? How many of the infections related to food consumed in the United States? And this means taking out people who travel and get sick because they ate some contaminated food in other places, and less important perhaps to public health, but critically important for the groups that are responsible for the safety of food in this country, to understand that level of bounding.

And the data sources we have on travel, we've collected it in FoodNet case control studies, and now are collecting it in FoodNet on all the cases, and this is a, this is an important contribution.

So we can talk about attribution, thinking only about what the state of the food was as it came

from the kitchen at the point of consumption. And so in an outbreak investigation, what did you eat? I ate a, you know, a tuna salad sandwich. Well, maybe that was it. Now there was lettuce in there. It might be the plant. There was tuna in there. It might be the seafood. You know, we can talk about that later, but the point is it's the sandwich that came from the kitchen. That's the point of consumption issue.

And, so what was the relevant contribution of each food group as it was consumed regardless of the original source of the food or of the contamination? And that can reflect cross-contamination in the kitchen, and a whole set of issues that can really blur where the contamination originally started from, but are very important if you want to deal with it at the kitchen level.

So we can look at our series of foodborne outbreak investigations. We can look at the case control studies, the sporadic cases, and get information about that point of consumption level of attribution, a challenge we have for the future actually to put these different sources of information

together.

Then some people when they talk about attribution, they're really talking about the point of processing attribution, that is at the point of slaughter or other processing step, as the food left the processing and then went on to cause illness or not, regardless of what happened in the kitchen. And that level is a different sort of information but that, of course, obviously is very important if what you're trying to do is to make sure that the steps you're taking at the food processing level are reducing illness.

So the relative contribution of each food group based on what level of contamination there was in the food, as it passed through food processing, and that could reflect, of course, cross-contamination during shipping, transport and processing itself of the foods as they ultimately came from the farms. But, it does not reflect what happens later in the kitchen.

The data sources for this is more complex, and one of the really intriguing methods has been to

look at sampling foods at processing for pathogens and then compare the strains that come out of those foods at processing with the strains that come from patients. And here's where the molecular fingerprinting tools and other subtyping methods that allow that comparison have been really important. Using that overlap in patterns to show the fractional contributions of each food. For this to work, it takes large numbers of isolates from each food at the processing level and I think we will see that this has been most available for *Salmonella* in meat and poultry, but it also requires the collaborative comparison of those isolates with the ones from sick people. This is a good example of that kind of collaborative approach that we're very excited about.

Finally, there's attribution that is preharvest, and that preharvest attribution, sort of what about that reservoir, which group of animals or which group of plants or was it humans? Where did it all start from? And that's yet a different sort of question for attribution, and perhaps sometimes the most difficult to answer of all. This is before the

cross-contaminating events that might be mixing things up and to answer this, would require sampling animals or plants perhaps back on the farms or production sites, and a systematic comparison of those strains with people. Actually, few system collections are available to do this outside of the ones that come up and operate trace back testing. So this is largely a desired thing but something we're not aware of a great way to approach systematically in most cases.

Let me end by saying that food is complex for us. It requires a substantial effort to analyze it. The attribution is the burden of illness, to specific foods can be done at several levels of food production and when people talk about attribution, they may be referring to one or another level, that different methods and data are used for the different levels appropriately, and the results may not all be the same. When we're using different data and different methods, the results may come up a little bit differently. We hope that the global picture is complementary but it may not always be consistent, and we can expect further development in the methods as we

gain more experience and as we discuss this further.

Thank you very much.

(Applause.)

DR. HOLT: Thank you, Rob. I'd like to introduce our next speaker, who will give us another Federal Agency Perspective, Dr. Robert Buchanan with the U.S. Food and Drug Administration.

MR. BUCHANAN: Thank you, and for those of you, I'll try and move around you can see me over the screen. Like Rob, I'd like to thank FSIS for hosting this conference today, and I appreciate being invited to represent the Food and Drug Administration. And, I'm also looking forward to learning a lot during the day.

And what I'd like to do in my 10 minutes and being charged with both establishing a perspective and providing a definition for food attribution for the Agency, what I'd like to do is break it into basically three major segments. I'd like to define a little bit our needs in food attribution first in relation to our regulatory program. Then I'd actually like to define food attribution from our perspective and provide a

couple of examples of where it fits into our regulatory process, and then I'd like to finish it up a little bit with some of the challenges we face in doing that.

And I'll start off a little bit with our commercial, but is it also one of the important things to understand in the Food and Drug Administration, is that we are committed to maintaining and building upon our international reputation as a risk-based, science-based food safety agency. And, emphasize the fact that in order for us to do this, food attribution in its broadest sense is a critical resource for our ability to meet that goal. And that as an organization we're continually striving to be public health oriented, science-based, risk-based, cost-effective, proactive and responsive at the same time, a learning and self-correcting organization and to continuously improve in that process.

And, we've learned that in order to do that as a regulatory agency, it's tremendously dependent on our ability to acquire the data that we need to meet the needs for sound decision making.

We need that data for a variety of activities in our regulatory programs. We need to have that data to establish scientifically sound standards and guidance. We need to be able to make decisions about how we're going to devote our inspection resources, identifying the highest risk foods that we need to pay the most attention to, making decisions about where we put our efforts in terms of imports and domestic food. We have to make decisions often about what season and where will we put our inspectors at what part of the year, or in what region of the country.

And we also need this to design better education and outreach programs and food labeling approaches since these are very important means by which we help improve food safety.

We need to be able to determine where in the farm-to-table continuum that Rob just talked about are the likely sources of contamination and we also need to make decisions about where interventions are going to be most effective in terms of mitigating the risk we have in our food safety systems.

We need to be able to differentiate food safety concerns due to inherent risk. What are the capabilities of our food safety systems versus those where we have compliance failure.

And on the international scene, we need to be able to evaluate the equivalence of different food safety systems, so we can make determinations on whether the food produced in one location, one region or one country is equivalent to those that we expect from our own domestic industry.

So that brings me to the charge I was asked to take on which was defining food attribution in terms of FDA's needs and requirements. And I started asking around and I asked people like Jack over there in the audience, representing our epidemiologists. I asked our policy people what their thoughts were. And what I got was that old proverbial, you know, five blind men and the elephant, each one was feeling a different part of the animal and coming up with their own conclusions of what food attribution was needed.

So the lesson I learned in getting ready for this meeting is that in terms of FDA, we take a very

broad view of food attribution to make really a very simple determination. What is the information that we need to understand who is getting sick and why? And more importantly, then how can we mitigate that so that we can improve public health?

And as I thought about it more, basically when we look at food attribution, we're looking at a very broad definition of what I would go back to my roots in pathogenic microbiology, to define the disease triangle, the interaction between the host, the agent and the food that winds up leading in foodborne disease to incidence of adverse events.

The other thing that we need in that process is not only defining what that triangle is, but what is the impact of diversity, diversity in the way the food is manufactured, diversity in the host that we deal with and diversity in the agents that we're concerned about. And I do note that in this slide, that I used the term agents on purpose because while today's conference is focused on infectious diseases, we're responsible for a variety of potential adverse events including chemical risk, nutritional risk and a

variety of other things that we're concerned about. So, in fact, I'm going to give an example of a chemical related attribution issue that we have as one of the examples as I go through.

Again, trying to take an approach of defining our needs in terms of in part what we have available and then in part in terms of what our regulatory needs are, I do note that we have at this point limited sources of information about the different components of that triangle in terms of the host. Really, the places that we get out information now are outbreak data, sporadic case data, annual disease statistics which are something that we think that are not always collected most vigorously but it's incredibly important to making risk-based decisions, food consumption surveys. For example, as you'll see in a minute, having the capability of acquiring data through NHANES turns out to be a critical resource for the FDA.

And then things like consumer practice surveys are also important to understanding the host and the diversity in that host in terms of potential

mitigation of disease.

On the food side, we have even less resources. In addition to small amounts of published data in the scientific literature, there are a few microbiological baseline studies that become available and we're primarily limited right now to outbreak investigations.

So what do we need to know in order to function as a regulatory agency? We need to know in simple questions, who gets sick? And equally important is who doesn't get sick? What foods are involved? Where did the foods come from? What was done to those foods? What are the contributing factors in the handling of those foods and their sale and distribution and use in the home to contribute it to the foodborne disease? Was the adverse event as a result again of an inherent risk? You've reached the limit of the capabilities of the food safety system. Or, was it a failure to actually apply the food safety system? What is the frequency and the level of the contamination in food? And did the consumers know what to do with the food once they got it? All of

these are important things. For example, if we found in that last one that there was a misunderstanding on how this food should be handled, we would put our effort and our education programs as opposed to if it was a failure to follow current guidelines, we would have to be able to put more resources into inspection and oversight.

I might note that this is becoming increasingly important to us as the country and world moves to adopt basically a risk analysis framework dealing with food safety. And as we have to deal with risk assessment as a way of doing business, both nationally and internationally, it's incredibly important that we have the data so that we can transparently lay out our decision making process.

I might note that this is now part of the way that FDA must do business in terms of both the Executive Orders that are in place, in terms of evaluating risks, and one that's just cropped up in the last few years and one we're still learning to work with is the requirements of the Information Quality Act. As we put out our scientific evaluations

and we put our regulatory proposals and guidance, the impact that the Information Quality Act has on our ability to demonstrate conclusively the scientific advice we providing has gotten incredibly important.

Internationally, with the WTO becoming more involved in international trade and Codex Alimentarius adopting a risk analysis approach, again we're spending much more time looking at the details of attribution.

Just a couple of quick examples, this is one where we looked at with our partners in FSIS, quantitative risk assessment on *Listeria monocytogenes* and these are some of the attribution factors that we had to deal with. One I might note, it's incredibly important for us to find out more about the information on the immune status of the population.

Many of you are familiar with the NARMS Project that FDA, CDC and FSIS have been working on in terms of antimicrobial resistance and the importance of being able to attribute disease in antimicrobial resistance.

One that we learned in terms of working

closely with our partners down at CDC and learning to understand the different aspects of attribution was a risk assessment and the subsequent risk management decisions we've made about *Vibrio parahaemolyticus* in oysters, being able to attribute that portion of *parahaemolyticus* outbreaks to oysters, knowing the difference between the source of the oysters and the location of the illness and a variety of other factors.

And then I did want to point out that this is not just about microorganisms when it comes to food attribution. Currently we're actively trying to figure out what to do with acrylamide, whether it is a problem and these are some of the attribution factors that we've had to consider as we've gone through the process of learning about acrylamide and trying to manage that risk in the food supply. Things like using the NHANES data to develop assays for adduct formation in the blood samples that are taken. Surveys of acrylamide levels in different food products, basic research on the formation of acrylamide and things like how toasty do you make your

toast, all of these leading to help us make decisions about our regulatory programs.

We do face a couple of important challenges. One of those things, you know, you get new regulatory authority and you're surprised as a result of the Bioterrorism Act. We finally have the responsibility for registering food plants and we always figured we had a lot of food plants that we were responsible for, but our estimate was about a sixth of what the actual number is as of right now. We have, we're responsible for over 300,000 manufacturing facilities with about a third of them being domestic and two-thirds of them being foreign. The global nature of the food industry really hit home to us.

We desperately need better information about sporadic cases and being able to attribute them, and likewise, we still have that big chunk of cases out there, adverse events for which we have no cause.

So in summary, because they're flashing I'm out of time, I hope I've left you with an impression that FDA needs in food attribution are broad and diverse, and that we remain committed, in fact, with

working for our sister agencies and all of our stakeholders to find solutions to those challenges because for us to be able to do our job that we've been asked to do, we need to know where to put our effort and where to put it wisely.

And with that, thank you again for inviting me, and I look forward to learning for the rest of the day.

(Applause.)

DR. HOLT: Thank you, Bob. Next, I'd like to introduce Dr. Timothy Jones of the Tennessee Department of Health and Tennessee FoodNet Site, who will give us a state and FoodNet Site Perspective.

DR. JONES: Thank you. It's a honor to be here. I was charged with summarizing the perspective of 50 states and 3500 counties in about 9 minutes. So forgive me for making some over generalizations, but I think the first thing to say is that at the local level, we're faced with just exponentially increasing challenges. A few generations ago, you know, we had to worry about 40 foods, 80 percent of which came from less than 50 miles away from where they were consumed.

Now there are 65,000 items on grocery store shelves, 365 days a year, and it greatly increases the differential diagnosis of where our disease are coming from.

I also have to admit a huge sense of bewilderment at the local level. These are acronyms that I gleaned from only two Federal reports on food safety, and I dare say that at the county and state level, a few of us could say what more than five of these acronyms stand for which means that when one of your agencies give us results, particularly if they're conflicting, at its best, it leaves us perplexed and at its worst, suspicious about why they're different.

So the local and state level is really quite simple. I think we view ourselves as at two ends of the spectrum. We really are the ones that are interviewing sick patients and the patients want to know why they became sick, and we want to know, too. And so we need to know what to put on our lists, our differential diagnosis at the beginning of our investigations.

And then there's this huge black box that we

feed data into with models and mathematics and things that most of us don't understand, and we just really want simple results because the patients want to know why they got sick and we want to either be able to tell them or at least give them some probabilities and most importantly, define an intervention or target our education.

So I think at sort of the front line level, the goal of attribution is to use those results for prevention and we need to know where to focus our preventative efforts and that has a very limited meaning at the local and state level.

You've seen this description before. I think, you know, again on these planes, again, it's important to remember that, yes, pathogens are important but 80 percent of the diarrhea in this country never has a diagnosed pathogen. So we're dealing with a very small slice of the pie.

You heard about food vehicles. It's very important to remember that in only a quarter to a third of foodborne disease outbreaks do we at the local level ever even have any idea what the food

vehicle was. While the pie is big, much of our data is coming from, or your data, is coming from a very, very small slice of that pie, and it's important to remember the limitations of that.

And then there's the third dimension, and from production all the way to the source of prevention, and I think I would summarize by saying the local and state perspective is what's by far the most important to us, is that bottom layer because that's where we can do an intervention. It's in the kitchen. It's in the restaurant. It's at the point of preparation, and we can do very little about the steps above that.

I think it's also important for us to remember that a disproportionately huge amount of what we understand about the epidemiology of foodborne disease comes from outbreaks, but a huge majority, over 90 percent of the cases that we deal with are not associated with recognized outbreaks. And we have no chance of being able to define a vehicle or a source in that huge majority of cases.

One of the things we worry about very much

at the local level is restaurants. Almost half of the money that we spend on food in this country is spent on food consumed away from home and two-thirds of all of the outbreaks that we're investigating are associated with restaurants, which means that at the local level, the lesions or the defects, the cause of these diseases that we are concerned with really have to do with preparation. You know, we're looking for where there was a temperature abuse, where there was a cross-contamination, where there was poor hand hygiene. And no matter how much contamination came through on products higher in the chain, if they'd wash their hands, if they'd cooked it properly, if they cleaned the cutting boards, we wouldn't have seen the disease. And those are the things, you know, these downstream lesions are the ones that local and state food safety folks are trying to or have a hope of being able to control. Hand washing obviously done poorly and is a huge challenge.

And I think for us finally at the local level, while attributing disease to specific food commodities is important, we also have the burden

constantly of being cognizant of things outside that traditional box. You know, two-thirds of the foodborne disease that we see is neurovirus, and that's very rarely from a food product. It's almost always from poor hygiene, person-to-person transmission. It's the majority of what we deal with.

There's also, you know, petting zoos and day cares and multiple other sources of direct contact transmission. I think we have to remember that when we look at models like the Danish model, which used PFGE and molecular subtyping to attribute or to say that these isolates in this disease look a lot like a particular animal's pathogen, that that may not come from eating that animal's meat. But it could come from, you know, direct contact with the animals or indirect contact other than through food.

And I think finally the thing to remember is that this is a rapidly moving target, and many of us unfortunately because of our bureaucracies and limitations and data sources, are working with data that's old, and that if we are working with data that's from 2002 or 3 or 4, you know, peanut butter

wasn't on the list, that green leafy vegetables were far lower on the list. And so it's less useful to get attribution results with old data if we are -- for folks that are on the frontline that are having to deal with, you know, the most recent causes of things.

So I guess I would summarize by saying that at the local or state level, the primary value or importance of attribution, first of all is to limit for us the list of suspects when we are beginning an investigation. You know, we have to have a differential diagnosis. We need to keep our eyes and ears open, but we like to have a target to start with. And good attribution data can help us to focus on the most likely causes. It also helps us tremendously in patient education. We can't always say for certain where a patient acquired a disease but at least we can give them an idea of the likelihood and probability.

It's also very important for us to guide our collection of data because we realize that, you know, we're a source of much of the data that your agencies are using. I think that at much of the local and state level, this is less of a concern than it is for

FoodNet sites where we have resources to be able to do case control studies and pay a little bit more attention to it, and for us at that level, extremely important to be using our resources to provide that black box with the folks there with the data that's most useful to them.

And then ultimately, for us and for all of us, the highest priority is to end up with data that's really useful to focus interventions, and if that's not the goal of the data or the outcome of those models and algorithms, it's largely a wasted effort. So I will stop with that.

(Applause.)

DR. HOLT: Thank you, Tim. I'd like to move on to Ms. Jenny Scott, with the Grocery Manufacturers of America/Food Products Association, who will give us a Industry Perspective.

MS. SCOTT: Thank you, Kristin. And I don't have any PowerPoint slides because I figure that by the time I got up here, everything would be said and I would probably have to change what I wanted to say anyway.

I was asked to give industry's perspective on attribution and how it's used. And as with the states, you have to recognize that, you know, industry is not just one entity there, that there's a very broad range there. I think within industry, we're pretty much agreed on what we think attribution is, and that is assigning the cause of foodborne illness to the food responsible for causing illness.

It's an easy definition and we recognize that getting this type of information is not easy. It's quite difficult, in fact. So we are very appreciative of the efforts of CDC and the state and local health departments and FSIS and FDA who investigate outbreaks and look into sporadic cases and try and determine what foods are responsible.

When we're looking at outbreaks and illness, ideally we're looking for an organism to be isolated from a patient, from the epidemiologic investigation to implicate the food, that the same organism, even down to the PFG subtype to be isolated from the food, and this is pretty much a conclusive basis for indicating which foods cause illness. We also know

that we're not always going to get those types of data, that sometimes we're going to have to rely on EPI investigations alone and a strong enough epidemiologic study can be indicative that a particular food is responsible for an outbreak.

Now although I define attribution as assigning the cases of foodborne illness to the food responsible for causing illness, for us to use the information it really has to go beyond that. We really have to know the factors that were responsible for the illness occurring. Preventing a pathogen in a food is an ultimate control measure. But in many cases, that's not going to be possible. We all have responsibilities for keeping pathogens out of a food. Clearly, if they're not there, they can't cause illness, and while we acknowledge that it's industry's responsibility to keep pathogens as low as we can in raw meat and poultry for example, we also know that these are products that will never be sterile.

If you consider something like illness from an open-faced roast beef sandwich, where the roast beef is clearly identified as the cause of illness, we

isolate the organism from the roast beef, it's really not the fact that the *Clostridium perfringens* were there to begin with, but the real problem is the improper holding temperatures that resulted in growth, the high levels, that caused the illness. And this is very important in determining where we dictate our control measures. We don't think it would be particularly fruitful to try and focus our control measures on keeping *Clostridium perfringens* out of raw meat or poultry, but certainly controlling temperature in establishments that are preparing these products is within the realm of something that we can do.

So while the food industry defines attribution as assigning foodborne illness to the food that's responsible, we want it to go beyond that and get down to these factors that tell us what went wrong. So that's why we're very -- to see this food safety box that Rob Tauxe and Tim Jones talked about. It does go beyond where we are just assigning it to a particular food.

How do we use the foodborne attribution data in industry? Well, the bottom line is for industry

that this is a basis on how we allocate resources. We want control efforts to be put where they will have the most benefit in terms of public health. We're embarking on an effort to focus inspection resources based on risk, and a significant portion of a plant's RBI measure as defined by FSIS will be the product of its inherent risk, which clearly should be tied to how that product is linked to foodborne illness, the attribution. But, you know, again, we really have to look at other factors as well.

Industry uses foodborne attribution data in doing their hazard analysis for their HACCP plan. We need to know what hazards are coming from what foods in order to establish control measures for those where we can establish those control measures. But we also look at attribution in a bigger sense as being the way the agencies are going to focus their efforts on preventing foodborne illness, and for industry, that's probably more important. What's important to the Agency to determine is where the controls need to be because they're going to make us put controls there if they believe that that's an important source.

So if you think about that, how much emphasis should we be focusing on *Listeria monocytogenes* in foods that don't support growth, if they're not responsible for illness. Having good attribution data will help us designate where we can appropriately put our resources, where the agencies should appropriately put their resources.

So from what I've heard here, there are some pretty common themes with respect to attribution, that food attribution is very important, and the reason it's very important is so we can properly direct our resources. I think we're all in agreement on that.

Thank you.

(Applause.)

DR. HOLT: Thank you, Jenny. Next I'd like to introduce Mr. Christopher Waldrop with the Consumer Federation of America, who will give us a Consumer Perspective.

MR. WALDROP: Good morning. My name is Chris Waldrop. I'm the Director of the Food Policy Institute at the Consumer Federation of America. Consumer Federation is an organization of about 300

pro-consumer groups representing 50 million Americans across the country. Our member groups include state, local and national consumer advocacy organizations, senior citizen organizations, consumer cooperatives, anti-hunger and food safety organizations, as well as a host of others. We were started in 1968 to advance the consumer interest through research, education and advocacy.

I am here today to talk about the consumer perspective on attributing illness to food. Food attribution data is the ability to identify which foods are vehicles for specific cases of illnesses. And it's a basic element for prioritizing and allocating resources to reduce the level of foodborne illness in a population.

Foodborne illness, as we all know, is a very serious public health problem in the United States, and for several years, we've had declining foodborne rates but now progress has stalled. According to the CDC, there's been little further reduction in the rates of campylobacteriosis, salmonellosis and listeriosis since about 2001. And the Government

failed to meet its National Health Objective of reducing the rate of listeriosis to 2.5 per mission by 2005. This total demonstrates that neither industry nor Government is meeting their obligations to the public. It is imperative the Government food safety regulators take the steps needed to reduce the human and economic cost of foodborne illness and food attribution data is an important component of that.

Now food attribution data is valuable for several reasons. One, it is objective and quantitative information, and it establishes actual links between foods and specific cases of illnesses.

It also gives us a better understanding of food pathogen combinations and their associated risks. This is useful for several reasons. One, it gives appropriators greater information so they know where to appropriate resources to combat the problem. It gives the industry better information so that they can apply particular interventions in their processing plants, and it gives regulators better information so that they can prioritize and allocate limited resources to protect consumers.

It also allows us to scientifically justify a lot of the assumptions that we make in designing food safety interventions and food safety programs to reduce foodborne illness.

We cannot wisely target limited health resources without knowing which foods are vectors for which diseases and we need to be able to attribute illness to particular foods in order to insure that the resources we are devoting are proportional to the illnesses being caused.

Now this need for food attribution data is not a new thing. There's been a multitude of documents that said this is important, a multitude of agencies and stakeholders who have said it's important. For example, the Institute of Medicine and National Research Council in 2003, in their scientific criteria to insure safe food report, noted that a cause/effect relationship needs to be established to allocate the burden of foodborne disease among foods and food groups.

Also in 2003, the Food Safety Research Consortium put together a Food Attribution Data

Workshop. They in their report said we must be able to identify or perform food attribution and associate foodborne illness with specific food vehicles.

USDA and other Government agencies have also acknowledged this need for information for a long time, and USDA has often promised Congress that they've been already at work preparing the data. CDC and FDA are getting off light because I didn't have time to go through all your testimony and pick out quotes. But in 2000, for example, Under Secretary for Food Safety Catherine Woteki said that CDC was working on contributing illness to food. In 2004, USDA is fulfilling the Vision statement, said that to achieve the best level of food safety, attribution data was essential, and they noted a study by the CDC and the University of Minnesota to get attribution data that would be ready by fall 2004.

In 2005, FSIS responded to Congress and said again, significant progress was being made on food attribution data collection, and they highlighted a CDC point-of-consumption attribution study which they said would be ready by fall 2005.

In 2006, FSIS again said progress was being made and highlighted the University of Minnesota study which was now delayed until July 2006, the point-of-consumption attribution study which was now delayed until June 2006, and a new study, a mathematical modeling project they highlighted which they said would be ready in May 2006.

So this, this -- USDA, the other agencies have all acknowledged the need for this and it's become very evident through their statements to Congress and in other correspondence.

But that begs two questions. One, after all this talk, years after years, of all these different projects, where are the results of these promises? You know, maybe we'll see some of them today in this later session, but where's the Minnesota studies, these mathematical modeling projects? Are they ready? Are they coming soon? Or are we just expecting more delays?

And, two, FSIS, of course, has acknowledged or has showed the need for attribution data year after year. It's invested time, money, resources, effort

into these projects but the question is why does the Agency now insist that food attribution data is not necessary or important enough to go ahead on their risk-based inspection programs?

And I am going to talk about risk-based inspection for a couple of reasons today. One is because I think that this meeting has come up in the context of the Agency's efforts in risk-based inspection and two, I think the two are very much connected.

These are important questions that hopefully we can get some answers to at the end of the proceedings today.

Now good public health programs should be data driven. I think we all agree on that. The data is necessary to challenge a lot of the assumptions that we make about the potential effects that we think will happen when we put in particular interventions or food safety programs.

I think when the answer seems the most obvious to a particular problem, that's when we might be in danger of neglecting to determine whether or not

the data backs up what these assumptions are. Now I'm not suggesting we need perfect data before we move ahead, but it would be reckless and irresponsible to move ahead on particular programs and public health programs without excellent and adequate data.

This is especially true when food attribution data could be acquired within a reasonable amount of time and with just some focused effort.

Agencies need to make collecting food attribution data a priority. We've heard that the agencies do think it's a priority but collectively they need to focus their efforts, their resources and make this a genuine priority and, and try to advance a lot of the projects that we've heard talked about today.

In regards to risk-based inspection, there's no compelling reasons to rush ahead on that until we have good food attribution data. There's been no justification to say why we need to move ahead on implementing a risk-based inspection program before we have this very important information. And a lot of this concern, and a lot of the reason that I'm

insisting on this is based on past precedent. In the mid-nineties, CFA and other consumer groups were concerned that the HACCP rule that the Agency was putting in place was not sufficiently stringent especially in terms of their *Salmonella* standards. FSIS, in our discussions with them, assured us that as the industry met the standards, they would ration it down and CFA trusted that and they supported the HACCP program. But since that time, the *Salmonella* standard has really not changed. So as a result, consumer groups are justifiably reluctant, at least CFA is, to accept these future guarantees and the promises that this will be done at some point in the future without seeing meaningful action.

Finally, because we're going to be discussing expert elicitation later, we don't believe that expert elicitation alone is sufficient for risk-based inspection. We don't think that FSIS should legitimately move ahead on risk-based inspection until it has the data necessary from food attribution to back up a lot of its assumptions.

FSIS has said it will use expert elicitation

to determine the relative inherent risk imposed by various types of processed meat and poultry products, but there hasn't really been any mention of using other data to back up this expert elicitation, and we think that's a problem. The 2005 elicitation was roundly criticized by both industry and consumer groups and the 2007 instrument is the new elicitation is being done right now. We think that this meeting can provide a lot of useful information and insight into helping them guide and adjust that instrument, and we hope that that will be incorporated into this new elicitation.

Now we're not saying that expert elicitation is not useful. It is particularly useful in identifying areas in which further effort is needed, and where we can reduce uncertainty. But expert elicitation is limited because it's based on opinions. It's based on perceptions of the experts rather than on observable data. And it should be used as a supplement to primary data collection and not as a substitute for it.

Our recommendations are that dedicated

efforts need to be done to collect food attribution data as a collective group of agencies. Resources, time and energy need to be put together and this needs to be a genuine priority as opposed to something that, you know, we're working on, it's delayed, and we'll get around to it at some point.

FSIS and all agencies should base its programs on data and not just opinion and they need to use this data to justify the assumptions, the opinions, the perceptions and perspectives they are getting from other sources.

And finally, FSIS should not move forward on risk-based inspection until serious efforts are made to collect this data. Without it, we're afraid that the Agency and other agencies will be simply hazarding guesses and not really allocating scarce resources appropriately. Thank you.

(Applause.)

DR. HOLT: Okay. Well, now we move to an important part of the morning, is a 20-minute break. So everyone be sure to come back on time at 10:15. Thank you.

(Off the record.)

(On the record.)

DR. HOLT: Good morning again. For those of you who came in a little late, I'll just reintroduce myself. I'm Kristin Holt with FSIS, and I'm FSIS' Liaison with CDC in Atlanta, and I'm serving as your Moderator today.

If everyone would please take their seat, we'll go ahead and get started. The next part of our agenda is seeking Additional Views on Definition. So this is a period where people can come to the microphone and I'll take turns alternating, picking somebody out on the audio bridge. So is there a run for folks to get to the microphone? We had many perspectives this morning on how do we all define and use attribution. So I don't know if anyone has any additional ideas, additional views on the definition of attribution.

(No response.)

DR. HOLT: Let me go to the audio bridge. Does anyone have a question or a comment or view?

UNIDENTIFIED SPEAKER: Again, as a reminder,

if you would like to ask a question, press *1 now on the touch tone phone.

(No response.)

UNIDENTIFIED SPEAKER: I have no questions from the phone line.

DR. HOLT: Okay. Well, I think the perspectives expressed this morning were very clear. Let me -- last call. Anyone else?

(No response.)

DR. HOLT: Okay. Well, this is great. Well, let me then transition us. I mean there's a lot of periods during the rest of the day for more discussion. So we'll just make up a little time here, and let's move onto the next session which is Current Methods and Activities to Develop Attribution Data.

And our first presenter is Dr. Chuanfa Guo with the Food Safety and Inspection Service, and Dr. Guo will describe a model that attributes proportions of human illness to different food commodities such as chicken, pork and eggs, based on the distribution of serotypes causing human illness, and the distribution of serotypes recovered from

different foods and the data from food consumption patterns are all rolled into the model.

So a key point regarding this first approach that we're going to talk about today is that the model attributes illness to commodities based on serotypes recovered at the point of production and that this approach does not address the issue or question of the final food product that was consumed. Dr. Guo.

DR. GUO: Thank you, Kristin. It's really a pleasure to hear different perspective and the point of view about food attribution. And I would like to thank you for the opportunity for me to present our model at the meeting today.

The attributing human salmonellosis to food source, we use a statistical approach to quantify the contribution of major food sources to human salmonellosis. The model used *Salmonella* serotyping information from both human cases and food sources to provide a link between public health endpoint and source of infection. The model compares the number of reported human cases caused by different *Salmonella* serotypes with the distribution of *Salmonella*

serotypes isolated from food sources.

The *Salmonella* attribution model was developed by Hald and colleagues, in Denmark and was applied to Danish *Salmonella* surveillance data. The model is often referred to as the Danish Attribution Model, or simply Danish Model.

Danish Model quantifies the contribution of animal-food sources to human salmonellosis. The model uses a Bayesian approach, is Monte Carlo Markov Chain simulation to estimate the number of human salmonellosis cases. The model is written in a software, WinBugs.

It is a joint effort by FSIS, CDC, FDA and state partners under the FoodNet Attribution Working Group and the Modeling Subgroup to adapt Danish Model to U.S. data. The objectives include estimate the number of cases of human salmonellosis attributable to various food sources, support risk managers and regulators when deciding how to allocate resources, and equally important with that, identify the data needs and data gaps for our future effort on this important area.

I would like to give a brief description about the model and the data. There are four important parameters in this model. One is *Salmonella* prevalence by serotype in a food source. We call it parameter p. And the amount of a particular food consumed, we call that parameter M. And the food source dependent parameter, that's a parameter. And *Salmonella* serotype dependent factor, that is what we call q parameter.

These four parameters were used to calculate lambda. Lambda in the model is the expected number of salmonellosis cases by different food sources, different serotypes, for given years. And in addition to lambda, lambda is all food of our model. In addition, parameter a, that is food source dependent parameter and the parameter q, that is serotype dependent parameter, is -- here. So also be estimated by the model, also all food from the model.

Here is the attribution data we used in this model. Human salmonellosis cases by serotypes, for the year from 1998 through 2003 were obtained from PHLIS. And we have *Salmonella* prevalence by serotype

in different food product from FSIS in-plant samples for years from 1998 through 2003. Shell eggs is from Pennsylvania SE Pilot Project, that is, I want to put a note, that that is from early years than other food product. And we also have the consumption data and we also used outbreak and travel information from FoodNet.

Now I want to show you the preliminary model results. This is a pie chart to show estimated percentage distribution of human salmonellosis cases for year from 1998 to 2003, because our model include only the food testing data from meat, poultry and eggs, and the model does not attribute other food sources such as produce, seafood and other to attribute the salmonellosis to the other food categories. So they are 41 percent salmonellosis cases is this model is in the category of other and unknown category. And from the data, we have put into the model, the model attributes 19 percent of salmonellosis cases to ground beef, 18 percent to chicken, 12 percent to eggs, 8 percent to turkey and 2 percent to pork. Egg product and intact beef account

less than one percent.

This slide is to show the estimated attributions for meat, poultry and eggs, based on the numbers of culture confirmed human salmonellosis from 1998 to 2003. As you can see, for the first year in the data for this model is 1998, the model attributes over 7,000 salmonellosis cases to ground beef and the year going on, by 2003 the model attributes 3,000, a little bit over 3,000 cases to ground beef. So the trend for ground beef is declining, decreasing. And opposite to the ground beef, for chicken, it's increasing at the same time period. So the trend is up for chicken. That is the preliminary results the model show.

This statistical model, as I said, is adapted from the one developed in Denmark, may be used to attribute human cases of salmonellosis to specific food commodities. And our work on this model, we have been applying Danish Model to the U.S. data, has proved difficult. And this model does not attribute all observed human cases of salmonellosis to specific food product. For example, like produce, seafood,

because the limitation of data for these food.

The model does not attribute human cases to non-food sources, such as environmental exposures, pets, farm animals and others.

And the shell egg data are very limited use in this model. So I would like to emphasize the model results just shown here are preliminary.

And for future efforts, as you know, we started with the best data we have, that is the data for meat and poultry. We would like to explore how we can obtain better data from produce and other food sources currently not included in the model by working with other federal agencies, including FDA and the way we work these industries to gather better data.

Under the model currently, the Danish Model treat the *Salmonella* serotype in the food product, the prevalence, as a constant. That just means if the prevalence, a particular prevalence for a serotype in a product is zero, we don't get any positive sample, the model cannot predict or estimate any cases attributed to that product and serotype. And for the future update, we would like to modify the Danish

Model, give that prevalence a probability distribution, so we may better attribute the cases.

And for the future, we would like to explore, to use *Salmonella* subtyping information and the model will be updated at least two more years. The model will undergo further technical and scientific review. And as I said before, this is a project under FoodNet. Here are the contributors. I would like to thank you everyone for their contribution and thank you again for opportunity to present our work results. Thank you.

(Applause.)

DR. HOLT: Thank you, Dr. Cho. Next I'd like to introduce Dr. Patricia Griffin with the Centers for Disease Control and Prevention. Dr. Griffin will talk about using data from outbreak investigations to attribute illness to food.

DR. GRIFFIN: Good morning. I'm enjoying being in this academic center where we're all learning from each other.

Why use outbreak data to attribute illness to various food commodities? Well, for most

illnesses, the cause of the food can only be determined if the person is part of an outbreak. Outbreaks capture information on both common and uncommon agents and both common and uncommon food vehicles.

eFORS, the Electronic Foodborne Outbreak Reporting System, is the major source for this project. About 1300 outbreaks are reported each year from state and local health departments. We're using a frozen data set from 1998 through 2004. We developed a software program for this data set. The program does not work for later years because the database has since been restructured. Nine thousand outbreaks were reported from '98 through 2004. Fifty-six percent of them had an agent determined and sixty-five percent of those had a specific food determined. Eighty-seven thousand people were ill in these outbreaks.

We categorized over 1700 foods in these outbreaks and listed the names of every one of those foods. We accommodated many problems such as duplicate names and we categorized the foods into

commodities.

We developed a hierarchical scheme for categorizing foods into commodities. So first we divided all foods into land, plant and seafoods. In the land category, by far the largest is meat and poultry which includes beef, pork, poultry and game, and the other two categories are dairy and egg. In the plant category, the largest one is produce which includes fruit, nuts and then the vegetable category which we subdivided into leafy, root, vine/stalk, sprouts and fungus which means mushrooms. The other two categories in plant and grain/beans and oil/sugar. Oil/sugar is process plant food such as vegetable oil, sugar and honey. In the sea category, we have fin fish and shell fish.

We then divided foods into simple and complex. Simple foods are simple. They contain only one food commodity. Complex foods contain more than one commodity.

So let me give you an example of an outbreak from a simple food, 100 people ill. The simple food item is steak. The commodity is beef. So where would

it go on this chart. You can see steak. We simply assigned those hundred illnesses to beef, which is in the meat/poultry, land category.

Let's do an example now of an outbreak in a complex food item. A hamburger sandwich causing an *E. coli* outbreak. The causative ingredient is known and 100 people are ill. Well, a hamburger sandwich, this one contains ground beef, lettuce, tomato and a bun. If ground beef is the cause, we can assign the illnesses to the beef commodity. So we simply assign those illnesses to the beef commodity, meat/poultry, land. Pretty simple.

So let's consider this same example but the causative ingredient is unknown. Well, the cause is probably beef or lettuce, but we don't know. Tomato and bun never caused an *E. coli* outbreak. So let's see how to assign this one. It could be ground beef, but then again it could be the bun. It could be lettuce or it could be tomato. Pretty complicated.

So how do we assign these 100 illnesses? There are a couple possible methods for assigning illnesses from foods. Method 1 has a lot of appeal.

Use only data from outbreaks of simple foods. For example, use outbreaks due to ground beef, but don't use outbreaks due to hamburger sandwiches. That sounded like a great idea, but the problem is most implicated foods are complex.

So we go to Method 2, use data from both simple and complex foods, determine the ingredients of the complex foods and model the relative importance of each ingredient. So how would we model the relative importance? We make high, low and middle estimates for each ingredient. The high estimate assumes that all the illnesses were due to this ingredient. For example, we say all of the illnesses were due to ground beef. The low estimate is to say none of the illnesses were from this ingredient, none were due to beef. We're going to blame the lettuce. Or the middle way is partition the illnesses into ingredients based on data from prior outbreaks, and only assign illnesses to commodities that have been previously shown to transmit this pathogen.

So back to our example of the hamburger sandwich outbreak. We're now looking at beef and

lettuce as possible vehicles. Grains/beans and vine/stalk have been eliminated because they haven't caused prior outbreaks. So of these 100 illnesses, based on a hypothetical set of prior outbreaks, we assign 60 of those illnesses to ground beef and 40 of this illnesses to lettuce.

So let me go further on our hypothetical examples, summing all outbreaks, and again this is not real data. This is explaining our methods. So for all *E. coli*, 50 percent of illnesses in all outbreaks -- we'll go the beef in this example, none to pork, 40 percent to vegetables and none to shellfish. For the U.S. foodborne illnesses estimated in 1999, we published this paper, and we estimated that there were 62,000 *E. coli* illnesses. So we can apply these percentages to that 62,000 in the entire U.S. population.

Then we can do the same thing for *Vibrio*. It's a smaller number of total illnesses, so that that 95 percent of shellfish that's *Vibrio* is applied to a smaller number of *Vibrio* illnesses, and then we go along and can do it for all of our agents until we

come to the total 14 million estimated U.S. foodborne illnesses due to known pathogens, and we have a percent due to each commodity.

This is our natal plot, showing the estimates of illnesses attributed to food commodities in the United States on this frozen data set 1998 through 2004. If you look at the X axis, you'll see we divided it like that scheme into land animals, plants and seafood. And you'll see those commodity groups within land animals, plants and seafood. The Y axis is attributed illnesses by the methods that I just described.

So if you look at the land animal categories, I want you to focus for all of them on that blue bar which is the middle estimate. You can then move your eye to the high bar, to that red triangle which is the high estimate and to that green mark which is the low estimate. But it's easiest to look along those blue bars. In land animals, the highest blue squares, middle estimates, are for dairy and poultry. For plants and for overall, the highest number of attributed illnesses is for vegetables.

And you can see that the seafood product, very few illnesses are attributed.

So some limitations of this method is it's based on reported outbreaks from health departments. Many outbreaks are not detected, not investigated, or not reported. Investigations of outbreaks is based on resources, on severity of illness and on many other factors.

Our methods are based on frequency of illnesses and outbreaks. Some food pathogen combinations cause few outbreaks but many non-outbreak illnesses. For example, *Campylobacter* infections from eating chicken. Our analysis program only works right now on this frozen data set, and our analysis relies on estimates of the number of foodborne illnesses due to each pathogen that we published in 1999.

Our future in plants include creating computer programs to apply the methods to later years, creating models to measure trends, revising estimates of the numbers of foodborne illnesses due to each pathogen, improving foodborne outbreak

investigation of reporting. So more outbreaks are reported to the eFORS database, so we have more data points. And we want to modify the model to use information from studies of non-outbreak illnesses.

So in summary, outbreak data can provide estimates of the amount of foodborne illnesses due to each food commodity including all foods that have caused outbreaks, all pathogens that have caused outbreaks, and data from complex foods. This method relies on estimates of the number of U.S. illnesses due to each agent, and future possibilities for the method include measuring trends and adding information from non-outbreak cases.

(Applause.)

DR. HOLT: Thank you, Patricia. I'd like to introduce our next speaker, Ms. Caroline Smith-DeWaal, with the Center for Science in the Public Interest, who will talk to us about the Outbreak Alert Database.

MS. SMITH-DeWAAL: I told Dr. Raymond that this is a great meeting because it's all of my favorite people talking about my favorite subject

which is risk attribution. And I think what's interesting here is we've seen a couple of really complex models and I'm very interested to hear about CDC's model. I think it's going to be an important contribution to this. But I never heard about it before this meeting. So I think it's at least been very, very valuable to us.

Our outbreak database started in 1997. I am a lawyer. I am not a scientist. I do want to thank, by the way, Farida Bhuiya who is sitting in the back of the room who is our staff level epidemiologist, and also Kendra Johnson, another epidemiologist who actually worked with Dr. Agwunobi in Florida before she came to CSPI who did most of the data entry for our latest database.

We started the database in 1997 because I figured out that I couldn't do my job unless I could figure out what the food attribution was because I was managing all food on behalf of a consumer organization representing over 900,000 consumers. At that time, data from CDC was not available without a Freedom of Information Act request. So we had to

FOIA the data, but with our continued requests, CDC started posting line listings every year on the Internet. And in 1999, CSPI began to publish our database on our website. We have a report that's available but we've been publishing it since 1999, and last year, our methodology was published in Food Protection Trends which is a peer reviewed journal of the International Association of Food Protection.

Our database contains 5,000 outbreaks covering 15 years of data. It's maintained in Microsoft, accessed by either microbiologists and epidemiologists. We use CDC's definition of an outbreak which is two or more people acquiring the same illness after consuming the same contaminated food, but we are selective in choosing the data because we want an identified food and pathogen. If there are unknowns in either of those categories, it doesn't make it onto our list.

And the reason that we are so selective is we want, in fact, the best investigated outbreaks. They have to come from a reliable source. In recent years, mostly we have used CDC but in early years

where CDC's data was incomplete, we looked for scientific journal articles, health department postings, and everything. If we were using a non-CDC source or a non-peer review journal source, we would go back to actual state health and local health departments to confirm the data. So the data is very credible, and we clean it and double check it for duplicates every single year.

And there's the form that we use for entering. This one is a chocolate case with icing outbreak from 1990, which does show that bakery products do cause outbreaks.

We have 13 food categories but we started the project, really looking at USDA versus FDA regulated food. So that's the first categorization we make. Under FDA, the produce and seafood categories, they're the big ones and eggs are actually an improving category. It used to be a major category. But really there are outbreaks in all of these categories.

The USDA regulated outbreaks, which is the ones I'll talk about today are beef, pork, poultry

and luncheon and other meats.

And then we have this catchall category of both where if they at a meal and they couldn't figure out if it was the potatoes or the turkey that caused the problem, it's kind of a catchall, not terribly useful but we've got it.

The outbreak categorization for USDA regulated foods breaks into 13 subcategories. And we have a category for complex foods, which we called dishes. So if we can't figure out what the core ingredient is, it'll move into a category which says beef was a principal ingredient but it also contained the bun, the lettuce, the tomato and the ketchup. So it will go in the beef dishes category.

This shows you the outbreak trends for USDA regulated food categories. Now in about 1998, CDC started greatly improving their outbreak reporting through eFORS. So we have a line there distinguishing the outbreaks from '90 to '97 and 1998 on. Significantly within this outbreak data, we observed that illnesses as a rule for USDA regulated products are going down. The peak years were 2000 or

1999, and the exception here is poultry, and we were very pleased to see action taken last year to address the problems in poultry because we had observed that poultry continues to be a major contributor to both outbreaks and illnesses linked to outbreaks.

This is a breakdown of our data by who is reporting, states that are reporting, and I recently gave a presentation to the National Council of State Legislators to show them the importance of actually funding their public health departments to do this work. But what we see is that we're actually getting better reporting among our northern states, and our southern states are decidedly lower. By the way, this right here is 1.5 to 2 outbreaks, apologies to my staff, the final one didn't get up there, but for every state they're reporting about slightly over 2 outbreaks per 100,000 state population. And we want good reporting. So the fact that some states are much lower than that, doesn't mean they're not having the outbreaks and it probably means they're not reporting them.

Foodborne illness outbreaks overall we've

gone over, kind of why are they difficult to investigate. But in an investigation done by Scripps Howard News Service last year, they found that the cause of about 64 percent of the outbreaks reported to CDC were unknown. We've heard similar figures here today. And only about 36 percent of reported outbreaks are diagnosed. So what our database really does represent, this smaller subset of the full outbreak data.

There are limitations of our outbreak data. One of the most frustrating ones to me is the fact that CDC doesn't release the data very promptly at the end of the year. So we are just now getting 2005 outbreak data. We have people on staff all the time who are ready when the data comes out to put it into our database. So it really is a matter of getting the resources into CDC to get their work done and the data scrubbed before they can release it.

Our data also does not include deaths or hospitalizations again because that's a component that does not emerge from CDC's database. And we estimate that it really only represents about 25 to

30 percent of foodborne illness outbreaks because it excludes these outbreaks with unknown foods or unknown pathogens.

In addition, there are some pathogens, like *Vibrio vulnificus* or *Campylobacter*, that just don't show up in the outbreak data. And they're definitely causing illnesses but they're causing more in the way of sporadic illnesses.

I started the database in part because of the value to my work legislatively as I started to look at budgets for different agencies, but I think the database is equally critical to the issue of HACCP and developing food hazard combinations. The industry, since they're implementing HACCP, need to know what are the pathogens reasonably likely to occur in their products and our database does provide that information.

Our data, it is a point-of-consumption attribution data. I looked at Rob's chart this morning. We're playing three-dimensional chess here. We are not playing on a one dimensional board, and I appreciate that and that's why I think there is

actual value to the use of experts sometimes in evaluating the data because you can't assume that because someone ate it and got sick at this point, that the pathogen didn't enter much earlier in the food supply.

In addition, we can identify the frequency of food and pathogen outbreaks. The press has told me, I get the data to them much faster than anyone else, but when we have a peanut butter outbreak, I can tell them very, very quickly how frequent, how common this is. In that case, it was very uncommon. *E. coli* in scallions is very uncommon. We have had scallion outbreaks but not linked to *E. coli.* So I can identify really within a matter of an hour usually the frequency of different food/pathogen combinations.

And in addition, it tells me what states are reporting. It tells us the difference between home and restaurant prepared foods. By the way, anyone is welcome to ask for our data, to get queries on our data, because again we respond to those all the time for the media and would to industry and

others as well.

So I want to show one application to our database, and I'm told I only have a minute here, so I'm going to have to go very quickly. USDA asked 23 experts, mostly from industry, to rank 24 categories of processed meat and poultry products. This expert elicitation has been criticized. It didn't address the severity, and there were some lack of boundaries reported. But I'm using it here just as an example of how our database can be used.

Here we ranked, because there isn't a direct line up between these categories which are the categories the experts were asked to comment on, and what is reported by the public health officials, I took -- I asked my team to group them into low, moderate and high risk categories. And in the low risk category, it's mostly ready-to-eat. Medium risk, it's mostly intact meat products, and in the high risk, we have mostly poultry, almost all poultry and all the ground meat products. And these are the rankings we saw on Monday at this meeting. So that essentially reviews that data.

So this is what the outbreak data showed with respect to those three categories of below risk, moderate risk and high risk. We, in fact, have lower outbreaks, fewer numbers of outbreaks linked to the low risk foods, and higher with the high risk foods and the same tracks with the illness data.

Now I also asked for it to be broken down by pathogen because I'm a very curious person and always want to know what my data looks like. So here we highlighted a couple of categories for you, *Salmonella* clearly tracks between the moderate and low risk products as does *E. coli*. *Campylobacter* shows up only in the high meat product and moderate meat product categories, and *Listeria* shows up only in the low meat categories.

Now what's interesting is *Clostridium* and *Staph aureus* show up really a lot in the meat categories. In fact, *Staph aureus* is more a moderate risk meat category and those are -- again, this is where experts come in. Those are hazards that often are from post-cooking handling of the product. So if we wanted to tackle those pathogens, we would rank

different meat products as perhaps high risk here.

In addition, *Shigella* shows up really as underreported in this data, and I'm going to show you why, but note that in the high risk category it's number 9, and in the low risk meats it's number 10, and it doesn't even show up in moderate risk. Well, here this slide's pretty complicated, so I tried to put a lot into this presentation. Here's the FoodNet data on frequency, and again you have *Salmonella* and *Campylobacter,* you know, in terms of frequency, you're not going to be using the outbreak data because we know that *Campylobacter* is showing up a lot more in the FoodNet data which is the sporadic case data. And in addition, the *Shigella* which I pointed out earlier is probably underrepresented in the outbreak data. *Listeria,* the frequency of *Listeria* according to FoodNet is really low compared to the other hazards. So that's showing up consistently both in the outbreak data and in the FoodNet data.

Now we also included the -- estimates to bring in hospitalizations and deaths because you have

to consider severity as you do this risk attribution. And again, you see the data there but deaths from *Listeria* are clearly a significant concern as are hospitalizations. But *Salmonella* and *Campylobacter* definitely stand out in all the data sets as being very important.

So outbreak data alone cannot be used to rank food risk, and experts should also be looking at sporadic cases and product testing, the actual food tests that are being done to determine severity, the hospitalizations and deaths must be considered, and foods -- outbreak really is very hard to get. So the best thing we could be doing is getting better reporting at the state and local level. I don't know exactly where Tennessee ranked but it's in the lower reporting. So I really would like to see more resources just at the state and local level to get these outbreaks reported. That would make our work easier, CDC's work easier, and the food attribution go better.

And I think we are just at a point where food attribution -- we have to recognize the

appropriate role of data and experts, because both are needed. You cannot rely on data solely and you cannot rely on experts alone.

This is our contact information in the event that any of you want to access our database, we're welcome to have questions. Thank you.

(Applause.)

DR. HOLT: Thank you, Caroline. I'd like to introduce our next speaker, Dr. Freda Angulo, Centers for Disease Control and Prevention, who will talk about using data from illnesses that are not part of outbreaks.

DR. ANGULO: Thank you very much. There's been much discussion already about the public health surveillance pyramid in which someone, of course, at the bottom of the pyramid must become ill and then they must seek medical are. When they do seek medical care, a specimen must be collected and then the specimen sent to a clinical laboratory where the case would be identified. And then finally at the top of the pyramid, we have a laboratory confirmed case and some of those laboratory confirmed cases

will be parts of outbreaks.

The proportion of laboratory confirmed infections that are associated with recognized outbreaks varies from year to year amongst the different pathogens. And even within a pathogen, by the various subtypes of that pathogen. For example, the latest FoodNet data shows that about 5 percent of the laboratory confirmed *Salmonella* infections are associated with recognized outbreaks, but it varies by serotypes and as much as 25 percent of *Salmonella enteritidis* laboratory confirmed cases are associated with outbreaks.

For *E. coli* O157:H7 infections, it also varies from year to year but in recent years, about 20 percent of laboratory confirmed *E. coli* O157:H7 infections have been associated with outbreaks.

Back to public health surveillance, as emphasized with the circle on the pyramid, most public health surveillance activities are conducted at the top of the surveillance pyramid. And many, but not all patients with laboratory confirmed infections are interviewed by local and state health

departments, and it varies from state to state and from locality to locality to the extent that they will interview comprehensively the laboratory confirmed cases.

But information from these patient interviews may be used for attribution and it would be focused on particular at point-of-consumption attribution, the term that was introduced by Dr. Tauxe.

One of the important examples of information from patient interviews that can be used for point-of-consumption attribution is information from patient interviews on travel outside the United States prior to illness onset. This is vital information to end up with estimates on attribution of domestically acquired infections. And patient travel information is reported to CDC for the major foodborne diseases. It's reported nationwide from all laboratory confirmed *Listeria* infections and all *Vibrio* infections and all *Salmonella* Typhi infections. And as reported within the 10 states that participate in FoodNet, from all *E. coli* O157:H7

infections and from all *Salmonella* infections.

Besides travel information, information useful for point-of-consumption attribution on other exposures can be gathered from patient interviews. And we can categorize those in two specific broad types of information. One is the individual case reports from patients, and the second is then case control studies.

First, the individual case reports, nationwide surveillance is conducted using individual case reports for all laboratory confirmed *Listeria* infections, all *Salmonella* Typhi infections, all cases of Botulism and all cases of *Vibrio* and those data that are collected on these individual case reports can provide important information for point-of-consumption attribution.

For example, amongst the *Vibrio* infections, information gathered or reported to CDC on these individual case reports tell us the proportion of the laboratory confirmed *Vibrio* infections that are associated with wound infections, and therefore, the wound infections, what proportion of those, which is

most of them, are associated with the recreational contact with water.

Similar amongst the *Vibrio* infections, the individual case report reports the proportion of the cases that have eaten oysters prior to illness onset and other seafoods. So from these individual case reports, we can gather point-of-consumption attribution information.

Within FoodNet, we have conducted a special one year study for all *Shigella* infections in which all laboratory confirmed *Shigella* infections were interviewed to determine the proportion of *Shigella* infections that were associated with day care center, international travel and with other recognized sources of *Shigella* infections, and resulting with us being then able to understand what proportion of all *Shigella* infections are foodborne. And in current estimates, it's about 25 percent of all *Shigella* infections are, in fact, transmitted through contaminated food.

So this information from individual case reports for attribution has strengths and

limitations. It is useful for distinct exposures as I described with the example with *Vibrio* and the distinct exposure like a wound infection versus a foodborne infection for some of those pathogens. And it's also useful for uncommon exposures such as eating oysters prior to illness onset. But the limitations of these individual case reports is they're only practical for uncommon diseases. In other words, the local and state health departments are interviewing all of these cases and it's not practical to assume that local health departments will interview everybody who has a laboratory confirmed *Campylobacter* infection, for example. And therefore, only a limited number of diseases have these individual case reports.

And furthermore, for common exposures, you need a comparison group. For example, amongst the *Listeria* infections, *Listeria*, if reported, a high proportion of the *Listeria* cases have eaten deli meats. While it's hard to understand the attribution of *Listeria* to deli meats because eating deli meats is, in fact, a common exposure for the general

population unlike eating oysters which would be a more uncommon exposure.

So for those type of common exposures, we must have a comparison group. And so to compare the exposures of ill persons, that being the cases, with exposures of well persons, then, of course, we conduct a case control study. And you could call this a case control study of sporadic illness.

In this case control study of sporadic illness, it's important to emphasize that these interviews of well persons is not a routine public health surveillance activity and, in fact, it does require human subjects review and approval. For public health officials to interview a well person about their recent activities requires a Human Subject Institutional Review Board permission to conduct those interviews.

However, FoodNet provides an efficient platform for conducting these sporadic case control studies. FoodNet has conducted 16 sporadic case control studies from 1996 through 2006. This just shows a timeline of these sporadic case control

studies that have been conducted within the FoodNet platform, and it lists the various different ideologies of those sporadic case control studies.

A couple examples of some important contributions of sporadic case control studies, FoodNet conducted a *Campylobacter* case control study in 1998 and 1998. It was a 12 month study, in which 1600 cases and 1600 controls were involved, and it determined that *Campylobacter* infections, an important exposure of *Campylobacter* infections was international travel, and that provided important information to understand the attribution of *Campylobacter* infections to domestically acquired infections. Also the sporadic case control study demonstrated that eating chicken outside the home was an important source of *Campylobacter* infections. That is a signal that does not come up strong within the outbreaks of *Campylobacter.*

Another example is the recently published *Listeria* case control study, and that *Listeria* case control study was -- I'm sorry. I misstate the dates in which it was conducted. It was conducted in the

early 2000s. It was a 3-year study in which 169 cases and 376 controls were interviewed. An important risk factor or important exposure identified in that *Listeria* case control study was eating humus. Humus has not been identified in outbreaks of *Listeria* but that's important signal that comes from this sporadic case control study.

This may be difficult to read from where you are sitting, but this is a graph that shows each of the sporadic case control studies that have been published by FoodNet, and I would just like to highlight that this dotted line is the beginning of the study preparation. For example, in the *Campylobacter* case control study, it took a year of preparation to receive all the human subject approval, develop a protocol. We conducted the study for a year, and then this is a timeline to publication. So there is quite a delay from envisioning the sporadic case control data study, the concept and agreement to allocate the resources to the study design, the development, the human subject approval, conduct of the study, peer review,

necessary revisions and publication. And this is just a standard peer reviewed science approach.

So therefore to highlight the strengths and limitation of these case control studies for attribution, they're excellent for memorable exposures such as reptile exposure, people will remember whether they had reptile exposure even if we interview them several weeks of their illness onset. And they may be useful for common exposures like ground beef but there will be problems with people's memory of these common exposures. They have been very helpful to identify exposures that have not yet been identified in outbreak investigations, but these case control studies have limitations. In particular, they're tremendously resource intensive, and they therefore need to be focused in a limited period of time and on specific exposures.

So you heard earlier the presentation about using point-of-consumption attribution information from outbreaks, and to have the most useful information on point-of-consumption attribution is the combined information from these outbreak

investigations with the information from interviews of cases that are not involved in outbreaks.

For example, with *Campylobacter,* outbreaks tell us that produce is an important source of outbreaks, *Campylobacter,* as is dairy products and there are some chicken outbreaks. However, the non-outbreak interviews tell us that international travel is an important source of *Campylobacter* infections and eating chicken outside the home. So we're working on methods to combine this information into a more holistic measurement of point-of-consumption attribution.

In summary, data from cases that are not involved in outbreaks are useful for attribution. It enables, in particular, attribution to be focused on domestically acquired infections, and can be useful to understanding other exposures, those being ascertained through individual case reports and through case control studies. And combining the information from outbreaks and information from cases not involved in outbreaks will be helpful for point-of-consumption attribution. Thank you.

(Applause.)

DR. HOLT: Thank you, Fred. I'd like to introduce our next speaker, Dr. Sandra Hoffman from Resources for the Future, and Dr. Hoffman will talk to us about using data from expert elicitation to attribute illness to food.

DR. HOFFMAN: Thank you. I appreciate being invited to be here today. I'll be discussing research that I've conducted with colleagues at Carnegie Melon University and Resources for the Future, attributing illnesses caused by foodborne pathogens to food consumption.

This is a project that grows out of work of a collaboration with Glenn Morris and Mike Taylor and Mike Batz from University of Maryland, developing a foodborne risk ranking model. I'd especially like to thank Mike Batz for his help with the outbreak data used as a point of comparison in this study.

There are three major points I'd like to make today. First, I want to talk about how knowing why you're attributing food can affect the way you do attribution. Second, I hope to show you that expert

elicitation can improve the information basis for risk management. And, finally, I want to talk about how our expert elicitation study contributes information relevant to risk-based food safety management. And I'm going to do that in 10 minutes. So we'll see.

I want to share some of the basic lessons that I've learned in the past few years in thinking about foodborne illness attribution, and I think things have kind of come up in our discussions today, but I think it's important to highlight them.

First of all, as Dr. Tauxe pointed out, you can attribute foods to many dimensions, to many different factors. But I think it's important to recognize that decision needs really are going to end up driving the attribution. It's important that they do that. But I think as you do that, I think one of the important things is to stay clear about what the need is and what dimension you're measuring on. I think some of the disagreements we've run into and some of the confusion we've run into in categorizing for attribution has resulted from wanting to meet

multiple needs. And it's important that you maintain kind of a consistent set of categories that are not overlapping, and if you start to mix needs, you can run into problems with that kind of issue of inconsistency and categories.

Finally, I think it's also useful to point out that it's useful to have kind of a tier and multiple studies on attribution, and it's useful to start with thinking about dividing up the whole pie and working down. You could do attribution of just being focused on the particular problem you're concerned about, but if you start from that bottom up perspective, I think you can run into danger of not being able to add up your estimates. And so a lot of the approaches that we've been seeing today are taking that kind of approach of starting with the whole pie and dividing it, attributing it to factors within the pie.

My second major point is that expert elicitation can be useful in attributing risks. More often than not, complex decisions have to be made with imperfect information. The question is not

whether expert judgment will be used but how it will be used. Expert elicitation is a set of methodologies that can provide systematic structured means of assessing expert judgment and eliciting it. It's been used since at least the 1970s by many Government agencies as well as in industry in a wide range of areas from assessing safety of nuclear power plants to assessing exposure estimates in air pollution. My colleague, Roger Cook, who I think is here today, is working on a project in the Netherlands, there he is, using expert elicitation for attribution of microbial foodborne hazards. So it's been widely used, widely tested.

As with all sciences, expert elicitation results are only as good as the study. The methods used in expert elicitation do vary and like many areas of science, there are differences of opinion on which is best. Since time is short, I will just leave it at saying there are several good textbooks and surveys. I've listed a few here.

Expert elicitation can help shed some light on food attribution data gaps. We've been hearing a

lot about the difficulties of collecting data on food attribution. I think it's starting back with Dr. Goldman's comments about the difficulties simply of reporting and identifying what's foodborne much less what particular food caused an illness.

Outbreak data is certainly improving greatly but it's still incomplete and likely to remain incomplete. It's simply a difficult data collection task. Furthermore and also just simply by definition, it excludes sporadic cases. Furthermore, there's studies indicating that outbreak cases and sporadic cases may be associated with different foods. So we're covering a part of the universe with outbreak data and it may be different than the sporadic cases.

FoodNet was created to provide information on sporadic cases but it's not yet nationally representative. It's improving. It's great. We need to do more of it, but it's not yet -- we still have those data gaps.

Most importantly I think experts have knowledge and experience relative to assessing the

association between foodborne illness and food consumption that's not brought into epidemiological data. Whenever you sit down and you talk about what's the likely source of foodborne data, what you start hearing people draw on is information about microbial ecology, information about food consumption patterns, what they know about the way processing is done, what they know about the way industry is -- who are the good actors, who aren't the good actors, where do we think things are under control. So if you're coming up from kind of a risk assessment perspective, there's a lot of information that people have and know that help inform judgments about the likely association between foodborne illness and food.

What expert elicitation does is give you a structured way of synthesizing that information. It's only once. Formal risk assessments are certainly another but this is one additional way of bringing more information to the table.

What we did was surveyed 44 nationally recognized food safety experts. These are people who

have spent their careers in government, in academia and industry from a wide variety of fields relevant to microbial food safety. Forty-four is a large panel for expert elicitations. We used a formal survey. My expertise is really in survey research, and with a panel of 44, it was large enough to allow us to also use some statistical analysis to begin to understand patterns of responses that we saw.

Each expert was asked to attribute all foodborne illnesses associated with a particular pathogen to the consumption of 11 types of food. We followed Ms. Caroline Smith-DeWaal's categories for food consumption. It allowed us to compare to another set of outbreak data and provide some consistency and comparability. We did this for the FoodNet pathogens plus toxoplasma and neuroviruses because of their importance in the -- report.

These food categories were designed to span the food supply and as I said, are a modification of the CSPI categories.

From our data, we estimated four measures of what I will call uncertainty or if you're more

comfortable with knowledge, the flip side of uncertainty is knowledge about food attribution. One is to what extent do our respondents agree with one another about their best estimates. Let me back up. I forgot to say one thing. What we asked our respondents to do was to give us a best estimate which in Bayesian terms is probably closest to a medium, as well as a 90 percent credible interval or upper or lower bound around that estimate. So we have for each expert both a measure of central tendency and their upper and lower bounds.

So when we measure uncertainty, we can get four different measures of uncertainty or knowledge about food attribution. The degree to which this group, this panel is agreeing about their best estimates, the degree to which they are agreeing with the outbreak estimates, the degree to which the experts mean confidence intervals and variability in the expert's individual uncertainty or confidence intervals.

We use these measures to characterize knowledge about food attribution of foodborne

illnesses in this panel, in a way that I hope will be useful to decision makers. What we're looking at is the thinking that there's a difference between the cases where you have a large body of experts agreeing with one another, agreeing with the outbreak estimate and saying that they're highly confident about their estimate. In a case where they're agreeing with one another, they're saying they're highly confident about their estimates, but they're not agreeing with the outbreak data. That suggests that there's probably information out there that's not being captured in the outbreak data that they think is important or the case where the experts are not agreeing with one another. Obviously if they don't agree with one another, they're not agreeing with the outbreak. Oh, boy. And they're not confident about their estimate. See you can see different qualities of information are available.

Just to illustrate, I'm presenting charts of three of these measures for food. The one on the left compares the correlation among experts' best estimates on the vertical axis, and the correlation

between experts' best estimates and outbreak estimates on the horizontal axis.

The chart on the right compares correlation of experts' best estimates with the mean individual uncertainty or confidence interval. So here you can see some examples. Seafood and poultry are both cases where the experts are highly correlated and have moderate size credible intervals but experts believe that outbreak data tells the full story about seafood but not about poultry.

Another case is eggs, produce and breads, where there's a high level of expert correlation with one another and with outbreak data but experts are far more uncertain about their estimates for produce than they are for eggs and bread.

So it starts to tell you something about the quality of the state of knowledge or the quality of information that this panel of experts thinks we have about food attribution.

We're able to do some regression analysis, and since I'm short on time, I'm going to skip over this. I think one of the major things it allows is

to do is to check for some construct validity and also gives us a few patterns that may be useful in policy.

The major stories that come out of our attribution empirically is the high concentration of foodborne illness among food pathogen pairs. We have 121 food pathogen pairs and a fairly small number are really causing most of the illnesses and deaths. I think the same thing is coming out of the CDC data as well. On many, but not all certainly, our expert and outbreak based attribution estimate agree that there are very significant exceptions. I show a couple of here for the case of illnesses. They also occur with deaths. One that I think probably many people would probably recognize is the issue of produce and poultry and *Campylobacter.*

So I want to return to my three major take home messages. It's very important as we talk about attribution to be clear about why we're doing it, and to make sure that the categorizations we use remain consistent and not to allow different decision needs to drive us towards inconsistencies in our studies.

I hope I've begun to show how expert elicitation can be a valuable supplement to more conventional scientific data, especially in cases like foodborne attribution where we have significant data gaps. And I think our expert elicitation provides an alternative set of estimates attributing foodborne illness to foods, but perhaps more importantly, it can help characterize what food safety experts think they know and don't know about the association between foodborne illness and the consumption of specific foods. Thank you.

(Applause.)

DR. HOLT: Thank you, Sandra. I'd like to introduce our next speaker, Mr. Michael Batz, with the University of Maryland, who will speak about ranking foodborne risks under uncertainty: comparing outbreak and expert attribution to illnesses to foods.

MR. BATZ: Thank you all, and thanks for allowing me to talk today. I think with only 10 minutes, I think I'll be able to keep you awake but I have so many slides that if you have epilepsy, you

may be facing a risk-risk tradeoff in terms of paying attention or not.

I'm at the University of Maryland School of Medicine. I used to be at Resources for the Future where Sandy is. And I'm the Executive Director of the Food Safety Research Consortium. I just want to set this up to give a little bit of perspective of where what I'm going to be saying is coming from. And the purpose of the consortium, it's really a loose collaboration between seven research institutions for the purpose of developing analytic tools and decision tools to help make more risk and science informed decisions.

Our role with food attribution has come primarily through one project which is the risk ranking model which I'll talk a little bit about, and we've had a couple of meetings and a couple of workshops similar to this one, and I think this meeting is great because it continues the discussion in which there really is a need to continue to get agreed upon nomenclature, agreed upon sort of understanding of what we mean by attribution and what

some of the different perspectives might be. There's also a SRA meeting that a lot of these talks were at and these things have really moved things forward.

The risk ranking model as Sandy mentioned came out of a funded project by Robert Wood Johnson Foundation and subsequently funded by a CSREES grant, really in an attempt to make a first step at broad resource allocation type priority setting. So the goal really for us in that context was to start by identifying what the worst problems are from a public health standpoint, towards the idea of moving forward down the line in the future towards being able to identify the best solutions. And that discrepancy is important because I think it relates to why we chose to attribute the food and how that relates to attributing to causes and contributing factors.

Our definition of food attribution is similar to what's been presented earlier today in the sense that we're talking about a percentage attribution and this is just an example because it's very similar actually to what Patty presented

interpreting the outbreak data, quantifying these things into some percentages and applying them to incident estimates. For example, if we have an estimate whether it's based on mean or something else, that there are some number of foodborne cases, that is of total cases, some percentage are foodborne and then of those foodborne, attributing those.

Now to do this, the important thing for us is that things have to add up to 100 percent. So certain kinds of attribution approaches where things can add up to 100 percent aren't useful for us. That doesn't meant that they're not incredibly useful for getting at those food pathogen combinations but for us, we need to use some data that gets at that sort of broad level 28 pathogens across all foods.

The point of attribution has been discussed already, the point being to distinguish where a specific attribution approach attributes illnesses even to a specific food which might be considered or a vehicle, you know, at some point in that continuum. For us, we're starting with public health impact. We want to look at point of consumption.

So if we want to look across these things, really the data set that we can use, imperfect as they may be or, you know, starting with this outbreak data and although it represents a very small number of total percentages, it really is the only national data set that covers a broad number of pathogens.

One reason why this is important from a risk ranking modeling standpoint, is that comparative risk assessment or something like this, you want to have as few methodological differences between your risk, you know, your risk hazards as possible. So you want to minimize the effect of methodological differences between these things you're ranking. So for us that's one reason why we want to use one thing for all.

Now moving forward, the data may be so poor that, you know, and uncertain that it may be preferable to give up that methodological consistency to do a little bit more picking and choosing of attribution method between, you know, between different pathogens, largely because we see from the work and from what Sandy has done and when you look

at case control studies and outbreaks, that certain type of approaches seem to work better for certain pathogens than others. The serotype stuff that Chuanfa presented on *Salmonella,* some of those same kinds of Bayesian statistical approaches to looking at subtyping for *Campylobacter* have not found reservoirs at all because those methods depend on something that happens to work for that specific pathogen. So moving forward, we may be able to move towards using a more combined approach of trying to integrate all these different attribution approaches.

One thing that's been brought up today, that was presented in Patty's talk, it is part of Caroline's talk as well, is that interpreting outbreaks is messy business. It's a dirty data set in the sense that, you know, this data is collected. It's temporally variable. It's geographically variable. It's dependent on human interpretation and human investigation, limited by resources and effort and all kinds of other biases. So you end up with foods in there that may or may not be easy to interpret. You may end up with things in there such

as, you know, homemade cougar jerky I think is in there, you know, but it's hard to go very far when you have, you know, you're attributing risk to home smoked meats of large predatory cats.

You know, but you still have other issues such as whether or not when you're reporting this stuff, whether or not you're considering a tomato a food or a vegetable, whether you're categorizing things by whether they're a row crop or a tree crop, and this is a mind killing exercise of going through this, and I really love where CDC has ended up, you know, they've tried a few approaches using recipes to try to do these things and breaking these complex foods which really are probably about half of the data that are in foodborne outbreaks where you have a know ideology and no vehicle. So what I tried to do with complex foods is try to bend them in a couple of different ways to try to understand, you know, what is the real variability in terms of how these things can be bent.

So two questions that come up with complex foods are whether or not to include them or exclude

them and then, you know, compute your percentages with them as a category or without because obviously you're going to change something. If complex foods are 40 percent of your outbreaks or 50 percent, you leave them in, you're going to be doubling or having things. And the other thing is whether or not you make any effort to try to break up that complex foods into two ingredients which is a subjective exercise but one in which hopefully we can try to manage.

So these are our broad 13 food categories which again I'll mention. So far we've had three presentations on outbreaks and this is third or the fourth category set that we've seen, and I hope that moving forward I can concede some of this and we can all come together to agree upon some uniform categories.

So these are just two lines here, the first being where it's the most conservative, where we have these complex foods and where we're not trying to -- we're just going to leave them in the complex foods category. We have another one where we try to put it with a primary ingredient. So if it's an omelet,

we're going to go ahead and say it's an egg. If it's a hamburger sandwich, we would put that in beef, although, you know, we've seen another approach today. So I'm not suggesting that this is the only or the best approach.

So there's the 41 percent and you can see, the numbers go up. I mean it's not a surprise when you move some of these things out and for *Salmonella* you can see that a lot of these things are egg containing dishes, that then get recategorized.

When we move to killing out that category obviously those numbers change again, and so what you end up with is in the left-hand column sort of a low, in the right-hand column sort of a high, and in the middle sort of a low, high, high, low, overlapping kind of things. This isn't particularly meaningful other than just to show that, you know, for a specific pathogen, that uncertainty and just where to bend things has a pretty huge impact on which vehicles get identified.

And this issue of being able to deal with this sort of issue which is sort of a, you know, it's

not a probabilistic uncertainty, it's this kind of bending issue but it's -- there really is an issue with interpretation that pertains to dealing with outbreaks.

Now comparing outbreaks to experts, I think Sandy talked a lot about that. So I don't want to go into a lot of detail about this, even if it is the title of my talk, but I think it's been covered a lot, and this is just one estimate. And this is old data. It's preliminary but it shows you that this is the mean outbreak for one cut of it. So the mean outbreak attribution percentages and box plots for expert attribution, and you see the biggest difference here is this shift between produce and poultry. And the lesson is that, you know, does this actually impact rankings of what we would say the most important foodborne pathogen or food pathogen combinations are. And the answer is yes. I presented hospitalizations here because deaths are very heavily rated to a few pathogens and so are illnesses where you end up, everything becomes a neurovirus.

But the point is just that difference between these data sets that we might use for attribution really does impact in the end result, and it may not be apparent to somebody viewing those end results that you have these underlying problems or differences between these data sets.

So I think we've talked a lot today about the problems of outbreaks and the problems with expert elicitation and the benefits of both of those things, but I think it's important to recognize that we're not going to have perfect attribution as Ms. Scott sort of said in the first sort of sentence today. So I could have changed the slide but even excellent attribution, and I'm not sure how close we'll get. You know, we have a surveillance pyramid problem where we have a hard enough time getting a hold of how many people get sick for a certain, you know, pathogen let alone taking it to a food let alone getting back to the contributing factors or the sort of behavioral causes.

We also have an incredibly dynamic system that's changing over time, both in terms of

antimicrobial resistance and durable immunity of the population, but also in terms of food trends, consumption trends and so on. So we have to recognize that whatever we do here is going to be a snapshot.

I think moving forward though, there are some opportunities to do things right, and that is we can come to consensus on terminology. We can move forward with some categories and we can try to find ways to combine these data, connect them and compare them side-by-side. I think it is a useful thing to do, and I think that the more we go after that, the more we can try to isolate what those real data needs are.

My sort of last take home message is just sort of a personal perspective, and that's just that I don't think we can wait forever for attribution information. I think we need to present the data as best we can, try to be as transparent as we can about the biases and limitations and uncertainties of the data, but move forward understanding that hopefully by presenting that analysis we can improve the data

over time and improve the results over time and improve the decisions over time. So that's it, and although I didn't get my presentation in time to have handouts, I will be happy to give it to you at a later date. Thank you.

(Applause.)

DR. HOLT: Thank you, Michael. I'd like to introduce to you Dr. David White, center for Veterinarian Medicine at the Food and Drug Administration, and Dr. White will talk to us about using data at retail.

DR. WHITE: We'll jump right to the end. Thank you very much, and I'd like to thank FSIS as well as for inviting CVM to present their views on attribution.

Ours is a little different than that. Our main focus is looking at antibiotic resistance as we're the organization that approves antimicrobial use in food animals. That's again what we're looking at, the negative potential consequences of such use.

And how we do that is through a program called NARMS, the National Antimicrobial Resistance

Monitoring System, and this is a national collaborative network between the FDA, CDC and USDA as well as public health laboratories in all 50 states and local health departments in 3 major cities.

NARMS was developed to monitor changes in susceptibility and resistance of select zoonotic bacterial pathogens as well as commensal organisms, we've added *Enterococcus* and general *E. coli* as sentinel organisms, recovered from animals, retail meats and humans to antimicrobial agents of both human and veterinary importance.

There are three testing sites involved in NARMS. The first is FDA/CVM in the Laurel facilities, the Office of Research, which looks at retail meat and poultry, the CDC that you've heard a little bit about today that deals with our human isolates, and USDA looks at isolates from food animals on the farm and also through the FSIS isolates at slaughter --

I'm going to focus today on the retail meat part of the program, and I just want to stress again

that there are two other imports and they all need to be put together to really look at the big picture.

With regard to retail meat sampling, it's based on a collaboration with CDC and FoodNet. We have all 10 FoodNet sites participating in the retail meat sampling. There's a similar random sampling scheme at each of the FoodNet sites. Each site purchases 40 meats per month, and that's 10 packages each of ground beef, pork chops, chicken breasts and ground turkey.

All 10 sites at their own facilities culture for *Salmonella* and *Campylobacter*, and we have 4 of the 10 sites that look for *E. coli* and *Enterococcus*, Georgia, Maryland, Oregon and Tennessee. And why we only do four is we have such high prevalence we would quickly overwhelm the system if we had all 10 sites look for that.

Once the bacterium are recovered, the isolates are then sent to the Office of Research where their individual is confirmed and we also perform antimicrobial susceptibility testing and we've instituted a molecular subtyping now of all

*Salmonella* and *Campylobacter* isolates through the PulseNet program.

Just to give you an idea on the number of meats sampled per year, it's grown dramatically from our first year and this is the newest part of the NARMS program, too. It's been in place since 2002. We started with about 2500 meats in 2002. Our preliminary data for '06 is about 4300, and that will rise to about 4800 meats when we have all of our data in, and that's with all 10 sites. So we're really shooting for 4800 retail meats being sampled per year which is the largest I think study of its kind in the United States right now on an ongoing basis.

Here's some data on *Salmonella* prevalence between 2002 and 2006, and please remember that 2006 is preliminary. As you can see, most of the *Salmonella* we're recovering in the retail meats is coming from poultry, either chicken breasts or ground turkey, and those figures, hover around 10 to 13 percent for chicken breasts and between 12 percent up to 15 percent for ground turkey. We repeatedly recover low rates of *Salmonella* from both ground beef

and pork chops. The pork chops traditionally about 1 percent. And remember, those are about 1200 meats we're testing for each of those commodities. It's a very low *Salmonella* prevalence rate for ground beef and pork chops.

If we look at the comparison of *Salmonella* between what's being seen in the human component of NARMS at CDC and what we're focusing in on poultry, we see a lot of diversity from the *Salmonella* serotypes being recovered. For 2004, in the human CDC component we had approximately almost 1800 *Salmonella* isolates that were included in the program, and here the isolates from the retail meat components from chicken breasts and ground turkey 157 from chicken breasts which is about 13.4 percent of the chicken breast samples were positive, and 142 from ground turkey. Again you can see really that there's much more diversity in the human *Salmonella* serotypes. We're seeing a lot more commonality in the serotypes being recovered from chicken breast and ground turkey, and those are from all 10 of the sites.

If we try to take a look at the top five serotypes among human and retail poultry isolates, we do see some interesting similarities between the serotypes but interesting as well in terms of attribution. We do see some distinct differences. For instance, if you look at the human, we see Newport and Javiana in the top five. You don't see either of those in the poultry. If we did expand out to ground beef and cow, you would see Newport show up. However, Javiana does not show up really in any of the commodities at all, to me suggesting that there's not a food and/or -- for this. This is coming from somewhere else. So again it's an attribution.

The more difficult serotypes though would be Heidelberg who we do see this in every meat. We see this in every food animal. So again, if you see a *Salmonella* Heidelberg outbreak, it might be a little more difficult to determine where it originally came from than some of these other serotypes where we only see it associated with one particular food and one particular animal.

We also have the ARS/FSIS data from slaughter and all I want to point out here is that if we look at the ones highlighted in orange, those are ones that also are matches with what we're seeing in the retail mates. So we are seeing overlaps in terms of the *Salmonella* serotypes being observed at slaughter -- and retail.

With regard to resistance, and I'll go over this real quick, because I know this isn't the focus of this meeting, again this is our focus at CVM and for those of us dealing in resistance, there's a lot of antibiotics we test. There's a lot of acronyms. So just to quickly tell you what they are. The ones on your left, the first five, are all beta lactam antimicrobials. AMP is Ampicillin. AUG is Amoxicillin Clavulanic Acid. FOX is Cefoxitin. TIO is Ceftiofur, which you may have heard of Ceftiofur. It's an expanded spectrum beta lactam -- is a third generation Cephalosporin. AXO is Ceftriaxone, a third generation Cephalosporin that would be used to treat salmonellosis. GEN is Gentamicin. KAN is Kanamycin. STR is Streptomycin. CHL is

Chloramphenicol. TET is Tetracycline. SUL is Sulfamethoxazole. COT is Trimethoprim. NAL and CIP are Nalidixic Acid and Ciprofloxacin. But just to give you some idea, these are really four main drugs of human health importance for *Salmonella* in terms of what could potentially be used. Just to give you some ideas, these are really the four main drugs of human health imports for *Salmonella* in terms of what could potentially be used.

Just to give you some quick rates for all four, they're pretty low. They range from 0.6 percent, Ceftriaxone resistance, 0.2 percent to Ciprofloxacin, but two things I'd like to point out in terms of how we look at attribution is say, for example, we take a look at Ceftiofur and also Gentamicin, you can see some differences between the resistance phenotypes in the *Salmonella* recovered from the different origins, and if we focus in on these three, this is what we're seeing. You're seeing the majority of Gentamicin resistance coming from *Salmonella* recovered from ground turkey where the majority of Ceftiofur resistance is coming from

*Salmonella* recovered in chicken breasts. And I always treat this data as peeling layers off an onion. You need to look at one level, believe it or not, because we start to see a serotype influence. If we look at this data by serotype, you see that the majority of Ceftiofur resistance is actually, in effect, *Salmonella* Typhimurium and no other serotype, whereas we look at Gentamicin resistance, it's almost 100 percent *Salmonella* Heidelberg, and this is happening with other serotypes and other resistance profiles as well.

So it's important as well to get down to the serotype level and actually if I can may play, we need to get down to the molecular subtyping levels that's been presented on several occasions as well. We need to keep peeling away these layers until we get down to what we need to really look at that.

And in terms of NARMS, we partner with PulseNet as I mentioned. All *Salmonella* and *Campylobacter* isolates in the retail part are submitted to the PulseNet Program, a PulseNet certified lab by CDC. So far in our database, we

have over 7,000 entries with approximately 4,000 *Salmonella,* 432 *E. coli* and those are primarily 157s, over 2600 *Campylobacter*, and that includes the -- and 69 *Vibrio*. And we're also using this data for research as well. We're trying to spin enough research because we are a research laboratory looking at biosource tracking, virulence studies and, of course, antimicrobial resistance studies. So I think this is a great thing to tie up attribution with molecular subtyping.

We've been moving in NARMS to present the data side by side by side. In the past, each of the three arms has presented their own annual report, and three months ago, we presented our first executive report which showcases data side by side by side, from food, animal slaughter and human. I think this was a fantastic idea. It was a long time coming. It's on our website if you want to look at it. It really can show you the big picture from farm to fork in terms of *Salmonella* serotypes being observed as well as associated resistance profiles.

The 2004 report is being worked on now, and

we hope to have it out hopefully by early summer on the web.

And what I'll try to end with is one way how we're using the data at CVM in terms of attribution and risk assessment, we have our own risk assessment process in place and it's really based on a guidance 152 for industry which is evaluating the safety of antimicrobial new animal drugs with regard to their microbiological effects of bacteria of human health concern, and it's a typical risk analysis where we have a release assessment, exposure assessment and consequence assessment. They all factor into a risk estimation and then we look at risk management strategies.

The exposure assessment of this process includes pathogen, pathogen load so to speak, pathogen prevalence. So we are needing that type of data for our types of assessment.

In terms of risk management, the steps range from denying the drug approval to approving the application under various use conditions that assure the safe use of the product. So we are adopting risk

assessment as well on drug approvals.

That's perfect timing. In terms of acknowledgements, there's quite a large dedicated staff at all three arms of this program, and I wish I could acknowledge them all. There's a lot of other people, too, of course, at the EPI funded sites that without them, we could not do any of this work. CDC PulseNet as well, as well as USDA -- and FSIS.

And with that, I'd like to thank you for your time and invitation again, and if anyone has any questions, I'll be out later on for lunch.

(Applause.)

DR. HOLT: Thank you, David. We're not going to bolt out the door yet. We have on the agenda a little discussion period here from 11:55 to 12:15.

Before we move into the discussion, and maybe to stimulate a little discussion, I just want to recap. I think we see there's a lot of work being done, a lot of studies have been completed especially the FoodNet case control studies that Dr. Angulo presented, a lot of important work out there. We

didn't talk about international projects but we could have probably rolled in some speakers from the European Union into the agenda and overwhelmed you.

Could I recognize some international visitors. I think we have a couple, maybe one or two international folks.

Thank you. Thank you for coming so far.

One thing I think we know is there's a lot of work being done and all the work is important and maybe, you know, we can't just vote for one and dismiss the other. It's all very important. Each has different strengths and weaknesses, and they're not really easy, right? They look like they're really tough projects.

I want to open up the microphone to any comments, discussion. We'll start in the room, and then we'll go to the phone.

DR. COOKE: My name is Roger Cooke. I'm from Resources for the Future, a Chauncey Starr Senior Fellow in Risk Analysis, and also from Delft University of Technology in the Netherlands and in the Department of Mathematics and I've done a lot of

work with expert judgment in the context of risk analysis, much of it in the field of technical risk but also substantial work in the area of food safety with a group of Ari Havalar (ph.) at REVM in the Netherlands.

And I would like to offer just two brief lessons learned with regard to using expert judgment. These lessons we have learned sometimes repeatedly, and the first lesson is that the questions that you pose to the experts must have a very clear operational meaning. They should have physical dimensions and the questions you ask of the experts should also be questions which you could ask of nature if you could do the experiments or perform the measurements.

Why is this important? It's the only way to really make exactly clear what you are asking and if experts interpret the questions in different ways, it's the only way to go back and disambiguate what the different interpretations are. So that's the first point. The questions you ask of experts should be questions, which you could ask of nature with

physical dimensions.

The second point is it's really useful to get expert external validation. This is not easy, but it is very useful for two reasons. First of all, expert judgment by its nature is very noisy, and any validated tool that you can use to reduce this noise is going to pay off substantially. The second reason is that there are a lot of people out there who for very good reasons are suspicious of using expert judgment. And using expert external validation is really the only tool we have to try and address those concerns.

I would like to mention if you Google RFF Expert Judgment Workshop, you will find a website of a workshop that we did at Resources for the Future last year, and there's a lot of useful information that you can download from that. There is also a special issue of Reliability Engineering and System Safety that will be appearing shortly. Sandy has an article in there, and there will be some other articles in there which I think you might find useful to peruse. Thank you very much.

DR. HOLT: Thank you for the comment. We appreciate it.

Let me move to -- I'm sorry. Wolf, go ahead, and then we'll go to the phone. Can you identify yourself please?

DR. MAIER: Yes. I'm Wolfgang Maier from the European Commission. I work here in Washington in our Embassy delegation as we say in Food Safety, Health and Consumer Affairs. I have maybe two questions, which are a bit related to each other, although they might not sound like being related.

The first question is recently I have heard a very interesting -- about serological data being used in food illness or food related illnesses, and I haven't heard of that today. So I wonder what expert thinks about the value of serological information which could be used to link market survey data on the prevalence of certain strains of microbials and the level of antibodies being present, which are also quite strain specific sometimes in the population because it's quite cheap and efficient to obtain a representative sample of serum from the population.

So it's quite a cost effective means to obtain representative samples for the entire population, to look at the serological. I mean obviously it doesn't really cover the kitchen stage of the food chain, but it could relate the retail and the population, serological prevalence.

And another question about surveillance in food attribution, it is obvious that if you want to aggregate data and if you want to evaluate data statistically, you need a certain level of harmonization, of categorization, of agreed definitions but are there also tradeoffs because on the other hand, the real expert ties on an outbreak is local, and at the local level, people can react very quickly and interview people and ask the right questions maybe to identify the source locally. And if you have a -- system of reporting, there may be tradeoffs if you inference is local level too much by -- questionnaires and procedures and so I wonder whether -- as I said, these two questions seem at the first place not being related, but they may be anyway because you link the market surveillance data to the

serological population data and have the food attribution data, the kitchen stage, covered by a more empowered local level. So that's basically question. I have no answers. That's really a question.

DR. HOLT: And as Moderator, I'm going to open the floor to any comments. Wolf, let me recharacterize that and correct me if I'm wrong. I think on your first point, you're talking about using serotype data maybe to carry that into expert elicitation and to also possibly use human sera like serologies --

DR. MAIER: Yes, it was at the Food -- Meeting in Georgia, in Atlanta recently, four weeks ago or so. I think you were present. There was a contribution about the use of seriological data in the population to characterize exposure towards certain serotypes and the guys have developed this -- to the extent which I spoke to them and afterwards to detect exposure which was in the time window of six weeks to three months ago or something like this. So it was quite sophisticated and clean procedure, and I

was quite impressed about this. So I was wondering whether this might be an avenue for further research to the extent of other microbials or other exposures because I thought it's quite good because it is a reason because it eliminates part of the mess because you can really obtain as well as -- a representative sample which could cover the entire population, this maybe 2,000 seriological samples and could turn into a lab and have an accurate window or picture of previous exposure to certain serotypes of pathogens.

DR. HOLT: Do we have anybody who would like to -- Dr. Tauxe.

DR. TAUXE: Thanks. I think the work that you're referring to was again a very interesting new model coming out of Denmark, that we were eager to hear more about. Yes, another Danish Model. I think we're eating a lot of Danish here both in Europe in the United States. And it was really an attempt to solve the problem of the pyramid and estimating the size of the pyramid by looking at how much seriologic evidence of infection there is in people whether they were ill or not or whether cases were reported or

not. It's an interesting approach. It's one that I think a number of countries are probably going to want to explore. There's still a lot of unanswered questions about it, but it was especially to allow sort of constructing pyramids from different countries to decide how is the burden of illness, how does it look like? You know, does France have more infection than Denmark or the United States or less and how can you compare that? A very interesting approach, but one I think that needs a lot of further consideration and standardization before we understand exactly how to interpret it.

I think your other point was that a lot of the investigations that we talk about, and certainly when we're looking at the outbreaks, are local, and that it is the local and state efforts to investigate those are the essential part of the foundation on which a lot of this is built, but I would certainly echo that and enhance that. And there is a balance between how do you standardize across a group of different counties in the case of Europe, different states in the case of the United States, how do you

standardize the approach while you still preserve that local flavor, local expertise and local differences that are important, and that's a balance we have to face, yes.

DR. HOLT: I'd like to move to the telephone call ins, take a call from the audio bridge.

UNIDENTIFIED SPEAKER: Yes, we have a question from Patricia Buck. Your line is open.

MS. BUCK: Hello. My name is Patricia Buck, and I'm from the Center for Foodborne Illness, Research and Prevention, and I basically concur with the gentleman from Denmark has been saying here, that we need to look at other models that can provide us stronger resources for developing attribution data. Expert elicitation, of course, is a starting point, but it cannot replace valid data, and I would caution all of our efforts, which have been immense.

I'm so impressed with all the presentations this morning but we need, as one of them suggested, a higher integration or collaboration between all of these parties so that we can get to the root of the

problem which is identifying the foodborne disease and how it is linked to a specific food product.

So I don't know if that's really a question but more of a comment. It's been very hard sometimes for me to hear. Sometimes the reception isn't 100 percent, but I want to reiterate the idea that we need more data on which to base our future plans for food production and inspection in the United States and I strongly applaud the FSIS for holding this meeting. Thank you.

DR. HOLT: Thank you for that comment. I'd like to move then back to the room.

MS. SMITH-DeWAAL: Thank you. I just want to pick up on what Wolf and Rob Tauxe have been talking about as well. This is Caroline Smith-DeWaal, Center for Science in the Public Interest.

One of the things that has developed in our food safety system just in the last 15 years is the use of food testing. It wasn't really done even in the early 1990s. It's really something that we're just starting to employ. In countries like Denmark and there was also a major study in Iceland, they've

actually trapped pathogens back to the farm through retail and into the human populations. And this is a very strong tool that could be used in this country but it would take the commitments of not only USDA but FDA to also be tracking these pathogens in the food products that they regulate.

And that's just a huge question. Could FDA, which doesn't have the resources today to manage the food that it regulates, could it actually implement a very sophisticated sampling program at retail or even in process, that would allow us to track these illnesses. I think it would be extraordinarily powerful if it could be done on the scale of the U.S. as it has been done in a couple of other countries for various products.

DR. HOLT: Thank you for that comment. Anyone have any thoughts? And this afternoon we will have discussions about data gaps. We're coming up -- okay.

DR. BUCHANAN: Hi. I did want to make one comment or maybe just a challenge because I listened to all the presentations, and I'm wonder if we could

in considering outbreaks and sporadic case data, et cetera, if we might be able to get more in terms of what regulatory agencies need in terms of root causes by subcategorizing some of this data set.

For example, as I was thinking about outbreak data, we basically have two different types of outbreaks that occur. We have what we'll call catastrophic failures where we see an incident that's associated with a single time point, usually a single lot, and that's typically associated with a single failure of the food safety system as opposed to an outbreak that involves a diffuse number of cases over a long time period. Typically I would think of that as a root cause would be an ongoing failure in good manufacturing practices.

And so I was wondering if we could get more fine tuning by going back and getting a group of experts that are one composed of our epidemiologists and then a second group that are more used to going back and tearing apart what actually happened that led to the outbreak, and subcategorizing this information so that we could again try to find root

causes and get a better tuning of the attribution. Thank you.

DR. HOLT: Thank you for that comment. I think we heard that some this morning in the perspective discussion about really getting down to the root cause because that will lead us to think about interventions.

Let me take another caller question from the phone bridge?

UNIDENTIFIED SPEAKER: This is a reminder that if you would like to ask a question please press star 1 on your touch tone.

(No response.)

UNIDENTIFIED SPEAKER: I have no questions from the phone lines at this time.

DR. HOLT: Okay. Well, let's move onto the lunch period then, and reconvene here at 1:15. And if you need ideas about lunch, you can check with the registration table.

(Whereupon, at 12:15 p.m., a luncheon recess was taken.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:20 p.m.)

DR. HOLT: Okay. Let's go ahead and get started. I hope everybody had a good lunch and everybody had lunch. In this day of doing Blackberries and phone calls, sometimes we don't get lunch. So hopefully you all had a good lunch.

We're back now to shift gears a little bit with our discussion and we have a panel of questioners and I don't know exactly -- we spoke with you before the meeting but I think you guys hopefully have some questions after hearing the talks this morning. We can just move on and, Nancy, would you like to start?

MS. DONLEY: Sure. I'd just like to say thank you for holding this meeting, and it is a pleasure to be here. My questions are probably -- I'm probably of the group sitting around this table, probably the least -- I was not good in science when I took it in school, and I'm no better at it now, but I like to think I'm a logical person and that I can, you know, think logically and follow things on a very upper level. I will not be asking questions in the

minutia today because that's not just something I feel I can really do.

But that said, I just, I guess kind of just going to throw this out to whoever I suppose in Government would like to answer this question that, you know, we're sitting here today probably at least I think I can conservatively say 10 years after various governmental agencies and other stakeholders have said that there is a real need for food attribution data. And I guess my question is why are we finally getting around to it today at least a good 10 years later, and even to the point where were are trying to define, get the definition of what it is?

DR. RAYMOND: Nancy, while I certainly can't speak for 10 years ago, or even 10 years up to 2 years ago, the history of food attribution data, I will tell you why we're here today and that's because with the listening sessions we've been having regarding risk-based inspection, it's been driven home to me monthly that attribution data is sorely lacking, and if we had better attribution data, we'd have a better risk-based inspection system. So this was a decision we made

along with CDC and FDA to co-host this meeting, try to get this ball rolling down the hill a little bit faster. It's not going to solve the problem today or even this year, but we felt it was important to get a lot of the experts around that have attribution data. They do it in different ways. They talk different languages. They have different graphs. If we can find ways we can share our data together with the different Federal agencies, with the not for profits like the information that Caroline put up there today, if we can get this type of group together more frequently, I think we can make better progress. That's why. It's just -- I heard the message, I'm trying to respond to the message along with our partners at the FDA and CDC.

MS. DONLEY: I guess I'm just concerned that again, and this has been said, that we're rushing to do something now that we, you know, it's kind of like that we're rushing, we're putting -- charging full speed ahead and working on I think less than adequate data here to put something in place that we've been talking about for over 10 years. And it's really,

really, really kind of very discouraging to me as a consumer, as a mother who has lost her child to a foodborne illness, that there is so much discussion that goes on on a high level up here and it never materializes down into anything. And then when finally someone says, hey, we really do need to do something, such as, and I'm taking this again up to the broader picture here which is a risk-based inspection system, which again I don't want to slow anything down that is going to be ultimately beneficial and spare others what my son had to go through. But I want to do it, let's do it right. And it's just again, it's just that we go on and on and on and say we need to be doing this, we need to be doing that, and we talk, talk, talk, talk, and nothing gets done.

DR. RAYMOND: And I hope that a year or two from now you won't have to come and repeat that same message of talk, talk, talk and nothing gets done. I really do intend to try to get something done. Again, it won't get done completely on my watch by any stretch of the imagination. We all know that. But I

do think that talk is important and I think getting this group together today hopefully is just the initiation of something that will progress with or without RBI.

We are going to have a separate meeting where we will discuss attribution and risk-based inspection and, you know, we're trying not to do a whole lot on that today. What we're really trying to do is just make food attribution data better for CSPI, for the FDA, for the CDC, for the USDA. I mean we all need better food attribution data. I think we have made progress. I don't know how it's to be measured. I do know when we had the spinach outbreak, you know, in seven days we had a recall and that's pretty darn fast, and that's a measurement of what we can do today that we couldn't have done 11, 12 years ago. That's progress and as we have unfortunately outbreaks that give us better attribution data, that attribution data improves.

We met with the CDC yesterday and I don't want to put words in Fred's mouth or Art's not here I don't think right now, but basically for every person,

for every 100 people that have a foodborne illness, probably less than 10 will have attribution. That means 90 we don't know where it came from because they're usually sporadic cases and if you have a sporadic one case, you're probably not going to be able to find the attribution unless you have a person who eats one food product.

So there's limitations to what we can get done and how quick we can get it done, but I know we can do better than what we're doing.

MR. BUCHANAN: Nancy, I hear your frustration, I empathize with your frustration, and we need to have you know that we share in many ways your frustration but it really is a -- I think it was Tim's picture of that blurry taxicab. The progress that's been made in the last 10 years, Caroline showed in one of her graphs, where our ability in 1997 as a result of a concerted effort just improved in terms of attribution. During those past 10 years, we've had this incredible amount of advances in terms of science. And I think we're poised now after a 10-year investment in the type of science, the type of

infrastructure we need to do that, that we're poised to make that next leap fairly quickly. And so I commend the FSIS and CDC for getting this meeting together because I think this is where we're ready to make that next leap forward.

And it does tend to go in big leaps just as in '97 it went from here to here in terms of attribution. I think now we have the infrastructure not only here in the United States, but we've been working with our partners around the world in terms of this attribution. And so I'm hoping to see the next one take place very quickly.

DR. GRIFFIN: Patricia Griffin, CDC. I also feel frustrated. Those of us who work in this area work so that we can provide information for improving public health, provide information that our colleagues in industry, regulators, the public, need to make decisions. So it's frustrating that it moves slowly.

I just want to point out, some of the things that have been part of this process, FoodNet was created in 1996, following the big O157 hamburger outbreak, and FoodNet data, we needed to accumulate

for several years before we could make estimates of how much illness due to food for each pathogen there was in the United States, and we published those in 1999. Until we had those estimates, we couldn't begin to figure out how much foodborne illness was from the different food commodities. So that was a step that had to happen first. We had been wanting to do that for many years before that, but we couldn't do that until we had published those estimates.

And the reason we were able to publish those estimates was the combination of FoodNet data plus outbreak data plus increased resources that came from the Food Safety Initiative that began I think around 1998.

The other thing that happened with the Food Safety Initiative is that the states began better reporting the outbreaks and converted the system into an electronic system. And so the data that you saw that I presented today, was all from that new electronic system, and that had to accumulate for several years before we had enough data that we could use to do that sort of attribution. So it's very

frustrating in the amount of time it takes but we're very grateful that we had the funding from Agriculture to start FoodNet and then the increased funding from the Food Safety Initiative for all these work on food that allowed us to start a lot of programs that's resulting in the sort of efforts that you're seeing that are going on today.

MS. DONLEY: Patty, do you -- those were times because that was -- a lot of things were happening as a result of the 1993-1994 O157 epidemic, and a lot of money was channeled into food safety work in the CDC. Where is that today? Are you still at that level of funding? Has it increased, decreased?

DR. GRIFFIN: Well, a lot of programs were improved as a result of those initiatives and those improvements have been maintained.

MS. DONLEY: But have you been allowed to grow? Now like the FoodNet sites, we're at 10 now. Weren't we at 12 at one point or --

DR. GRIFFIN: No, we weren't at 12 at one point. The FoodNet, we think that 10 sites is really a good proportion of the population on which to obtain

good data. Our challenge with FoodNet is to continue to have those data, those sites be able to provide the sort of data that we need to make extrapolations to the rest of the United States.

MS. DONLEY: Karen, can I ask just for a point of -- where did she go? I'd like to just say if any of my other colleagues have anything to jump in on this panel, I don't mean to obviously keep going along, but as this conversation is going on, if you have questions to ask, I would say jump in.

DR. HOLT: I was going to rotate around and we'll keep cycling back if we have time. Thank you, Nancy Donley. I'd like to introduce Skip Steward.

DR. SEWARD: Skip Seward. I'm with the American Meat Institute. This question, two related questions really. The first one has to do with, it seems to me that there is a data gap in characterization of microbial isolates that would come from areas that are downstream from the processing sector, and those are obviously maybe a little bit more complicated to get or require more effort in time because we don't have necessarily agencies that are

devoting their time to going in and sampling at food service, retail, consumers' homes and so forth, but it seems like that's important when you look at the data that suggests that a lot of foodborne illnesses are related to activities that occur in those areas or contamination that occurs. So the question is really the obvious one is, you know, what are the various agencies doing individually or collectively to try to improve that -- close that data gap and make that information -- build the strength of that data?

And then a related question is that if you look at the millions of dollars that are being spent by the Federal agencies on microbial testing and sampling, if you were to put that together with the agencies, see any reallocation of those resources that could help improve the attribution project, if you will, to try to get better information because obviously particular agencies when they get awarded certain money tend to use that money focused simply in their own area of regulatory activity or what have you, and may not be really contributing in the long run in the big picture to the bigger picture of food

attribution in trying to solve this on a U.S. national basis. So how would you reallocate the resources to help get at some of the information like I asked in my first question?

DR. JONES: Nancy -- this is Tim Jones. Nancy and Skip both asked questions about resources, and I guess because I'm not a Fed I can answer them more bluntly than others in the room.

You know, as one of the participating states in FoodNet, I can tell you that our budget is exactly the same or a little bit less than it was in 2002 which means that given increased salaries and increased expenses, you know, we've lost 15 or 20 percent and this year we're at risk of having to cut sites or cut employees at our current sites. So, you know, the perception of being level is not really level in the real world.

And, you know, I think for a few hundred thousand dollars that each of the FoodNet sites get, that's an incredible investment in terms of the amount of data that are generated and used by a huge number of agencies. The reallocation question is a difficult

one. I hate to say two and a half minutes in what we spend in Iraq would pay our entire FoodNet budget in Tennessee but even money that's currently spent on food safety, a little bit can go a long way when it's put out on the front lines.

DR. BUCHANAN: Bob Buchanan, FDA. Skip, one of the things that I tried to articulate in my opening remarks is that food attribution, the definition we use is really quite broad. And the question of testing versus food attribution is not one that you can pull apart. Critical to any attribution is also knowing what's out there in terms of the potential exposure, and if those two don't match, something's wrong. And so sort of saying attribution, testing, if you pull those two apart, you're not going to get the data you need, that we need, in order to make regulatory decisions. So it's both.

DR. HOLT: Okay. Let me move onto Caroline Smith-DeWaal.

MS. SMITH-DeWaaL: Thank you. I have two questions to CDC, one question but I'm hoping Dr. Raymond and Dr. Buchanan will both answer it, and

then one question to Tim from Tennessee.

To CDC, one of the criticism that has been leveled against the expert elicitation that USDA did, one of them, there were many, was that they don't have data getting down to those specific, those 24 categories of meat products of which I don't know, 8 or more are different types of ready-to-eat meats. You have a number of whole meat products as well as a number of ground meat products. And in looking back at the outbreak data, as you saw, I had to clump these categories into very broad, large categories to kind of try to get it to match up at all with the outbreak data.

So my question is, is it realistic to collect data on these very specific food types? I talked to Rob Tauxe while you were doing the peanut butter investigation, and he mentioned that you had to use a questionnaire that had 300 questions on it in order to get down to the Peter Pan Peanut Butter that was responsible for that outbreak. So can you tell us, is it realistic that we're going to have the outbreak investigations getting to these 24 specific

meat categories?

DR. TAUXE: Well, I think this is the fine grain categorization question, and we -- the one part of it is when you're trying to figure out where an outbreak is coming from, and you really have to consider an awful lot of possibilities. The nature of food is so complicated, there are a lot of possibilities and we're fortunate that peanut butter was one of those 300 questions or it might not have been quite so obvious as soon as it was, which wasn't very soon.

But I think your central question is what about fine grain categorizations once there's a whole series of outbreaks, in an outbreak data set, and probably everyone in the room has specific questions they would really like to ask of the data that turn out to be very specific and very focused often, and how can we do that? We're talking about chicken or poultry or seafood as categories that are way too broad for a lot of the questions that a lot of people would ultimately like to be able to ask of the data. And if it's so fine grained that there's just one or

two outbreaks in the whole system that correspond to that, and I guess the cougar jerky was an example of that, then we really can't -- all we can do is tell the story of that outbreak.

But if it's something where there is a meaningful number of outbreaks that can fit in a category, it would be nice to have a system that let one sort of construct new categories or apply new categories to the data and see, how does that break out?

But what we've become keenly aware of is that tomorrow someone else will have a different question that's a different set of categories and I like very much the concept that where there are key regulatory decisions coming on a specific issue to apply the categories that make sense for the key regulatory decision. And I hope that's something that we'll be able to do, but we should say up front that for the very fine grain, often the data, just there aren't enough outbreaks due to that specific food to make it possible, and we have to be looking at broader categories often.

MS. SMITH-DeWaaL: Just to follow up. USDA is releasing the *Salmonella* data quarterly now for the meat testing programs. Is there any way you can speed up releasing your outbreak data? I know you scrub it very hard but maybe breaking it up quarterly or somehow getting the data out faster because you're looking at really two year time lags, almost two full year time lags to get the data out right now.

DR. GRIFFIN: That's certainly our goal, to be able to get it out in a much more timely manner. We would like to get it out quarterly, and we would like to be able to when we get it out do some trend analyses. So all of that is in the plans, but how soon we can accomplish that depends on the other demands on the system.

As you know, this year there were the same group that puts out those reports was investigating a small spinach outbreak, small peanut butter outbreak and a few others.

MS. SMITH-DeWaaL: I'm going to jump to Tim. What do the states need to do that's better? I will correct my previous statement. Tennessee was in the

top level or top half of states reporting outbreaks, not near the bottom like some of their colleagues in the south. But what do the states need to really do the outbreak investigations and the reporting faster and better?

DR. JONES: You know, I hate to -- but I think to be honest that the local county and state levels, it's really resources, and most importantly people. You know, much of the funding of public health infrastructure, I mean we've been lucky in some senses that we've been able to ride the waves of successive disasters. You know, we got a lot of money for bioterrorism, and then it was West Nile money and then it was SARS and now it's PAN Flu. And much of those resources have been used to be honest for things that are real and really affect people all the time. So we've been able to subsidize FoodNet and our outbreak response programs. But a lot of those other sources are drying up and all of those cooperative agreements that I mentioned have had substantial cuts in the last year.

So I mean Patty alluded to it at the Federal

level. The same thing happens at the local level, and the very nurses that are called on, that I have to call up every day to say do this 300 questionnaire about spinach or peanut butter, are the same nurses that are giving vaccines and running an HIV clinic and tracing TB contacts. And that's really unrealistic when the demands are going up.

I guess along the same lines, money that we have no real expectation that it will continue, you know, one time end of the year money or bonuses. I mean I never want to look a gift horse in the mouth but we can't spend that on people. And it doesn't really help to have 15 computers per person if there's no one that knows how to use them. So from the local perspective, the only way we're going to get people is to have some stability in the support. I don't know if that answers your question.

MS. SMITH-DeWaaL: Thank you. I'm going to let Barb go.

DR. HOLT: Okay. Thank you. We'll go to Barbara Kowalcyk.

MS. KOWALCYK: Hi. My name is Barbara

Kowalcyk. I'm from Center for Foodborne Illness Research and Prevention. And I would like to thank FSIS and HHS for coordinating this meeting, because it's been very interesting. Food attribution data is something that is very near and dear to my heart. As Nancy, I have also personally experienced losing a child to foodborne illness.

I also have another interest in food attribution data being a statistician and data is the love of my life.

So I have several questions. I mean there were some common themes that seemed to jump out at me today. One is that for most food attribution, we are very reliant on outbreak data, and the other common theme was attribution data is very, very hard to get.

In terms of looking at outbreak versus sporadic data, I have a keen interest in this. My son was a "sporadic" case. But there seems to be some consensus that there are significant differences between sporadic cases of foodborne illness and outbreak cases of foodborne illness. And I understand that it's very hard to get at those sporadic cases but

I think it's very important.

The analogy that I would like to use is suppose you would like to estimate the height of trees in Pennsylvania. Pennsylvania has a huge number of trees. It would be very, very difficult to measure every single tree in Pennsylvania to find the average height. But that doesn't mean you just go out and sample those in your back yard or those in your residential neighborhood because they may not be truly representative of the entire population of trees in Pennsylvania. Pennsylvania has a lot of forests and so forth.

So my concern is -- I thought all the methodology that was presented this morning was very good, and I thought it was very appropriate. The question that I have and the concern that I have is it seems that we are inclined to take a leap from outbreak data to the entire population of foodborne illness. In essence, we're willing to take the height of our trees in our residential neighborhood and use that as an estimate for the height of all trees in Pennsylvania, which isn't necessarily appropriate.

And what do the different people that presented this morning, you know, what do you see as the solution to that? I mean how do you see that we can go ahead and come up with a better way than just using outbreak data? And I'd like to have this ongoing conversation because I'd like to get at solutions. I mean it's very difficult to obtain attribution data at the level that we really need and I would like to find out ways that would improve that.

DR. JONES: Tim Jones again, and I share the same concerns and I think, you know, you heard from a couple of people that between 80 and 95 percent of the disease that we see is not associated with recognized outbreaks. So all but one of the presentations today, you know, were focused on extrapolating from outbreak data. So I very much share the same concern.

I think the one presentation that -- I mean there were many, but I think Fred Angulo's presentation was a good introduction to what I think the solution is, which is case control studies where outbreak associated cases are specifically excluded and, you know, we're looking pathogen by pathogen at

sporadic cases looking for risk factors.

Now that will tell us probabilities. It will focus the number of targets. It won't necessarily answer the question for specific patients. You could see from Fred's slide though that, you know, each of those studies takes several years to complete, and we have to slog through them, pathogen by pathogen, but if we need to do that, I think that's the only way to answer you question, and there were a lot of pathogens that were not on the list that he showed.

MS. KOWALCYK: Thank you very much for your response. That begs the next question. Do the various governmental agencies have the computer and data infrastructure necessary to move towards doing more case control studies and developing the kind of data that we need to get good reliable attribution data?

DR. GRIFFIN: Patricia Griffin, CDC. If I can go to your last question and also the one before. As far as sporadic case control studies, we in FoodNet continue to target each year what are important issues

on which a case control study is needed to define a particular burden of illness and so FoodNet continues to do case control studies. Fred Angulo may want to say more about that.

The other point I wanted to bring up about your very excellent point about the concerns of basing attribution data just on outbreaks, and as mentioned, we do these sporadic case control studies partly so that eventually we will blend that data in with the outbreak data. And we still need to work out the methodology for doing that.

The other thing that's been happening in recent years, and the best example where we can see it happening is *Listeria*, but it's happening in a lot of other areas, is we're starting to get the whole pie for each pathogen, and we're starting to pick out those sporadic cases and realizing that some of them are part of outbreaks and define them as part of the outbreaks, so that we know a lot of the sporadic cases are truly part of widespread outbreaks and we haven't been able to find those outbreaks.

And PulseNet has been pioneering subtyping

methods that are now used in all of our state health department laboratories and they are subtyping many, many strains of pathogens and as quickly as possible getting those patterns into the central database. And with that information, we are linking those sporadic cases in which there are only a few cases in each state. That's how we found the peanut butter outbreak. That's how we find some of these diffuse ground beef outbreaks. And the more we improve that infrastructure of the isolates coming to PulseNet and being subtyped and then the state and local health officials having the personnel who can look over and say, you know, three isn't a big number but we haven't had 3 of this pathogen in a 2 week period for the past 10 years, and this may mean something, and let's see if the state next door has the same thing. That's how we find those, and then they decide to put their energy into investigating it and figure out the cause.

The more of those data points we find, the more we start to break up those sporadic cases, find the outbreaks and then our whole data set becomes more robust.

DR. HOFFMAN: I think I'd just like to add what's probably as much a question as a comment and that's why are we wanting to look at sporadic cases and outbreak cases and get the entire set of illnesses?

And so I want to come at this from the perspectives I've gained from looking at chemical hazards in environmental health where the epidemiological data, they would be thrilled to have what you have on microbial data because we're dealing with latency periods of 20, 30 years, and you just don't find the bodies but they're probably there.

So one question and to kind of comment I have is, to what extent is there a potential for taking a bottom up perspective on predicting illnesses to complement the top down approach of being able to identify the illnesses and attribute them back? Can we be in a position to use sampling and response functions to get at prediction? And what's the potential for developing that broadly enough that it can start to be used to supplement the epidemiological data?

DR. TAUXE: Well, that's sort of the essences of a risk assessment I think that goes all the way to the prediction of the number of illnesses that one might see. And a step or two beyond that then is, for instance, the seriologic assessment of exposures which might be a whole variety of exposures, actually food and non-food and difficult to separate out. But that's the direction that that takes, sort of recalibrating this from another end.

And I think I've been part of or have seen several of the risk assessment exercises and they are very interesting. They sometimes found or run into challenges because they're data gaps on that side, too, and you wind up fitting a dose response curve that's your best guess to fit what you think you ought to be getting or seeing, and that has its own complexities and sometimes would use the actual surveillance data to decide how best to fit that curve. So they tend to complement each other but I don't think they're necessarily independent. I don't know. Bob, maybe you'd like to comment further on sort of the risk assessment of, bottom up approach I

think was the word you used.

DR. BUCHANAN: Yeah, and we generally don't like to use bottom up or top down. Just different sets of data that we start with, and that was really the basis for my comment back to Skip about it's not and/or on microbiological data because we can do an effective way of predicting. And one of the strengths is that in any model approach, you want to have a set of data that validates your conclusions, and by taking both approaches, and having both sets of data, you can walk away with a lot stronger scientific basis for making decisions.

I also might note that there's as much benefit to be gained when the two data sets do not match each other, and when you have to go back and investigate. I might note just in passing an incident that happened when we did the *Listeria* risk assessment, and the epidemiological data for soft cheeses didn't match the risk assessment data that was, as you referred, based on microbiological testing. And we had long discussions between FDA and CDC over that issue, and then low and behold, we went

back and reanalyzed the data, and all of our data was generated on commercially available products from the marketplace. And we went back and looked, and all of the data that they had on soft cheeses was from illegal cheeses that were being brought into the country illegally, and that wound up to be an incredibly important decision because it reoriented our entire regulatory program for that commodity to focus on where the problem was.

DR. GUO: I try to address to use all the outbreak data and -- in attribution. First my comment is that the Danish Model, that is two separate -- overseas and the sporadic cases. So that is a model that's not based on outbreaks. When we adapt this model to apply to U.S. data, we have the human serotyping data from -- That data do not separate provided -- and outbreak information. But we do try to use data from FoodNet. That is a different year data of -- and outbreak information. So we use that information, try to estimate what is the sporadic portion in the whole data set.

So for this reason, this model I talk, is

actually a mostly sporadic cases. That is the model to answer the question, but I want to say as a risk assessor, I know no model is perfect. No model can answer all questions. The only way is collect data together to address the crisis. So each model answered particular crisis and so that is why I think that we gather together to present different perspective. This is Chuanfa Guo from FSIS.

MR. BATZ: I just had a few thoughts. I don't even remember what the original questions were, but I think in response to Sandy's question about exposure assessment and the role of risk assessment in these things, I think that was really the only sort of approach that has been used that really wasn't presented today in terms of, you know, broad approaches.

And the Dutch have done one for *Campylobacter* that was an exposure assessment where they looked at foods, non-food sources. It was presented in Berlin was the first time I saw it, and I presume they'll be publishing it soon. It had some benefits in that they were able to compare these

different pathways much in the way that the *Listeria* risk assessments were able to compare these different pathways, but because they weren't limited to, you know, say ready-to-eat meats, it did give a little bit broader of a perspective in terms of all these potential pathways. So it gave more information than I, you know, previous to seeing that thought would be possible through a risk assessment approach, just knowing how many resources have to be put in them. I think there were some simplifications that had to be made, but I think they still got some useful information out of it.

On the other hand, they estimated something like 10 times the number of annual *Campylobacter*, you know, illnesses using their gross response models than they would ever predict even including under reporting in the population, you know, which is saying something considering when people in the Netherlands, you know, get diarrhea, they're probably 10 times more likely to go to the doctor than we are. So there is room for exposure assessment. I think in the states we really haven't gone down this route but

I think there is a lot of potential to learn from that and compare it to the data that we can get from the human surveillance and the EPI side working backwards to identify causes.

I did have a thought, you know, one of the reasons why we all use outbreak data is because that data is a byproduct of an investigation that's done for a different purpose. You know, attribution is the purpose of that investigation, but it's really, you know, sort of a crisis response kind of role, and then we have this byproduct of data that we want to then go back to and address it. And there is a question, if outbreaks, if we see an increasing role of these outbreak investigations to provide attribution information, then perhaps we should rethink a little bit about how we ask those questions about what foods are, what those causes are.

Now, you know, I said some things about food categories and a lot of that comes from the perspective of interpreting data that already exists and there are some concerns about going down this route of, you know, giving a 12 digit code for

whatever the food is when you're doing reporting, and I don't think anybody would like to see it go that route. But I think there is a question as to whether there is room to improve the role of outbreak investigations for specifically improving attribution. And I don't know that it's cost effective or whatever, but I think it is an open question.

And I did also want to say that we have to be careful with things. I think that the Danish Model is one example of this where there's an approach that worked somewhere else because they have a very different way of collecting data. You know, in the Danish Model, they have a lot of sporadic illness information and a lot of isolates from human illnesses and they have a lot, I mean a tremendous number of isolates from different animal sources that are very well representative of all those major animal reservoirs. And so one of the robustness of that model is partially the use of the analytical method, but part of it is really the result of the fact that they said we think, you know, *Salmonella* is

occurring on the farm. We want to know where it's happening and we want to target the species that really matter. And, you know, their goal was on farm regulation and that's not really the same as we do it here. So I think that the roles of some of these things, the way they were originally done, were really driven by a different question than, you know, an attribution question in the sense that that attribution was for a specific regulatory purpose. And when we, you know, when we take -- I think that's similar to, you know, the purpose of it is heavily driven, and the reason why you have all these approaches is because there's a lot of different questions that we're trying to answer. I was rambling. I apologize but --

DR. BUCHANAN: Bob Buchanan, FDA. And I did want to note in terms of attribution models and things that work in other countries, as Mike indicated, that have been very powerful but I don't know would work in the United States. And what I didn't hear was anyone mention the Japanese Model for attribution data.

For those of you who are not aware of it, the Japanese government required all major catering activities to take a sample of each of their major entrees and food. They basically take a meal and they must put it away for two weeks in the freezer, and then if there are any adverse events that are reported, they then have a real sample of the food that was actually associated with the adverse events. Incredibly resource intensive. On the other hand, some of the best does response modeling and the best attribution data we have for outbreaks comes from that. It's had a tremendous impact on the risk assessment community in terms of being able to calculate some of these things. So again, a different model, a different tool, it works very well in Japan, and we're using it ourselves but I'm not sure it would work here.

DR. HOLT: We're going to cycle around. Let's move on then to Michael Rybolt.

DR. RYBOLT: Michael Rybolt, National Turkey Federation. I'll just reiterate what everybody else has said and thank Dr. Raymond and

FSIS and the other agencies for hosting this meeting. I think it's been a good meeting, very educational.

I guess my question is probably a little bit more targeted than some of the other questions towards our first presenter, on the Danish Model. The results came out as basically 41 percent other. Based on your input of other sources I guess are what that comes out as, if there were other data inputs in there from other commodities or from other products, would you anticipate that changing or would it be that 41 percent? Because if you look at the actual graphs for the different products, it really looks like we're modeling or plotting out the actual *Salmonella* data that we're getting from FSIS now through their sampling programs. I mean '98 to 2003, the pattern looks very similar to just the data that we collect through the micro sampling. So I'm wondering if that would -- do you anticipate that changing some if you input other data sources into the model?

DR. GUO: This is Chuanfa Guo, FSIS. As you said, there are 41 percent in this model, the pie

chart. There are 41 percent human culture confirmed cases that have been put in other unknown category. Since we started is the best data we have, that meat and poultry both. And we also have -- data from the earlier years. So that is if we got the better data, that mean we have other food product data. For sure that is the pie chart will have some change but I not expect to be totally changed. So since that will provide additional, since this model is the principal is compare the serotypes from human cases to the serotype as related from food products or food sources. So that is where we make better comparison, compare the distribution in the public health and -- that is human cases side and the food product side. So my answer is that there will be changes but I don't expect dramatic change. It will make the data better.

DR. HOLT: Okay. We'll circle back to Nancy, Nancy Donley.

MS. DONLEY: Okay. Again this is what's kind of wonderful about being the only non-scientist in the room is I'm kind of outside the box here. And

a general question of how does the whole idea of getting food, you know, attribution data that's going to be ultimately used in a risk-based inspection system work -- how does that all work with emerging pathogens or pathogens that we don't know about? How do they fit into this picture here? Gee, I keep directing my questions to you, don't I, Dr. Raymond?

DR. RAYMOND: Dick Raymond with Office of Food Safety, USDA. The reason I jumped up is you kind of hit an old nerve here from when I used to be a state health official and used to preach that public health to be effective has to be more efficient, has to be smarter and certainly has to be more nimble than it has been in the past. It has to be able to respond to emergencies as they arise. I don't think we've ever been more aware of that since September 11th, followed by anthrax and as Dr. Agwunobi mentioned, all the misconceptions we had about anthrax which we learned as we went through that crisis and got better quickly. If we'd had committee meetings for a couple of years to decide about anthrax spores, could they go through an

envelope, we'd still be dealing with anthrax.

So public health has changed. It used to kind of be an 8:00 to 5:00 job, but it's changed because the world has changed. We do have emerging pathogens. We have to think about SARS and try to figure out, is that pandemic flu or not, and look how quickly we figured out what SARS was. Science is better. The scientists are better.

So to respond partly to your question, emerging pathogens are all something we all worry about. We all have to be nimble. We cannot be restricted by rules and regs and laws that put us into boxes and do not allow us to be flexible. That's not part of the question.

The other part of your question is how do we -- something about the attribution data and risk-based inspection. I can't remember exactly how it was phrased but I just want to make a point that what we're trying to do today with attribution data, and how to figure out how to work together better and get the information better and get more robust, isn't just for risk-based inspection in the food safety and

inspection service. I can't speak for how Bob Buchanan may use it at the FDA. Is it risk-based inspection at the FDA or is it where he's going to put his resources based on attribution? So there's lots of different ways to use attribution besides just risk-based inspection. Does that kind of get to the question?

MS. DONLEY: Yeah, I guess, yes, and I don't even know if -- obviously attribution data means that you're working with known entities I guess. I guess, you know, there just is a general level of concern of how do we be proactive rather than reactive to the next bug that comes along and I don't know if this is the meeting to be having that discussion. It's just something that, you know, and something that Tim Jones said is that the lists of the pathogens that have been, you know, up on the board today is also just the tip of the iceberg as far as -- of pathogens that make people sick.

DR. RAYMOND: And someone had a slide towards the end that showed that, I can't remember how many 125 pathogen/food product combinations are,

15 of them account for what? Eighty or ninety percent of what we know. So the next new pathogen that we don't know today may take over as the king or it may be a little bit of a nuisance.

SARS was a little bit of a nuisance for a while. I don't belittle the people that got SARS and the communities that were locked down in quarantines, but it didn't become a worldwide pandemic like we feared. And so the next pathogen may or may not be with us for a long time.

West Nile came. It had its crisis moments in each state and it's still there but at a lower level.

Monkey pox by the way came and it was done pretty darn quick once we figured out which rodents were carrying it. We got them confiscated. So emerging pathogens will always be with us.

Using attribution though, you mentioned proactive. It also made me think as you were saying that, it isn't just for risk-based inspection for FSIS. I already said that. But the other thing is the better we can attribute illnesses to food, the

better our messaging to the public. You know, if two people got sick with one pathogen this year, I'm not going to spend a lot of resources educating on that pathogen, but *Salmonella* we have attribution data that show we got a problem with poultry. We're working on it. We're getting better, but in the meantime, we need to convince the American public to be extremely careful when they handle raw poultry products and how to cook it and so forth.

So attribution data can also direct our education efforts.

MS. DONLEY: And, Dr. Raymond, do you work at all with and I guess this would be also a question for Jenny Scott. Does industry have data that they share with you on this specific issue?

DR. RAYMOND: Patty's got the mike. She still wants to respond to your previous question. I think we'll do that and then I'm going to let Jenny do the industry one if she would.

DR. GRIFFIN: Yeah, Patricia Griffin, CDC. So you're asking about how to find those unknown agents that we think are out there or could be out

there in the future.

And sort of my bottom line for how we do that is by continuing to strengthen and upgrade our public health infrastructure. The main way that we find new agents, the most cost effective way, is by investigating outbreaks. Now Tim Jones and his colleagues, through FoodNet, did a study looking at why there are so many outbreaks we don't find the causative agent. And the answer is pretty simple. We don't get the specimens from the patients. So you need to get the specimens from the patients in a timely manner to find the pathogen.

And then beyond that, once you get those specimens, you have to send them to a laboratory, and then you need an epidemiologic investigation. If I get a diarrheal illness tomorrow, and I say, well, I was traveling, I ate here, I ate there, they test for the usual pathogens and they find nothing, it's not worth it for them to look in my stool specimens for everything possible in the world. For one person, it's not worth it. For one thing, they wouldn't know how I got that agent.

But if a health department or CDC does an outbreak investigation, finds a bunch of people ill and says, we know that all these people got sick from eating that pineapple, we know, we can target the food. So it's really worth figuring out what the agent was because we're sure they had the same illness. So really looking at their stool samples and Minnesota Health Department did an investigation like that several years ago, and they found a very unusual *E. coli* that was present in all of their stool samples.

So those are the sorts of investigations that we need to find the unusual agents. Our clinical laboratories look for only a small number of the agents that we know exist. The public health and CDC laboratories can look for many more. So that when we have those outbreaks due to unknown agents, we can bring those resources to there if the specimens are gathered.

We can also do studies of sporadic cases to figure that out and we can -- if we have good communication channels, we start to hear about other

pathogens. Right now we're very concerned about a pathogen that's based in hospitals called *Clostridium difficile*. It causes a diarrheal illness but we know that people are now acquiring it in the community, and we're interested in looking at how they're getting it into the community, and we're doing that because we have good communication channels with the people who deal with those organizations -- with those organisms.

So the bottom line is define these unknown agents. We need to continue to strengthen and upgrade our public health infrastructure.

DR. RAYMOND: So is the CDC now causing microbial agents organizations?

DR. GRIFFIN: Sorry.

DR. RAYMOND: A new categorization. They're getting organized it seems. While the mic is going down to Jenny, I want to -- one other thing, Nancy, when you talk about being proactive. I want to use BSE as an example.

You know, when it was discovered that prions were causing variant CJ disease in Europe and

they found out the cause of it, once the cow went down in the State of Washington on December 23rd, we became very proactive to prevent people in this country from getting variant CJD from eating the specific risk materials. And, you know, what we do with the feed ban, what the FDA has done, what we have done in the slaughter houses, we can still say that no one in America has ever got that prion from eating American beef. So I think it's a classic example of putting a lot of resources into an area that could have caused a disaster in this country.

DR. TAUXE: Rob Tauxe with CDC. I want to amplify that example and that issue and that if we wanted to be proactive and if we want to be looking out for where the next emerging foodborne pathogen could be coming from, before the outbreak that it causes happens, I think we should look at where most emergency foodborne infections have come from in the past. And that's out of animal reservoirs which means we should be concerned with issues that are going on an animals that may not have at first blush a public health impact but the connection between the

veterinary world and the animal world. And human health is pretty close and that link needs to be fostered and, you know, if the veterinary world or even Lord knows now, the plant health world is concerned about an issue, that's something that public health ought to have an ear out for.

The other is maybe it's happening in another part of the world, and links around the world are, you know, are so fast and so direct and so rapid, both for shipping people and for shipping food, that events that may seem very remote, and outbreak investigations that may seem very remote and unconnected are something we need to be alert to and those international and global networks for communication and collaboration and surveillance cooperation are really critical.

I mean the reason our 300-question questionnaire -- the reason one of those questions was peanut butter was because some years ago, Australia had one outbreak related to peanut butter, a *Salmonella* outbreak, and because of that, it made its way onto the questionnaire and we benefited from

that. So those links both to the veterinary world and to the global surveillance network are one of the good ways we'll get some advance warning we hope.

MS. DONLEY: I just want, my final comment is, I thank you, Dr. Tauxe, for bringing that up about -- I and my organization could not agree with you more the need that there just needs to be some more attention paid to the animal reservoir issue. It's critical. It used to be, you know, we could kind of be safe and say, hey, this was a meat and poultry product and we find now that these pathogens are no longer confined. These problems are no longer confined to just meat and poultry products but to other products as well, and they are animal reservoir pathogens. And Skip had kind of alluded to that with his question. That's a giant gap which I, you know, I guess it's not the scope of this meeting but I hope someone in Government really pays attention here that that's a huge gap that needs to be closed.

DR. HOLT: Jenny.

MS. SCOTT: Jenny Scott, GMA/FPA. I think the question, Nancy, was does industry collect data

and share it with the Agency?

MS. DONLEY: Yeah.

MS. SCOTT: And industry does collect a lot of microbial data, and particularly meat and poultry plants, and in meat and poultry plants, all of those data are available to the inspector. For the most part, I don't think the data are collected in a common database where you could say that, you know, across plants, maybe without attribution to plants, this is what we're seeing. There might be some room to do something like that particularly under risk-based inspection if there are incentives to plants participating in this type of program and sharing the data, collecting it together, for getting some credit for that and the interventions they're putting into place to deal with the results of data collection.

DR. HOLT: Okay.

DR. BUCHANAN: Bob Buchanan, FDA. I'd really take Rob to test a little bit on his comment about animal reservoirs. And animal reservoirs are important but you can't make the assumption that all emerging pathogens or all microorganisms concerned

come from an animal reservoir. Certainly, you know, you can get yourself if you blindly make those assumptions or follow what has always occurred, you get yourself into real trouble. Case in point, hepatitis in green onions, assuming that it was a food worker. *Enterobacter sakazakii*, something that was one of the most important emerging pathogens for infants in the past few years, has no animal reservoir that we know of. *Cyclospora* has no animal reservoir that we know of, and they're still looking. So I think you really need to approach attribution and certainly you don't want to throw away the lessons of the past but on the other hand, you need to approach any new emerging pathogen or any new instance of an existing pathogen, where you're not sure where it came from, approach it with an open mind.

Another case in point, we had to deal with an outbreak of Salmonella enteritis phage type 30 in almonds, and they looked all over for an animal reservoir and there is none. It lives in the hulls of the almonds as Linda Harris dramatically

demonstrated with research.

So again, we need to make sure we approach attribution with an open mind.

DR. JONES: So can I defend Dr. Tauxe? I guess in response to your examples, you know, these bugs done spontaneously generate themselves in almond hulls and not recognizing a reservoir is different than knowing what the reservoir is. And I mean I don't think that the primary reservoir for *E. sakazakii* is infant formula. It got there from somewhere. Where, we just don't know where. I guess for Hepatitis A, it depends whether you classify humans as animals or not. The *Cyclospora*, you know, we don't know that it wasn't bird feces. But it didn't generate itself on the raspberries. And I think, you know, for practical purposes, we have to put the money in the resources where we have a best shot of making a difference. And I think with the majority of foodborne pathogens, if you look at what's been on the front of Newsweek in the last 10 years, it's things with animal reservoirs, whether you go for SARS or pandemic flu or West Nile virus or

any of the things that are killing the most Americans. It's by and large -- if you're betting which is what we're doing, get a bet on animal reservoirs.

DR. HOLT: Over to Skip Seward.

DR. SEWARD: Skip Seward, American Meat Institute. One question that's come up is in terms of the structure of the database that CDC and CSPI and others are using for attributing certain microorganisms to certain food in case of food attribution. And is there an effort underway to really standardize that across at least the governmental organizations or CDC really taking a lead in that such that FSIS and FDA will use the same type of -- will use your database as sort of the standard so to speak? And then are you planning on under those food categories as far down as you can drill, are you planning to have another drop down menu at sometime to try to capture potential root causes that were associated with that food, where it can be done? So I guess that question really is for CDC to try to answer. Thank you.

DR. GRIFFIN: Yeah, this version 1 categorization scheme that you saw is actually the first version that we've put out for public viewing. This is the first time we've done it, but it's not the very first version that we worked on. We initially may have heard somebody talking about row crops and tree crops, and we played with other ways of categorizing things, and the reason we changed is we talked amongst ourselves. We talked with the regulatory agencies and got a lot of input into what sort of would work for people. So we shared this scheme with our regulatory agency partners and we all agreed that we were striving for excellence, not perfection here if I could quote. And this was the closest we could get to what everybody thought was workable, and it's workable right now.

And as for would we be subcategorizing later, if you look at that category fruit/nuts, well, obviously you'd love to separate it into fruit and nuts. And so one would hope that as we get more data, we will have a robust enough data set that we can subcategorize more. At this point, each of the

ends of that tree that you saw with the smallest categories that we felt that we could do a fairly robust analysis on.

DR. SEWARD: Dr. Griffin, just a quick follow up. What I was talking about in terms of a subsequent drop down is the root cause of what happened, whether it was mishandling, under cooking, and those types of practices that also were attributed, where that could be identified, so you'd have that root cause data in addition to just the food itself. That would be helpful and it seems like doable, if that information is available for certain outbreaks or certification investigations.

DR. GRIFFIN: Right. The database collects that information and it's of varying quality. And it's information that everyone is interested in knowing, and it would take another similar effort like this to try to figure out how to use that contributing factor data, whether we could model it in with this sort of analysis or whether it would be a different sort of analysis and how to judge the quality of that information. That's not an effort

that we have approached yet, but we have been working very hard on our form to try to capture as much as possible, what the contributing factors are so that we can do those sorts of analyses.

DR. SEWARD: Thank you.

DR. HOLT: I'd like to move onto Caroline Smith-DeWaal.

MS. SMITH-DeWaaL: Thank you. I wanted to respond to Skip a little bit in terms of our database. Our food categories actually have been in use for longer than the categorization, which I saw for the first time today from CDC. So it's very exciting that CDC is moving forward here. But we've got a fair amount of experience. Our database is really based on what people purchase and what they -- I mean when they go to the grocery store, they might be buying beef or pork or fruits or vegetables, but it's things that people know -- it's supposed to be a very common sense category.

We are hoping to make our database searchable on our website. It will be limited to the data that's published, our most recent published

database, but we are hoping to get it up and searchable in the next year. I'm looking at Freda right now. But there are -- it's a challenging project but it's one that we're really striving to achieve.

I have one comment and then I'm going to get to my question. I love the debate going on between Rob, Tim and Bob, and would suggest that it's worth a whole other meeting because the issue of animal pathogens versus human pathogens versus environmental pathogens comes up really clearly in the outbreak data. When I look at produce, which is not the subject of this meeting, 40 percent of the outbreaks in our database, whether you like the categorization or not are linked to neurovirus. About 25 percent are linked to *Salmonella* and *E. coli* as a combined category, which is just what I'm looking at. I mean I've got more animal pathogens than that, but I look at those as the two big ones in that category. And then there are environmental pathogens that we're very concerned about.

In the mean area we talked today about

*Staph aureus*, *Clostridium perfringens* and *Listeria*. Those come in often in outbreaks through environmental means and so I think that there are ways that we can start to look at broad categories because they suggest ways that we need to either address the problem in processing or address the problem in consumer and retail education.

I did a presentation at IAFP two years ago, where we broke out the food pathogen combinations by home prepared, the outbreak occurred in the home setting versus those that are prepared in the restaurant setting. And it's fascinating because they're different. The food pathogen combinations differ depending on where the outbreak occurs.

So I think that's a great topic for a meeting, and I'd like to recommend if the USDA -- this is really a rich area.

So I would like to suggest that USDA continue to really push forward on this issue of food attribution and how do we do it better.

But my question is how do we evaluate severity in the food attribution equation? One of

the big issues that the consumer groups have been grappling with is the issue of that low risk category which I put up which are largely the ready-to-eat meat products. But where the risk of illness is very high, high rate of hospitalizations, high rate of fatality. How do we evaluate that compared to the ground meat products where we have *E. coli* and *Salmonella* as the risk factors or the intact meat products? So I'm throwing open. Maybe Patty would like to start, but I'd really like your best advice on how to deal with severity.

DR. GRIFFIN: So that the sort of analysis that we presented to you today with the -- and I'd like to point out Tracy Ayers, raise your hand, Tracy, who's our point person on this data analysis is here at this meeting, but that sort of analysis that I showed you for illnesses can also be applied to hospitalizations and to deaths because we capture that information in the outbreak database. Does that answer your question?

MS. SMITH-DeWaaL: Yeah. When are you going to put that kind of data up on the -- in the --

because you may capture it in the outbreak database but it's not publicly available. Or should I FOIA it?

DR. GRIFFIN: Let's talk further about that.

MS. SMITH-DeWaaL: Okay. Thank you.

DR. HOLT: Move onto Barbara Kowalcyk.

MS. KOWALCYK: I have lots of questions and I did want to respond to a couple of comments, particularly again the exchange between Robert Buchanan, Tim and Robert Tauxe. I think that Robert Buchanan brings up a very important point. I do not want to get into the specifics of the animal reservoir versus non-animal reservoir, but you have to be very careful about the assumptions that you make. And we've heard a lot of -- robust is a term that I've heard thrown around an awful lot recently, and just for non-statisticians out there, robust is a statistical technical term that means that your model, or whatever, will hold up even under deviations from your assumptions. Okay.

So you have to be very careful about which

assumptions you make, and I think that that's the point that Bob Buchanan was trying to bring up. And that kind of leads me into this expert elicitation which has been very contentious recently especially for us consumer representatives.

The expert elicitation that was done for RBI has several significant deficiencies that we've discussed before, and I found today's presentation by Sandra Hoffman to be very interesting on expert elicitations.

The one question that seems to be popping up, I believe also in Michael Batz's presentation, is there seems to be a high correlation between, you know, when you have more outbreaks, there seems to be less difference between outbreak estimates and the expert opinion. And, of course, that then does raise the question is, is that really a confounding factor or is the outbreak data really what's driving expert opinion? Or is it a confirmation of the expert opinion? Am I making sense? And has anyone looked at that?

DR. HOFFMAN: That I'm aware of, no one has

looked at that. This is Sandra Hoffman. That I'm aware of, no one has looked at that. There are two ways of -- I'm identifying the right question. There are two ways of looking at that. Outbreaks in a sense are adding more information to the system. So to the extent that you look at differences between outbreaks and experts, as a measure of some kind of uncertainty about what's going on in the system, as you get more information, hopefully that difference is going to get smaller. That's one thing.

But the other is what is actually driving the expert opinion, and we don't have that yet. Annette O'Connor and I and others are hoping that we may get a NIH grant funded to look at that more. What we would like to do is look at the way revelation of information over a time period would affect. We'd like to resurvey people and see how different forms of information inform expert judgment, and that would give us a sense of what's happening there, but at the moment, we don't have that.

MS. KOWALCYK: Well, I think that that's a

very important research area that needs to be looked into because it gets to that underlying assumption and, of course, then it reiterates and I believe it's a point that I want to say Roger Cooke made earlier, that you need an external validation of some of the stuff so that you can actually see what's going on. I think that some of the methods that you raised in the expert elicitation, I'm not an expert elicitation expert by any means but I would hope that FSIS would look into some of the methods or at least similar methods that you employed in looking at inter-rater and intra-relater reliability type things. I think that those are excellent.

DR. BUCHANAN: I'm Bob Buchanan, FDA. One, I liked their expert elicitation. I did participate in it because they actually did try to measure the uncertainty around, made the experts figure out how confident they were of their results.

I might from just having been on several of these things, one of the issues when you get to outbreaks and why the uncertainty is associated is lower there, I've always thought a lot of it is

you're much more likely to see publications on outbreaks and your experts all read the same publications. And so after you built that up, what you're measuring is sometimes whether or not everybody is reading the same literature. And that doesn't make it wrong but that's one of the reasons there's less uncertainty.

MS. KOWALCYK: I did have a couple of other questions, and I think someone brought up the point earlier that sometimes when you have, and it may have been you, Bob Buchanan, that sometimes if you have differing opinions, that tells you just as much as if you have an agreement. And one thing that struck me just in watching all the presentations this morning, is there didn't seem to be a whole lot of research or at least by the participants here, on the outbreaks that don't have a source, or a source hasn't been identified for the outbreaks. And has anybody really been looking at that to see, one, are the number of outbreaks that don't have an identified source, is that increasing? What are you finding out from that 41, or actually more like 65, 60 percent of outbreaks

that you don't have a source, is anyone looking at what's happening in those outbreaks? And, is there any information that we can glean from that to help get us a better picture of foodborne illness attribution?

MS. SMITH-DeWaaL: I'm sure CDC can answer this, but actually the best investigation I've seen, it was done by Scripps Howard New Service, where they went in and looked at all CDC's outbreak data and they evaluated states to tell them what was being -- which states were actually missing the most information. So that was one piece of information.

MS. KOWALCYK: Well, I think this information would be use for several reasons. Just like attribution data, I mean we could probably spend all day here going through the list of things that we could use attribution data for. But, first of all, if the number of outbreaks that don't have an identified source is increasing, that would certainly boost a case for getting more funding at the local levels.

The other thing that I found interesting

and kind of a related topic, is the definition of an outbreak. I mean there seems to be, and this gets to the standardization question that Skip Seward brought up. And certainly it is helpful to have some level of standardization. I think someone earlier brought up the issue that you might lose information by standardization, and that is true. But I'm going to draw on my clinical background here. I've spent at least 10 years working in clinical research as a biostatistician, and they did finally come up with a cohesive list of adverse events. Because let me tell you, people spell headache 15 different ways, believe it or not and that's what was standardized, and all the pharmaceutical companies use that list of adverse events which I could see being very useful to develop a similar list here for food attribution.

But getting down to the definition of an outbreak, it's very different depending on who you talk to. I've heard about three or four different versions. I hear from the CDC two or more illnesses are an outbreak. Well, I can tell you from my own personal experience, my son, my husband and my

daughter all tested positive for the exact same strain of *E. coli* O157:H7. We were not declared an outbreak. And then I've heard from other people that that's because you're related. You know, if you weren't related, you would have been an outbreak. Well, I can tell you that my son ate three different hamburgers the week before he got sick. There was only one that all four of us ate. Only one of those meals did all four of us eat together.

So I think that it's important that one, we start looking at outbreaks that don't have attributable sources and also there needs to be this standardization at least on what's the definition of an outbreak since we are relying so heavily on outbreak data. And I'd love to hear what the experts have to say.

DR. JONES: I guess to your first point, I very much agree with you and I guess I can say that FoodNet actually has an outbreak working group which is looking specifically at unknown outbreaks. So outbreaks without an unknown ideology or without a known vehicle or both. I can say that an example of

dramatic improvement in that area is that the number of unknown outbreaks decreased dramatically when we finally got diagnostics for neurovirus, which for practical purposes was within the last five years, and that knocked off a huge proportion of outbreaks that we were suspicious of but could never confirm. But I agree with you, that there is a huge amount to learn about what remains and it is being worked on.

DR. HOLT: I was wondering, Barbara, do you have more questions or should we move on? I want to hopefully get through everybody. Okay. Let's move onto Michael Rybolt.

DR. RYBOLT: I just want to go back to the discussion earlier with Rob and Dr. Buchanan, thinking outside the box. Don't lock yourself into *Salmonella* may only come from a warm blooded animal because it does come from, you know, as you mentioned, almonds. And to that point, if we had some data on that, that demonstrated, you know, the serotypes that are common in those sources, I feel like with this model, with any of the models, we would capture that information a lot better and be

able to target that and have interventions in place, the poultry industry, the meat industry, you know, understand that *Salmonella* is in our animals and we need to address it. And therefore, they put interventions in place. So using that, having that information, knowing what serotypes there are that are associated with it, we can target those. That was really more of a comment than a question.

DR. GRIFFIN: To responding to that comment, and I think one of Nancy's comments earlier, and to Jenny's response, I think that, you know, Jenny's saying that perhaps industry could do more to make data on microbiologic testing available, would be a huge leap in addressing a huge data gap. We have been getting better information now from slaughterhouses, from FSIS. We have some information from cattle farms, from people who go out and do cultures. We have some idea of the prevalence of *E. coli* and *Salmonella,* certain serotypes on cattle operations.

But we have very little information in other areas, in processing plants, pathogens on

products, pathogens in plants. We just have very, very little information. And it's striking because some of the best microbiology in the United States is done in those plants by some of the best microbiologists in this country, and that information is lost for public health purposes. And it's a shame because I think it would be messy information. It would be, you know, a big job to figure out how to organize it and how to make sense of it with respect to human illness, but I think it would be very helpful.

An example that fits into the question of an emerging pathogen, is we have a serotype of *Salmonella* called Newport that we referred to recently as an emerging pathogen because this particular -- some of this particular strain, about a quarter of them, are highly resistant, in fact, resistant to anything that you would give a child who had meningitis. So this is a pretty bad emerging pathogen. And we know it's present on certain animal farms.

And as far as industry information that

people were asking about, we know that the presence of organisms like this is related to the use of antibiotics in animals. We have no information on how much of any antibiotic is used in any food animal in the United States.

DR. BUCHANAN: Bob Buchanan, FDA. I think this whole issue of reservoirs, and is one that is a developing science. And what we can't get trapped into is assuming those reservoirs have always been the same. Caroline and I have been talking for 10 plus years about *Shigella*, and the current wisdom is that *Shigella* has two reservoirs, higher primates or humans, except we see it when we do surveys of things like produce coming across the border. We find it at a rate, in one survey, as high as two percent of the samples were positive for *Shigella*, and I just figure out how you would get that high based on what we consider the traditional reservoirs for this organism. And coupling that with the expert knowledge that I have that the methods for isolating *Shigella* in culture positive cases are really terrible for most food. I've got to ask myself, is

there a reservoir out there, and is that what's accounting for the foodborne outbreaks. But we need to be able to go out and look for those things and, you know, sometimes it's tough. Field work is the hardest type of microbiology to do. Getting out on a farm and trying to track it down is really tough, and I will say, you know, the spinach outbreak, that was a great example of what can be done. We pulled an awful lot of resources in to get that done and done quickly thanks to CDC and California and FDA.

DR. HOLT: Okay. This is Kristin Holt. I'm going to go ahead and draw this wonderful discussion to a conclusion but I want to give a round of applause to not only our esteemed colleagues throwing out the questions, but the people who had to answer the questions did a great job, too. So we'll take a break and come back at 3:00. Thank you.

(Applause.)

(Off the record.)

(On the record.)

DR. HOLT: We're going to go ahead and get started, if everybody could take their seat please.

I'm going to open up a session here that we have, where do we go from here? And to lead off that session, is Dr. Daniel Engeljohn from the Food Safety and Inspection Service, to talk about FSIS next steps.

DR. ENGELJOHN: Thank you very much, and I'm delighted to be here and to share with you where we, as an agency, think we're going in terms of the information that we put together thus far particularly with our regulatory program and how we want to make some modifications to it.

I'll talk about our goals. Our goals are to use the current science to move us beyond the HACCP pathogen reduction regulation expectation, which in 1995, we said that while FSIS cannot quantify the reduction in disease incidents, which will occur with specific interim reductions in bacterial contamination of raw products, simply reducing the percentage of products containing the pathogen should result in a reduction of disease incidence.

We're beyond that point now to where we can

actually make some measurements, and that's what I want to talk about in my presentation today.

In addition, we want to expand the use of risk assessments to inform risk management strategies and to insure that we're collecting relevant and representative regulatory data. The vision that we have for this is to allocate FSIS inspection resources among and within establishments based on attributable public health risks. This would insure that all risk-based inspection algorithms that we use are scientifically based, they're objective and assessed, such as through sensitivity analyses in order for us to be able to determine what matters and how much does it matter in terms of making modifications, to identify the establishment characteristics and inspection activities that are best attributed to reducing the risk of foodborne illness. And we want to insure that risk-based activities are effective in protecting public health.

Well, how do we want to do this? I'll give you some examples of how we think our current public health driven programs are actually achieving the

goals that we set out and the vision that we put forward.

We have three programs that we have risk-based verification testing, designed to insure that we can actually measure the effect of our program in terms of how we've constructed our regulatory testing and how we conduct our inspection activities. The first being our risk-based inspection program for *Listeria monocytogenes* in which we sample high risk as well as medium risk and low risk products as well as all ready-to-eat products in a very risk based structured manner in which we use a risk assessment to inform us how to pull those samples. We initiated this in 2005. We've set a goal of insuring that we don't exceed a percent positive rate in our regulatory samples of 0.65 percent and we monitor that rate from one quarter to the next, to see whether or not we have an increase or decrease in the percent positives. And then we have correlated that percent positive rate with the public health goals that we have as a nation which are contained in the Healthy People 2010.

For *Listeria monocytogenes*, FSIS adopted the change that was put in place to achieve that goal in 2005. Although we did not meet it, we still have designated our program to insure that we are constructively and purposefully trying to achieve the goal that we set out.

For *Salmonella* verification sampling, this would be for our raw products program, and this in particular is related to what we want to achieve with our broiler testing program. This would be for all of our commodities but because we've had a persistent rise in the percent positives in broilers for the last three years, the Agency issued an initiative to purposefully drive down the percent positives in raw broilers. Our goal is to get 90 percent of the establishments which we have in our sampling program, and this represents nearly 99 percent of the production of poultry in this country, is contained within that sampling program, and we want to get those into Category 1 by the year 2001. And I'm going to present you some information that shows how we can monitor whether or not this has an impact on

public health.

And in our *E. coli* O157:H7 program in which we recently added beef manufacturing trim to that program, and we intend to expand that to include all raw components that are used to make raw beef. And this would be a risk-based program in which we're purposefully targeting sampling in a more structured way than we do now, and with that, we have a 0.2 percent positive rate that we monitor each quarter. And we have as well tied this to the Healthy People 2010 goals, which are related to human infections, but it's our best proxy for measuring how well our program is doing.

We look at program effectiveness. This would be something we would do with any program in which we make changes to see whether or not we're having the intended effect. Again, as I said, we want to get 90 percent of our establishments, in this case, broiler establishments, into category 1, which would be at or less than half the standard that we put in place back in 1996 when the HACCP pathogen reduction regulation went into place.

In order to achieve this, by the year 2010, at least six establishments would have to be added to the category 1 status every three months, every quarter, and so I've laid out for you a pictorial as to how we would move establishments along quarter by quarter in order to meet that 90 percent target by the year 2010.

But that's not enough. Just putting them into this category doesn't tell us much about the program. And so we've used the risk assessment to be able to make some determinations about what effect this has. So we predicted the public health benefits associated with this particular initiative. This would be real data. This is for the year 2007 going forward with the baseline being in this case at the end of calendar year 2006. And so from this slide you can see that the percent positive rate for broilers was at roughly 46 -- between 46 and 49 percent, and by the end of the year, we want to get that up to nearly 56 percent of the establishments into category 1.

If we were to do that, using the risk

assessment, we would predict that there would be a reduction in human illness associated with *Salmonella* from broiler carcasses moving from roughly, in this case, moving down from the 100 percent where we would start the calendar year down to just below 94 percent. So between a 6 and 7 percent decrease in risk associated with *Salmonella* if, in fact, we achieve the goal that we have in place for broilers. And at this time, we're on track with meeting those goals.

Another program we put in place in which we've directly tied a risk assessment to measuring public health benefit is our *Listeria monocytogenes* program in high risk ready-to-eat products. We asked the question which ready-to-eat foods pose the greatest risk of listeriosis. With FDA and FSIS, a quantitative assessment was done on the relative risk of a variety of products and in that, it showed that the highest predicted cases of listeriosis per serving in the total population would be the deli meat category.

So it gave us a perception in terms of what

products are actually causing illness, and in the annual perspective as well as on a per serving basis. And then with that, we asked the question, now that we know which products contribute to human illness, then what do we as an inspection agency need to do to mitigate that risk. Where can we apply a mitigation in the form of a regulatory action that would have the intended positive effect on public health?

With that then we modeled various mitigations in terms of things that we could require the establishments to do in order to control *Listeria* in the higher risk ready-to-eat products. In this case, we identified three different alternative approaches that establishments could adopt in whatever practical means that they had, and then we identified the relative risk reduction that would occur depending on which alternative the establishment chose.

You can see from this graph that sampling and sanitation presents little benefit alone, whereas applying a growth inhibitor or post-lethality treatment adds additional benefit, and the

combination of both has a significant impact in terms of reducing the risk.

With that then, we also set aside a number of our tests that we perform on a monthly basis. In this case, we allocate 800 samples every month towards testing the high-risk products that we regulate. And in order to know how we should allocate those samples, we run that through an algorithm that we have designed in the risk assessment, to identify how should we allocate the samples amongst the higher risk products, and this would supplement our random program that we have for all ready-to-eat products. So this graph would show how the risk assessment model based on the information that we've inputted, and this would be information about production volume, about the effectiveness of the food safety system, about the interventions being used and the alternative selected, to give us a perception in terms of how many samples we should allocate for each product category.

With that then, we plugged this information

into a risk assessment to predict what the effect our program, in terms of a risk-based program would have on public health. From this then, using the pre-regulation estimate of how many deaths occur as a consequence of *Listeria* in the products that we regulate, this being the ready-to-eat meat or poultry products, in which we estimated approximately 286 deaths per year prior to the implementation of a regulation. Then by implementing this risk-based verification testing program and the inspection activities that occurred in those operations, we predicted that we are saving at least 118 lives as a consequence of adopting the mitigations that we have in this rule.

This incorporates 800 samples that are specifically targeted at the higher risk products each month. It also incorporates quantitatively factors that we have identified for each establishment that we think affects risk. And then we've looked at those risk factors to see how much impact that they have. And we designed this program in order to assume that the adulterated product is

being removed from commerce.

So that's how we make a determination about the effectiveness of this program.

That's two examples of what we've done in terms of having in place risk-based programs already driving how we conduct our inspection activity and allocate our resources.

But where do we want to go? Well, we know that we can't continue to look at one pathogen, one product at a time, and have an effect in our overall inspection system. We really need to be looking at a more broad-based, global risk assessment model, and we're looking at attribution among all regulated establishments, the contribution of what they make to the impact on public health.

We need to be looking at multiple microbial hazards, in this case *Campylobacter, E. coli* O157:H7, *Listeria monocytogenes* and *Salmonella.* And then to pursue enhanced serotype information, subtype information in genomic and another attributable public health linkages in order to better ascertain what impact our products are having in terms of

exposure to the public for various pathogens and contributions to illness.

And then we have the products that we regulate. We regulate an intermediary stage between the farm and between retail and consumption, which means that we only have an impact on certain forms of the products. This is where we look at what the commodity is. You heard a variety of discussions this morning on how we try to relate the CDC data to the products that we regulate. We look mostly at beef, pork and poultry, and within poultry, we look at turkey and chicken differently. We haven't focused a great deal on the minor species that we regulate, but this is also an area contribution, and that's an area where we need to expand our focus.

We also need to look more intensely at our raw, ready-to-eat categories, and in this case, for those of you who know our system, our HACCP regulations require that each establishment identify a HACCP plan for nine categories of products. This would be nine processes within HACCP regulatory requirements.

Our expert elicitation identified 24 in which we further breakdown those 9 categories going from the species down to the various products into the forms that we regulate and could potentially, through a risk assessment, be able to model where inspection activities should occur more frequently or less frequently and whether or not they would have an impact in terms of the sanitation or performance of the establishment on their likely contribution to human health.

So this information is what we would plug into a risk assessment to model.

We also are looking at intact versus non-intact because we know that the way the product is processed makes a difference. We've traditionally just looked at the entire carcass or at the boneless trim that's going into ground beef or into ground poultry. But in terms of where we need to be looking, we also need to be looking at the parts and other forms of the product that are prepared in inspected establishments that may be consumed in the form that they're sold in out of the establishments

or that may contribute to the production of other foods at retail or in the home.

And then we need to better associate inspection findings with pathogen control. All this we would do through inputting information into a risk assessment to model and predict what we think the contribution would be in terms of impact on public health.

We need to do this in a timely manner as well as have continuous baseline studies to measure national changes. This is something that we committed to in the HACCP regulation. We are just now instituting a new poultry baseline that will begin in a matter of weeks, not months. And t his will tell us what has happened in terms of poultry for the pathogens that are on carcasses as well at two points in the operation, still looking at *Salmonella, Campylobacter* and other indicator organisms, to let us know what changes occurred since we originally did those baseline studies prior to HACCP implementation.

And our intention would be to use that new

baseline information to make determinations about whether or not the performance standards or the guidelines that we put in place need to be adjusted and probably lowered. In case that should happen, then the category 1 criteria would change for the establishments over what they are today.

In any case, we need to be looking differently at what we are concerned about. We need to look at the opportunity to look at a greater variety of pathogens, particularly emerging ones, so that we have an idea of the background of the types of pathogens that are on the products that we regulate and their potential to contribute to adverse public health outcomes.

So with that, what do we need? Well, what we really need to do is to continue having ongoing communication with all of our stakeholders, state and local partners, in order to have a shared understanding about attribution and what each of us contribute to that puzzle. And as I had said what we regulate is at an intermediary stage. The state programs regulate at the same stage that we do, as

well as regulate at retain.

We have jurisdiction to look at retail, and what we would need to know through data that would be collected and through the attribution information from CDC and elsewhere, whether or not it would be a fruitful exercise for us to shift our activities outside of the plant, and I would say that that would be something that would occur presumably once we are sure that we have operations within the Federal system well under control. In any case, we need to put our inspection resources where they have the best impact on public health.

And all this needs to be done with a purposeful and timely closure of the gaps associated with attribution and how it's used by the various stakeholders.

And with that, I thank you, and looking forward to the discussion.

(Applause.)

DR. HOLT: Thank you, Dan. Now I'd like to move onto public discussion on next steps, and before we jump into the discussion though, I'd like to go

back and recap Dr. Raymond's charge to us. And Dr. Raymond asked us to focus much of the discussion on the existing data gaps that we face on trying to make practical use of the current attribution data available, and that's probably also essential to the two questions that you see on your agenda.

I know people may be on the phone, and I'd like to open up the phone line for a question there or a comment or a viewpoint. Anyone on the audio bridge have a question or a comment?

(No response.)

DR. HOLT: I'll move back to the room. I think there were a few burning questions the last round and they may not have gotten answered or asked. So if anybody would like to get up to the microphone pose a question or a comment, go ahead.

MR. DEERFIELD: I'm Kerry Deerfield with FSIS and I did want to say something about some of the things that were discussed in the last session, but I think actually it is applicable to what we might want to do sort of in the future here.

I just want to hammer the point that Sandy

Hoffman made here by sort of respinning I guess the question that you asked, Barbara, about, you know, what are some of the things that we could do to help maybe get more information, better data, for attribution type of stuff. And I put the question around is like why aren't we using risk assessment more in the food safety world?

I do come from a heavy chemical background where that is like one of the primary ways that they look at, predicting instances of, not illness, but adverse effects in humans. And there are so many methodologies and tools out of the risk assessment community that could be used in food safety, which I have seen used a very limited amount. You just heard Dan Engeljohn talk about some of the risk-based sampling programs which I think shows a powerful, you know, contribution that risk assessment can use towards some of the things in food safety but there are lots of other things in the risk assessment world that can be used.

For example, why aren't we using animal models more? We could be talking about those

response relations. From there, compare that to the epidemiology data and start figuring out how we can extrapolate that information and then we can start gathering a lot more information about exposures to pathogens that you can't get from human epidemiological studies, the outbreak data. So start filling in a lot of these data gaps.

Another thing you might be able to think about doing is what are the new technologies that are coming down the pike that are just not being utilized I think very well. For example, genomic space technologies, the molecular things, we're just not getting into them very well. We're only scratching the surface with PFG patterns. We're only scratching the surface and looking at just serotypes. There is so much more information if we go into the whole genomic. You look at the -- all of these things can be used to characterize these things, not just the bugs themselves but the host. We had a question earlier about why aren't we using seriological types of things, you know, in looking at these attribution types of studies.

With these genomic type of things, you can look at the host reactions, take a page out of the toxicogenomics world where they look at systems biology and how a human being is responding to a stressor. These are things that can be used again to fill in data gaps among all these types of stuff.

And just one last, I have to put this comment in, coming from a pure risk assessment world, we're mangling our terms about risk here. We're not talking about inherent risk. We're actually talking about inherent hazard. Risk is something different, and I think we've been mangling these terms a lot this morning.

DR. HOLT: Thank you for the comment. Would anyone like to follow up or respond?

(No response.)

DR. HOLT: Well, we've heard a little discussion today about common nomenclature, and categorizing foods in different ways. I think maybe some of the meat of this discussion here is to throw out ideas about how we could move forward with some of these things that we came up with today, noting

common nomenclature is one, resources at the local level, outbreak cases versus sporadic cases, reservoir issues, that's one of my favorites, risk assessment top down or bottom up approaches or is it the other way around? Anybody have any other comments? We had some discussion earlier that might have cut someone off. If you wouldn't mind, identify yourself.

MR. REINHART: Bob Reinhart, Sara Lee Corporation. First I want to comment to all of the speakers and presenters that the information provided on attribution, food attribution was outstanding. And I'm pleasantly surprised. I normally wouldn't say something like that. I'm pleasantly surprised with what we did have and what we were able to go over and what was put up. And I know sometimes when things are being developed up, it's difficult to put it out in a public forum but a decision was made to do that and it's really appreciated. I think it drives to better results.

And the next comment I have is related to the future and the future steps, and I'm glad we're

looking to go forward with this and continue. And I have a recommendation that everyone could consider and that would be that the three agencies or four, depending on how you want to divide it up, develop a task force that works on food attribution continuously to look at how they can drive filling the data gaps, defining common protocols, bringing data together that exists out there, in all these different entities, either in government agencies or in the private sector in some format.

If that did happen, and they were able to identify specific gaps, well, then, yes, potentially that gap could be filled by industry data as an example, that gag could be filled by research, that's done and prioritized in the academic world. So I would recommend that it's considered and one of the agencies to lead that, but I think that would be a good way to continue this and to continue moving forward in a format that gets defined out. Thank you.

DR. HOLT: Thank you.

UNIDENTIFIED SPEAKER: We do have a comment

from the phone line if you'd like to take it.

DR. HOLT: Can you hold the phone question in queue please.

UNIDENTIFIED SPEAKER: And we'll come right back to the phone. Thank you.

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation of America. In his presentation today, Chris Waldrop noted that there were several reports that FSIS has reported to the Appropriations Committee or listed in public reports that would be ready, some of them get moved back every year. But the FoodNet project with the University of Minnesota, most recent date was July 2006, it was supposed to be ready, CDC point-of-consumption attribution study, June 2006; mathematical modeling project with FoodNet partners, May 2006. Are any of those finished?

DR. HOLT: I think we may have people that can talk about the status on those. At least for two of those, three that you mentioned, we did have presentations on those today. Dr. Guo, would you like to respond on the Danish modeling adaptation?

DR. GUO: This is Chuanfa Guo, FSIS. Under the -- we do have started Danish Model more than two years ago. That is I think the so-called mathematical model you referred to, our project. That is my guess, and also the University of Minnesota's project has been a pre-exploratory study of this project as a result continues to the current result. So all of this is related. So we have finished -- last year. We have continued to work, since last year continued to work. We presented that at a meeting of Society for -- and also presented it at FoodNet recent meeting and today we give another presentation, the same project. I think all of the project you mentioned is related. Maybe people give different names I think. That is my answer.

MS. TUCKER-FOREMAN: Can you tell me when it will be published so that the public, I have your presentation from today, but we would like to have the narrative of this and if it would be possible and I assume that the point-of-consumption project is one -- is that the one you were talking about Dr. Griffin? The point of consumption and you told

me while we were just chatting but when do you expect it to be ready?

DR. GRIFFIN: I'm very hesitant to give a date on a project for which we're still in a very early stage. So we don't have a date. Some of the steps that are needed are to finish the analysis, make charts and graphs, and then actually write the report. It'll go through scientific review both at CDC and at a peer review journal because I think it's very important to us and to the scientific community at large and to the regulators, to industry and to consumers, that this report which would be, we hope, "excellent but not perfect," be the best science that it can be and be science based. And it will then be reported in the Medical Journal.

We're hoping that our process at CDC will be done by the end of this year, but it really depends on a lot of factors that I can't predict right now. So we're not setting a date.

MS. TUCKER-FOREMAN: If I could just, thank you, just finish on that. All of these are studies that FSIS has said it is relying on in developing a

risk-based inspection system or they are referenced with regard to the development of a risk-based inspection system. I'm not sure what role they're playing in the development of the risk-based inspection system since some of them aren't completed and others -- well, since most of them aren't completed. Can you tell me, Dan, what role they're playing? For example, in the expert elicitation or in the development of your risk ranking by product.

DR. ENGELJOHN: This is Dan Engeljohn with FSIS. Well, I would respond by the fact that we have a number of risk assessments under development, which for them, it's taking the best available information that we have along with the information FSIS has from its regulatory testing program, and using our modeling techniques to make predictions. And so it serves as whatever information has been published is what we rely upon when we get things peer reviewed. So we would -- for those risk assessments, there is a peer review process for that.

In terms of for the risk-based inspection process and the expert elicitation and all those

other facts, as I tried to point out in the presentation that I had, would be that we would take information, the best available information that we have and put those into a risk assessment and try to model those factors as well to make predictions, and then that serves as the basis for which we could move forward.

MS. TUCKER-FOREMAN: And then the allocation of inspectors according to risk will not rely on the risk ranking that you currently have given out to us?

DR. ENGELJOHN: I think it's fair to say that everything that we have put together in terms of the risk-based inspection system that we've made available to the public thus far and that you've reviewed or at least had access to and have commented on, serves as pieces of information that inform others. And so nothing in and of itself serves as the sole determinant. They serve as pieces of information that can be modeled. We can look through if we, in fact, incorporate these in through risk assessments which would be the intent to wherever we

can incorporate that data, model that, do uncertainty or sensitivity analysis to see what has an effect on what, and then make judgments about how those things would work and how they could be applied.

MS. TUCKER-FOREMAN: Between now and July?

DR. ENGELJOHN: Because those kind of things are undergoing constantly in terms of the how we can continue to look, we've been using risk assessments now for quite sometime. They're actually required in the Department of Agriculture for any activity that we do which relates to public health. And so we use them constantly as means to inform us.

MS. TUCKER-FOREMAN: And you'll publish this more, this rounded out list ranking before you go forward?

DR. ENGELJOHN: I'm sorry. Are you referring to the second elicitation?

MS. TUCKER-FOREMAN: No, I have a document here that's a risk ranking and in each meeting we've had, that has been referred to as the risk ranking by inherent product risk that the Agency's using to decide how to allocate inspection. You've just said

it's only -- I think that it's only one piece, and I hope the 2005 one is a very small piece.

DR. ENGELJOHN: It serves as a small piece in terms of it informs us about what impact it may have, and then as our intention would be as we move forward, and we had identified is that our intention is to continuously update the science, get new information and better information and each time make determinations about how that would impact.

MS. TUCKER-FOREMAN: But in July, when you start this, what's the list you're going to use in July?

DR. ENGELJOHN: Again, we have two that we have -- one has been done and one that we're working on now, and both those together, if they present the same information or different, will be the source of I believe a public meeting that we intended to have on the issue to talk about how to use the --

MS. TUCKER-FOREMAN: Then what about the risk assessments? I'm sorry. It's just that you've got a date of July to get this done, and I'm trying to figure out which list is going to be used to say

this plant gets less inspection and that plant gets more.

DR. ENGELJOHN: And I think the intention was to provide the information from the first and the second, and identify differences there and talk about that in the next public meeting.

MS. TUCKER-FOREMAN: But it is not the risk assessments that you were describing. It's just these things?

DR. ENGELJOHN: Yes, the risk assessment I was talking about in my presentation related to how we can take all of this and put it into a more refined, more structured process to model and predict.

MS. TUCKER-FOREMAN: But that won't be what you base inspection on in the risk-based inspection program that starts in July?

DR. ENGELJOHN: Yeah, that would be on our current system, and the decisions we've made thus far.

MS. TUCKER-FOREMAN: Thank you.

DR. HOLT: I'd like to move to a question

on the phone bridge please. If you could state your name and your affiliation please.

UNIDENTIFIED SPEAKER: Yes, we do have a couple of questions on the phone line. Felicia Nestor, your line is open. Please state your affiliation.

MS. NESTOR: Thank you. This is Felicia Nestor, Food and Water Watch. I want to follow up on a question that Nancy asked and it sounds like the question that Carol was just asking. Nancy asked how the information about emerging pathogens was going to be incorporated into the RBI program, and I think what I would mean by that is, how is the Agency going to use attribution data in the algorithm? Now at the last meeting, the Agency said that you're going to be updating the plant list on a monthly basis. So what is your plan for how often to update the product inherent risk and is there an alternate plan, for instance, if there's some outbreak or there's good information about an emerging pathogen? Will the Agency then do another product inherent ranking? That's my question.

DR. RAYMOND: Felicia, Dr. Raymond, OFS. You were breaking up quite a bit on the call there. I think I have the gist of your question, however, and that is how often will we do an inherent risk product analysis? How will we merge emerging pathogens into the list of products that we currently have? And how will we use attribution data in the risk-based program? Is that --

MS. NESTOR: Yes, exactly.

DR. RAYMOND: Good. First of all, since we don't have attribution data that we can live and die by right now, or enough foodborne illnesses, attribution data will not be a single solitary factor going into risk-based inspection. There is a point in time, hopefully that we can change that and use the attribution data better. Right now we're counting on the 24 experts that will be doing the expert elicitation to use what attribution data is available along with what sampling data is available along with data we saw today that had comments about how many hospitalizations for different bugs, how many deaths for different organisms, et cetera.

Hopefully they'll take that into consideration, the severity of illness and special populations as we've heard need to be in that expert elicitation. So attribution will blend into that but it won't have a single point in the mathematical equation.

As far as new organisms that may or may not be emerging organisms in the foodborne illness world, again, a single organism is not a factor into this. What is factored into this is the risk of the product. We have certain organisms associated with certain products. And so ground beef, for instance, the risk of ground beef will be scored based on the organisms that are found in ground beef, the severity of illnesses created by those organisms and the frequency of illnesses created by those organisms. If a new organism pops up tomorrow, in ground beef and it's universal, and a lot of people are getting sick, we'll obviously have to do an immediate reevaluation. If a new serotype of *Salmonella* pops up, that causes the same types of infections as *Salmonella* Typhimurium, it won't be a factor because it will still be found in the same products. I hope

that answers your question.

MS. NESTOR: Thank you.

DR. HOLT: This is Kristin Holt, the Moderator. Let me get one more question from the phone bridge please, and then I'll go to the microphones here.

UNIDENTIFIED SPEAKER: We have a question from Patricia Buck. Your line is open.

MS. BUCK: Hello. This is Patricia Buck form the Center for Foodborne Illness, Research and Prevention. And my question is we have meetings coming up that's going to talk about industry and the sharing of data which I appreciate very much especially if it's going to be conducted, you know, as high quality as this meeting was. But one of the things that I would like to know about, when they talk about in the sharing of data, are we talking about the sharing of microbiological data? Are we talking about the sharing of antibiotic use in the animals type of data? Are we talking about the distribution risks that are currently proprietary to help us track back, you know, when these cases of

foodborne illnesses are identified? Could you give us or characterize for us a little bit more what you mean when you say it will be helpful if industry would share its data?

DR. RAYMOND: Pat, Dr. Raymond again, and I think it was your second question, I'd say yes. I'd have to say no to your first and third, but to make sure I have them in the right order. Industry has a wealth of data, microbiological testing primarily, and as someone else said earlier today, they have some of the best microbiologists and scientists in the country doing that work for them because of the pride they take in their product and obviously do not want people becoming ill from their product.

That is data that I would love to mind, and that is why we're going to have a separate conference on it --

MS. BUCK: Yes.

DR. RAYMOND: -- because it's very controversial. There are some in the industry who would love to share that data with us, particularly if there's some kind of incentive or reward in the

risk-based inspection system. There are others in the industry who quite frankly probably don't want that information to ever be made public. We need to figure out how to get around those issues and is it identifiable by plant? Is it aggregate? There's may things that we talked about last Friday in my office, in fact, when you were I think on the line that day but -- so I'm looking forward to a real healthy exchange of ideas on how we can use industry data.

Everybody in this room I think would tell me, Raymond, if you had better data, we'd be even more in line with you. Well, there's data out there. We can get better data if we can figure out a way to do that.

Your other question, proprietary list, that has nothing to do with risk-based inspection. It does have to do with recalls, and you know we're working on rules and regs for that. So I'll just say that for now.

And antibiotic use in animals is basically either an on farm or in the grow out facility issue, and it's not an issue in the plants that we regulate.

MS. BUCK: Well, again, I realize that it's not an issue in the plants in which you regulate but, of course, you do have the consequences of some of the problems that CDC pointed out, in some of its presentations, that there are, you know, *Salmonella* super 9 (ph.) is in our midst now, and it's very disturbing that we can't get to that type of thing through our regulatory agencies.

DR. RAYMOND: But, Pat, that is, that is a question for a different meeting and perhaps even a different agency than FSIS. Dr. Buchanan is sitting down here kind of cringing because it should actually be a FDA issue, but what we do know is we know bugs, like the antibiotic resistant *Salmonella*, that will enter into our risk-based formula because some of those bugs are very nasty bugs and that will present a higher risk, the seriousness of infection is going to be factored in with this elicitation. And so therefore the results of antibiotic use will be factored into the RBI.

MS. BUCK: Okay.

DR. RAYMOND: But I can't regulate on-farm

practices.

MS. BUCK: I understand that. I just brought it up as an issue because I feel that it's a very important issue that we haven't paid as much attention to as we should be.

And finally, I do have this comment. I realize that all this testimony will be made public for all of us to review and make comments on in 30 days plus all the comments, all the testimony from, you know, Monday's meeting, and the comments are also available in 30 days. I am very concerned that the timeline that we have put currently in place, which is now July implementation, of RBI is not going to allow all of the stakeholders with their, you know, jointed amount of expertise to make the type of comments that will really help you to devise that best prototype, and I would seriously hope that you would consider, you know, taking some additional time and moving back once again the implementation of risk-based inspection. I realize that that's something that you can say right now, but I'm hoping that you are thinking about that, given the fact that

everybody in this room has devoted an awful lot of time and energy today and as well, in the future, to try and provide you with the best guidelines for your new initiative.

DR. RAYMOND: Your comment has been noted, but I am going to -- we have 40 minutes left. I am going to take the microphone from Kristin here for one second and ask that the last 40 minutes we do concentrate our conversation on how we can move forward to get better attribution by working together. We have guests here from Atlanta. We have guests from the FDA area. We have the Tennessee gentleman here. We have lots of folks who have traveled a long ways today to talk about how do we get better attribution data. So I would ask the folks in the room and on the phone to try to focus on that for the time being.

MS. BUCK: Thank you.

DR. HOLT: I'm going to switch from the audio bridge to the room, and I believe Caroline Smith-DeWaal has been kind of standing and sitting. So I'll go to her.

MS. SMITH-DeWaaL: Thanks. I sat down during the phone portion. I think that what's really come out strongly for me today is that the value of the food attribution data really is in the validation of the expert elicitation. The data is not robust enough to use by itself, but I'm always looking for low hanging fruit. I'm always looking for what could we do quickly to improve that data, to make it better? And I'd like to suggest that reducing the unknowns from the state investigations would really give us a lot more data, and it would help to identify and isolate where the emerging pathogens may be coming in because right now we don't know if those unknowns are existing pathogens that just haven't been tested for because of weaknesses in the laboratory system or if those are, in fact, true unknown pathogens that we need to understand that may be entirely new.

So I think if we wanted to improve things quickly, there is a rich data source that's available that is partially investigated outbreaks at the state level, and if we could get those investigated more

quickly. I don't know if there's money in the FERN System, the Federal Emergency Response Network System, to go to the state laboratories for this purpose. You know, let's be creative and try to find a way to do that because that would improve that data right away.

Secondly, is the product testing data. I think that is critically important and whether it's collected by industry, whether it's collected by FSIS under their *Salmonella* testing program, their *E. coli* testing program and their *Listeria* testing program, and maybe a few others I haven't thought of, I think the product testing data is critical again to validate the expert opinion that you will probably be using for risk ranking.

So the key here is to reduce the unknowns and to get the best data possible, but I think it's going to be hard, and I know this data well. I have waited for CDC to get their data out to put our data together. And so I know this outbreak data set very, very well, and I just -- I told Carol Foreman and Barb Kowalcyk and many in our lengthy discussions on

this, the expert elicitation is an appropriate tool to use in areas where the data just isn't good enough to give you what you want to know. I mean you can't test, and I agree with the statement's earlier that if you can test the, you know, if you can test the question empirically it will give you a better expert elicitation but I think you can't avoid using expert elicitations to answer this particular question. Thank you.

DR. HOLT: Thank you.

MS. KOWALCYK: Barbara Kowalcyk, Center for Foodborne Illness, Research and Prevention. I actually had a different comment, but I'd like to respond to Caroline's first.

First of all, I do think the expert elicitation is an appropriate tool that should be used under the right situations. I think that the methodology that FSIS used in the first expert elicitation was significantly flawed and I think that there is a lot of other methodology out there and just one example of which is what Sandra Hoffman presented today, and these are things FSIS should be

strongly considering.

However, and I think the message was perfectly clear from almost every presenter here today, the expert elicitation is not the only thing we should be using. It should be a starting point to help identify the gaps that are in the system. What attribution data do we still need?

And the question that I would like to propose -- I mean I'd also like to first comment on Dr. Raymond's comment earlier, that I hope that the goal is that one day attribution data will be a large component of RBI, and I would like to see us move towards that model. And how are we going to get there?

So my question, I really have a question for the different agencies, both Federal and state that are here today. What specifically do you need that will better enable you to collect the type of food attribution data that we need to get an accurate picture of what is happening with foodborne illness? Do you need more resources financially and human resources? Do you need better regulatory

authorities? What exactly do you need in order to achieve this?

DR. RAYMOND: Dr. Raymond with the Office of Food Safety. Just speaking from my own personal viewpoint and not trying to speak for the other agencies, of course, but I think in my viewpoint, the one thing, there's probably lots of things we need, but the one thing that would be of the most benefit to all of us, to get better attribution is better collection of samples in ill patients and better reporting and quicker reporting from state and locals to coordinate with CDC, FDA and FSIS. When there's an outbreak, we ask them not to wait until they feel they found the source before they let us know, because if they find out it's ground beef, the trail is pretty cold for us to trace back and find out where it came from.

So I think we can all do a better job, but we've also been preaching to the healthcare professionals. I am one. I practiced medicine a long time. I didn't get stool cultures on every person that came in with the diarrhea because it was

probably going to be a virus. But somewhere along the line we need to look at, how do we obtain better sampling so we will get a better idea of what the actual rate of foodborne illnesses are? And again, if we now have an outbreak of three instead of a single isolate case of one, perhaps, perhaps that helps the epidemiologist figure out what the source of that one was.

So I know it's not being done much, and I'm not pointing the finger at the healthcare professionals because as I said, I did not do it every time either. If it was going to cost my patient $150 of hard earned cash to say you've got a virus, drink Gatorade and, you know, call me tomorrow, if the symptoms are worsening, it is just not cost effective. But somehow we have to figure out how to get better data.

I am appalled sometimes when I hear stories about people that are in the hospital with bad enough gastrointestinal symptoms to be required being in the hospital. I can't imagine why someone would not get a culture cooking on that one, because if you wait

until they get sicker, you wasted a day and we're working with the healthcare professionals trying to get some middle of the road there.

I'll let CDC and FDA if they want to comment on what they need. That's my major.

DR. JONES: This is Tim Jones, and I grabbed the microphone as you were walking up there essentially to say the same thing, and address that comment and Caroline's as well.

Caroline, you made the statement that we need to be creative, and I'm all for bolstering laboratory resources. You talked about FERN, money going to laboratories. But I don't think that's where the primary lesion is. You know, as Dr. Griffin said earlier, for the unknown outbreak, two-thirds of our outbreaks are unknown and in over two-thirds of the unknown ones, we do not collect a single stool specimen. And you can put all the money you want into a laboratory but if they have no specimens to test, it's not going to help. And what that's going to require is epidemiologists at the county level that can go out and get the stools, and

get them from providers and at state level test them for free. It's a matter of collecting them. And that requires people in the field.

DR. HOLT: Barbara, you have a quick follow up?

MS. KOWALCYK: Yeah. I have a question. I mean I agree with both what Dr. Raymond said and what Tim said. So is it just a matter of getting more money or do you actually need some additional regulatory authorities to fix the problem? Which one is it or is it both?

DR. HOLT: Dr. Griffin, you were going to make a comment.

DR. GRIFFIN: I wasn't going to answer that question.

DR. HOLT: Oh, well, I mean --

DR. GRIFFIN: I was just going to, you know, I like sometimes to offer the contrarian viewpoint and everyone's moaning, these unknown outbreaks. And just a little bit of a contrarian side. Unknown ideology is a shame, and we've talked about how to fix that with local health departments

having the resources to go out and get the specimens, and I've talked to some people here about how we'd love our eFORS program to be more interactive, so the local health department can plug in, you know, a 100 people at a banquet, got sick within 12 hours of eating a food. What's the differential diagnosis? It includes *Clostridium perfringens*. Oh, get stool samples and test them for this organism which is not done in a clinical lab. All the stool cultures that they send to the doctors are going to be negative. You have to have the state lab look. So that's an interactive program that we hope will help us to figure out the ideology.

As far as the unknown vehicle, we're always going to have a percent of outbreaks for which we don't figure out a food, and I would not look at that as failure because local health departments are going to go out and they'll investigate outbreaks in which only five people are ill. It is really hard to figure out the cause if only five people are ill. A lot of times they all ate the same meal, and it had several different foods in it.

So one of the markers of them going out and investigating more outbreaks is that they're going to find smaller outbreaks for which it's impossible to figure out what the food was, but that's a marker of them going out and investigating more outbreaks. In fact, we've tracked that for *E. coli* O157:H7 outbreaks. Our average size 10, 15 years ago, was very large. Now that median size of those outbreaks is five people. We don't always figure out the cause but because those local health departments have gone out and they've found the outbreak and they've looked into the organism, and they often send a message over the list serve (ph.) to other people in the health departments. We have five people. We can't figure out the cause. They all ate at Restaurant X. Next day, they get an e-mail back from another state saying, huh, you know, we have the same thing. It's that same restaurant and then you put it together.

So for some of them, there are always going to be an unknown vehicle but the more of those small ones you investigate, the more you're going to pull together.

DR. HOLT: Barbara, you were talking about resources, and I saw some heads nodding. Basically, does anybody want to tackle resources? Dr. Jones.

DR. JONES: I guess I've -- enough about resources, but I think your question about authority is an important one, and it's important to remember that, you know, every -- the laws that govern investigation of foodborne disease are state laws. I mean there is no Federal law. And we have huge authority at the local and state levels. So we don't need any more authority. We just need the resources to go out and enforce the authority that we already have.

DR. HOLT: On the phone bridge, could you try to get someone in the queue there, and I'll come back to the phone in a minute. And I'd like to come back to the room here.

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with Consumer Federation again.

I want to pursue the question about resources just a little bit because nobody wants perfect data but the data that we have now, most of

the consumer people believe is not adequate and for FSIS to -- on July 1st. So Buchanan, tell me, how many people you got working on this now? On your list of priorities, where is food attribution data?

DR. BUCHANAN: Of the different --

MS. TUCKER-FOREMAN: Of all your --

DR. BUCHANAN: Among all of them?

MS. TUCKER-FOREMAN: Uh-huh.

DR. BUCHANAN: I haven't the slightest idea. It's certainly one of our higher-level activities for our scientific and epidemiological staff. It is a priority area for us.

MS. TUCKER-FOREMAN: How many people you got working on it?

DR. BUCHANAN: Probably about five.

MS. TUCKER-FOREMAN: What difference would it make if you had 10?

DR. BUCHANAN: Is Jack still in the audience? No, he's -- here we go.

UNIDENTIFIED SPEAKER: Excuse me. This is the operator. We're having trouble hearing.

MS. TUCKER-FOREMAN: Bob Tauxe.

DR. TAUXE: We have quite a number of people who are engaged in the collection and some are cleaning out the foodborne outbreak response system data, and another large group of people that are also involved in the collection and cleaning of the PulseNet data. The assembling of surveillance data, we have a rather small group that is actually engaged in the analysis and attribution particular phase of that.

MS. TUCKER-FOREMAN: How many?

DR. TAUXE: Yeah. Two of whom have recently taken other positions at CDC. Before they left, I think there would be four.

MS. TUCKER-FOREMAN: Thank you.

DR. TAUXE: And then, of course, there is the FoodNet group that is also a working group that collaborates across agencies as well. So our current group size is probably four total current and, yes, with more people it would be substantially faster and also when we have large outbreak investigations, like the seven phenomenal outbreaks that happened in the last six months, three of which were traced to food

vehicles that had not previously been associated with foodborne illness in this country. That pulls in a lot of people and sort of an all hands on deck public health emergency system, and that probably itself delayed progress by a number of months.

MS. TUCKER-FOREMAN: Dr. Griffin, Dr. Tauxe, Dr. Buchanan, any of you all had any increase in staff to work on these issues in the last few years?

DR. BUCHANAN: Carol, you've read all our press releases. We haven't had any increase in staff in the last few years.

DR. HOLT: That was Robert Buchanan.

MS. TUCKER-FOREMAN: Dr. Tauxe, have you had any increases in your staff to work on this with all the publicity it's had?

DR. TAUXE: We have not specifically for attribution, no.

MS. TUCKER-FOREMAN: Dr. Griffin, how many people you got working on your -- survey?

DR. GRIFFIN: It's really the same program.

MS. TUCKER-FOREMAN: Yeah, okay. So I

guess most of us if we really think it's important, we have something that we could do to advance the cause.

One quick word in response on the expert elicitation. I think we all acknowledge that it is part of the answer but if you look at the RFF model for expert elicitation, and you look at the 2005 expert elicitation done by FSIS, it is not the same animal. It should not be called by the same name. And before it's going to be acceptable to use those data, if you're going to have any public credibility, you have to have an expert elicitation that has some credibility. That one did not. And you've acknowledged it was done by a group of 20 people, 2 public health people, five industry or former industry, most of them aggies, meat scientists, food microbiologists, not people who come at this from a public health point of view. You didn't use severity. You insisted that they use a healthy adult population and specifically excluded pregnant woman. Now tell me how you can come up with a risk for *Listeria* if you've excluded pregnant women from your

database? So I'm willing to use the results of expert elicitation if it's not garbage.

DR. HOLT: Kristin Holt, Moderator. I'd like to point out on the agenda, we may have just kind of moved into the other comment period, but I don't want that to deter anyone from having, you know, any comments or questions. I asked the audio bridge to queue up. So let me check in with the phone bridge to see if there's any questions or comments.

UNIDENTIFIED SPEAKER: At this time we have no questions but as a comment, we are losing your audio.

DR. HOLT: Is it the audio of everyone in here or just me, the Moderator?

UNIDENTIFIED SPEAKER: The last two gentlemen that were speaking, we were hearing like -- of the conversation, like every other word, and you seem to be doing something similar to that kind of skipping. Is there -- hang on just a second. Do you have two speakerphones in the room?

DR. HOLT: I'm sorry. Could you repeat

that question?

UNIDENTIFIED SPEAKER: Do you have two speakerphones in the room that you're using?

DR. HOLT: We have several microphones in the room.

UNIDENTIFIED SPEAKER: Several microphones. Okay. Just a moment.

DR. HOLT: And there will be a transcript posted on the FSIS website.

UNIDENTIFIED SPEAKER: Okay. I guess I'll just continue on, and we'll do the best we can at this end.

DR. HOLT: Okay. Thank you.

UNIDENTIFIED SPEAKER: And there's still no questions.

DR. HOLT: Okay. Sorry about the audio problem there.

Let me see. Sandy, you have been at the mic. If I could just start with you and then I'll go to Dr. Angulo.

DR. HOFFMAN: All right. I'd just like to pose what I really intend to be kind of a conceptual,

can we, is this worth discussing and thinking about. Maybe this isn't the right forum but maybe it is. Just a question about thinking about updating of disease incidence and attribution estimates. I know having done this, it's hard to do it. Doing a study is a long period kind of thing. But ultimately, you know, the fact that I know you're updating need, but the fact that, you know, it's now several years later, kind of what needs to happen, what would make it possible to have regular updates, but maybe also what would go into thinking about periodicity in updates because you've also got a lot of noise and annual changes and depending on the effort that it takes to either do disease incidence or attribution updates, you know, you may not want to be doing those annually, but is there a way of getting at more regular kind of a data set or set of estimates so one can start looking at trends more and have something kind of more systematized way of thinking about that?

DR. RAYMOND: Dr. Raymond. I think what I will take home from this meeting is getting back together with Dr. Agwunobi and possibly

Dr. Gerberdean (ph.), possibly Bob Brackett, whoever I need to get together with to talk about some kind of a memorandum of understanding. I know sometimes that's a bad acronym, a MOU, my God, another MOU, but we have signed one amongst the three agencies on how we will work -- we have an improved work plan for dealing with outbreaks both during the outbreak and in the follow up, and we feel we have a better way to skin that cat. We think it's been done very well but we think there's ways to do it better and to learn to make it more of a learning experience and I think we can take from this meeting today the same thing and consider drawing up some kind of a memorandum of understanding which would put some regularity of the Federal agencies and some NGOs, getting together on a regular basis and sharing the data and moving us forward is my take home. I hope that answers your question a little bit. Rather than like somebody said earlier, there's a lot of talk. Where's the action? I think getting together is perhaps the action. There's the verb that comes out of this talk.

DR. HOLT: In the room, Dr. Angulo.

DR. ANGULO: This is Fred Angulo from CDC. I was intrigued by the question that was posed about how have we used attribution data in the past, and I think it's worthwhile to think of the major successes that we've enjoyed in public health in the last several decades that rely on attribution data.

For example, in the seventies when it was understood what proportion of human *Salmonella* infections were due to turtles, there was an important intervention placed, that was regulatory in nature, the prohibition of sales of turtles less than four inches, and it resulted in a remarkable decline in human *Salmonella* infections.

There's similar successes on attribution with *Salmonella enteritidis* in eggs with fluoroquinolone-resistant *Campylobacter* and the use of fluoroquinolone in chickens which relied on the attribution estimate of how much of that fluoroquinolone-resistant *Campylobacter* infections in humans were coming from chickens and turkeys.

And even the recent success of decline in

*E. coli* O157:H7 in ground beef, we associate with interventions made in ground beef processing.

All of those rely on an understanding of attribution that compel the industries, and also in some instances, regulatory efforts, to make changes. So attribution has been used for a long, long time.

What is so exciting and while I understand the frustration expressed, it's been a decade or more and why is it taking so long to get to this point in attribution? What's so exciting is that we're on the threshold of having a comprehensive measure of attribution across all different pathogens using the outbreak data, and that's really, really, really, really exciting to be so comprehensive.

But it does point then to the next issue which is, once that is done, certainly the data gaps are going to become evidence as soon as that is published. It was pointed out that the one data gap that would immediately become evident will be how is this outbreak data different when you talk to experts on their understanding of the sources of illness and that will be a difference in this expert's

understanding of sources of sporadic illness versus outbreak, and I think that will be a very useful data gap to identify and I don't think we need to do sporadic case control studies on all of the pathogens, just those pathogens in which the experts thinks there's a big disconnect from the outbreak data from the sporadic data.

So in terms of identifying what needs to be done next, it's basically in two arenas in my judgment. One is to try to get this comprehensive report out quicker which can only be done if it's priority and resources are directed, and we're going as quickly as we possibly can with available resources currently.

And secondly then I accept the criticism that outbreak data could be improved if there were more resources at the local health departments and that's a longer-term solution that needs to be addressed.

DR. HOLT: Thank you. Jenny Scott, I think, was next.

MS. SCOTT: Jenny Scott, GMA/FPA. I just

wanted to make a comment about this whole issue of whether we can or can't move forward on RBI based on what we know about attribution.

I'm really excited about the focus that we have now in getting better attribution data. That's something we've asked for for a long time, and we would love to have perfect attribution data. But it is going to be a while before we get much better data.

I take you back to a comment that Kerry Deerfield made, that said maybe we ought to be referring to this as product inherent hazards, not product inherent risk, and he's probably right. And if you think about that, we do know a lot about the hazards that are associated from meat and poultry products. And we certainly have good reason to believe that if we decrease those microbial hazards, that we can have a positive impact on public health. And just because we don't have the perfect measure of the outcome of that, doesn't mean we shouldn't be going forward right now and we will then use the data that we get from better attribution to refine the

system.

DR. HOLT: Thank you. I think Nancy, you were at the microphone first.

MS. DONLEY: Nancy Donley from STOP. I too have a takeaway from this meeting. I have a lot of takeaways but one of the takeaways that I have is the screaming, silent message in this room of how the Government agencies are just plain strapped. And none of you can say it, but I can. And I think it's just really pathetic how our National Government, none of you people in the room here, I'm not speaking of you, you can't go to your bosses and say, I need more money. You're told what you can and can't do, but I can say these things. And I think it's just appalling what our National Government here is willing to put resource-wise into protecting consumers, the public, from the most basic of basic necessities and that's the food that we eat. And I think that where the whole National Government will finally hear where they'll come screeching to a halt and start throwing money again, like they did after the Jack-in-the-Box outbreak, is to have another

Jack-in-the-Box, God forbid.

This is just really, really -- it's sad. It's very, very sad to me, particularly again having -- it's what brought me into this arena was a tragedy, and why does it always have to be tragedies that make us kind of spin around and examine the situation and try to get proactive and do something about it.

I have heard some people kind of say that the money, looking specifically now at food safety as a category, they're saying it's not the slices of the pie, that USDA is getting, you know, we're only having so many illnesses attributed to food and poultry, and there's all this going to produce and it's not equitable.

No, there's nothing wrong with the slices of the pie. The problem is the size of the pie. It's too small. I really hope that if it's at all possible for you all to go to your bosses and say, you know what? The public is not going to accept a defense that this is all we had to do and that it's again just responding to a horrible tragedy to get

what you need to do your jobs. I very much appreciate where the Agency is coming from, in trying to put this together. I understand. At the end of the day, when we get this also in the slaughter plants, it is a budget driven process. And I understand that. I don't like it. I don't believe in it, and again I just had to say that I hope it doesn't take another tragedy to get our head head officials to pay attention, that consumers want safer food. Thank you.

DR. HOLT: We'll move to the microphone.

MS. CHINDER: Hi, my name is Chava Chinder (ph.) and I work for the National Association of County and City Health Officials. And I wanted to talk a little bit about resources and it seems she helped me out a little bit.

I did want to say along the lines of support financially, one of the things that we've talked about among our partners is storytelling, and I really think it would help kind of documenting our work in a way that is friendly to legislators and policymakers and people who do the appropriations and

people who want to hear from the public, not say from all of us scientific folks, but kind of more of the storytelling narratives of our experiences and why we need more funding or where this would be supportive. Where do we need resources? So that's something I think our agency will be working on with the counsel that we have other partners with.

And I also wanted to say something that would be helpful is I've heard everybody talking about what's happening at the local level, and I think Tim has done a wonderful job of trying to represent all of local public health, and I want to say that we should be probably be invited to meetings like this, more of them, so you can hear from their point of view what it is that they need.

I can represent as a staff members of an association, but I'm not the local public health professional. So I know that at our local levels, that I do represent, there's not always the epidemiologist or the environmental health specialist that's going to do investigations. There's a public health nurse maybe who's doing multiple tasks, to

mention that a little bit and trying to convince somebody to give you their blood samples, their fecal samples, is a whole privacy related issue, public issue and talking about these things I think publicly, about our messages, what do we want, how can we get reporting better, it has to be something that we're all saying the same message. And that it's friendly to the public so that they want to come report, that they're going to call your health department, that they're going to give you samples. You can have a great public health nurse but she might not or he might not be able to get that sample from somebody.

So I just wanted to put that out there as some communication and relationship building with your local public health people and representatives and get their perspective on some of these issues. And to also talk about communications issues that are not all funding related. It's about collaborating and doing message development and talking to your representatives. So thank you.

DR. HOLT: Thank you. I'm going to transit

this to closing remarks, and I'd like to introduce to you again, Dr. David Goldman, the Acting Administrator for the Food Safety and Inspection Service who will close up our meeting for us. Thank you.

DR. GOLDMAN: Thanks, Kristin, and thanks for all of you who have hung in there. I have the unenviable task of trying to recap. I won't do that exactly because a lot of the comments in the last hour or so have echoed some of the recurrent themes. So I won't try to do that exactly.

I will pick up on a point that Nancy Donley was making in that we shouldn't forget that attribution is about reacting to illnesses. Just think about that for a second. It means in the same way when we do a recall, we failed in some way to even talk about attribution. It means there has to be illnesses out there for us to learn about. So ultimately we need to apply whatever it is we learned about attribution to change policies, if we're one of the Federal regulatory agencies or to target interventions or mitigations as Tim Jones was stating

earlier if you're at the local or state level, in order to reduce pathogens on products, and therefore the exposures to hazardous products to decrease illness.

So we have to start from illnesses, work our way back through this collaborative exercise with the common goal that we all share of reducing illness. So I'll start with that.

I did a very rough calculation on the technical talks that we heard about the different methods. I estimate that there's about 35 years worth of work represented in the 7 or 8 efforts that you heard about. If you multiply that by probably on the average of four collaborators per project, it's a lot of effort that has gone into attribution. So I think the other thing that we took away, we all took away from this meeting, and we started out with this this morning, was this is a very complex issue. It's one that we all feel very strongly about and have an interest in but nevertheless it's complex.

I think Dr. Tauxe's model is a very good graphical representation of the complexity. I just

wish it was four dimensional instead of three. I mean it's that complex I think.

Attribution data and results are important to all of us for different reasons. As I just mentioned, the local public health officials and state public health officials who regulate perhaps mostly at the retail level, are interested in attribution data to help them shape their interventions, therefore to reduce the exposures of whatever products have been produced at retail from causing illnesses. The Federal regulators are also interested in attribution so that we can develop policy that will again reduce the exposure of the public to pathogens and products that we regulate. And as Dan Engeljohn pointed out, FSIS, just speaking for our Agency, has a very specific place where we regulate, and we could have a longer discussion about whether we should have greater influence on either end of that spectrum.

The industry has a great need for attribution data. They want to produce high quality product and safe product, and having acknowledged

earlier that some of the meat and poultry products inherently have *Salmonella,* for example, as a component of those products. We need to collectively find ways to mitigate and minimize the exposures that might result in illness.

And ultimately, we're all consumers but as consumers, we're all interested in attribution. We all have wondered I'm sure, when we've gotten sick whether mildly or severely, where that came from. I mean we've all asked ourselves that question, and it's not just an academic question. It's often a very serious question to know what has caused an illness and what we might do differently in the future having learned from that particular illness.

In a world with unlimited resources which we don't live in, we might investigate every single sporadic illness, investigate every single outbreak, subtype ever isolate that we have that comes from humans or from food or from the environment, and then we would have a comprehensive attribution picture. We probably won't get there but we can move in that direction and I think we're all interested in doing

that.

We heard some very interesting points about what we need to move from here to that ideal situation. I think having a common nomenclature is one thing that's been identified here. For example, having all isolates in PulseNet. I mean PulseNet is the goal standard for the current subtyping of microbiological isolates. And PulseNet holds out the promise of future systems of subtyping, which I think we would all like to subscribe to, and therefore be speaking with common terminology.

We've heard a lot about the use of outbreak data versus sporadic illness data, and the reasons that we use one versus another. And I think the one exciting next step is this blending project. We heard a little bit about it today but the blending project that CDC is sponsoring, I think will provide for a much clearer and more comprehensive picture of attribution. And so we'll look forward to that.

And finally I'd say that I'm surprised it hasn't been said yet, but for those of us who have lived and breathed FoodNet for a number of years, you

might recall that when FoodNet was established, that attribution was the third of the objectives that was set out at the beginning of FoodNet. FoodNet, as Patty Griffin pointed out, necessarily had to get a burden of illness estimate first, and then has done very well the last three years or so with modeling trends in illness across different pathogens and commodities or vehicles rather. And then finally the next five years or so, so roughly starting last year, for the next five years, attribution is kind of the key goal for FoodNet.

So for those who have suggested various venues for further discussions of attribution, I'd suggest that FoodNet is one place we need to put our time and effort among others.

So with that, I will close this meeting and let you know a couple of kind of housekeeping things. One is we said there would be a transcript. There will be a transcript back to us, the Agency in about five days. We'll clean it up and edit it and post it within a couple of more days. So about a week from now, you should expect to see a transcript. So you

can look at that transcript, you can pass it around to people who didn't make the meeting, and have them react to that transcript.

And the other thing is, early on we talked about having a second meeting on attribution that would be a little bit more FSIS centered. This meeting was meant to kind of survey the entire landscape about attribution. We intend to have a second meeting and the details of that will come out later where we will focus specifically on how FSIS will use or intends to use attribution data as it becomes available in a risk-based inspection system.

So with that, I appreciate all of you who traveled in from out of town, and have contributed to this, and we'll look forward to further discussions on this topic. Thank you.

(Applause.)

(Whereupon, at 4:30 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

ATTRIBUTING ILLNESS TO FOOD

Arlington, Virginia

April 5, 2007

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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Andy Vogel, Reporter

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