

UNITED STATES DEPARTMENT OF AGRICULTURE

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FOOD SAFETY AND INSPECTION SERVICE

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BETTER COMMUNICATIONS,
BETTER PUBLIC HEALTH OUTCOMES -
STRATEGIES FOR IMPROVED COORDINATION
DURING FOODBORNE OUTBREAKS

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May 15, 2008

8:00 a.m.

Renaissance St. Louis Grand and Suites Hotel
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Adjourn

1 P-R-O-C-E-E-D-I-N-G-S

2 (8:15 a.m.)

3 DR. HAGEN: Welcome to Better
4 Communications, Better Health Outcomes - Strategies
5 for Improved Coordination during Foodborne Outbreaks.
6 We've been planning this meeting for an awfully long
7 time, and we're just delighted to see all of you here
8 today.

9 My name is Elisabeth Hagen, and I am the
10 Executive Associate for Public Health in the Office
11 of Public Health Science of the Food Safety and
12 Inspection Service. And I'm going to be your
13 Moderator for today.

14 It's my pleasure to introduce you to our
15 Agency Administrator who is going to provide a
16 welcome, Mr. Alfred Almanza.

17 Al is an experienced and effective leader
18 who has established and maintained a high standard of
19 excellence during almost 30 years with FSIS. He has
20 a strong record as a FSIS manager for recruiting and
21 training the most qualified individuals in order to
22 improve the safety of FSIS regulated products and

1 does not hesitate to take swift and strong regulatory
2 action in order to protect public health.

3 Mr. Almanza served most recently as the
4 Dallas District Manager, which includes more than 350
5 federally inspected establishments. A Texas native,
6 Mr. Almanza joined FSIS in 1978. Prior to becoming
7 the Dallas District Manager, he served in a variety
8 of positions, including slaughter inspector, labor
9 relations specialist, special assistant to the
10 District Manager and Deputy District Manager.
11 We're glad to have Mr. Almanza here with us.

12 (Applause.)

13 MR. ALMANZA: Thank you, Elisabeth. First
14 of all, before I begin with my speech here, it's been
15 about eight months, a little over eight months since
16 I got to Headquarters and someone told me before I
17 came up there, that it was going to be an experience.
18 That was an understatement, but it has been a very
19 good experience from the standpoint of working with
20 the consumers, working with the industry, and working
21 with all of the groups that, that as the District
22 Manager in Dallas, I didn't have that appreciation of

1 how, how well everybody has to work together in order
2 to make this Agency successful. I really didn't. As
3 a District Manager, you tend to focus on what's
4 happening within your district and trying to keep
5 your hands around those things, not quite as an
6 enormous task as being the Administrator for this
7 Agency, and I would like to think that it has gotten
8 to be more routine. This job will never be easy, but
9 it gets to be more routine and a little bit more
10 predictable as long as we can keep things in
11 perspective.

12 So with that, it's great to be here. This
13 is truly a groundbreaking event in bringing the
14 consumers, the industry and the public health
15 community together. We have an opportunity to
16 develop better ways that we can coordinate during
17 multi-jurisdictional outbreaks.

18 Dr. Richard Raymond, the Under Secretary
19 for Food Safety, is on official travel for Secretary
20 Ed Schafer and therefore was unable to attend. As
21 many of you know, today's subject is one of his
22 passions. He's very committed to improving the

1 entire recall and investigation process and I know
2 he'll eagerly be awaiting any information that he
3 gets from this meeting.

4 On behalf of Dr. Raymond and USDA, I'd like
5 to acknowledge and thank the members of the Steering
6 Group for their efforts to make this summit a
7 reality. Dane Bernard from Keystone Foods; Caroline
8 Smith DeWaal, the Center for Science and Public
9 Interest; Subha Chandar, Robert Harrington, and Grace
10 Ibanga, the National Association of City and County
11 Health Officials; Brian Collins, the National
12 Environmental Health Association; Jack Guzewich of
13 Food and Drug Administration, Center for Food Safety
14 and Applied Nutrition; Jennifer Lemmings, Bela Matyas
15 and Tanja Walker, the Council of State and
16 Territorial Epidemiologists; Adam Reichardt and JoAnn
17 Schaefer, the Association of State and Territorial
18 Health Officials; Don Sharp and David Warnock, the
19 Centers for Disease Control and Prevention; Dan
20 Sowards, Association of Food and Drug Officials; and
21 Victor Waddell, the Association of Public Health
22 Laboratories.

1 I'd like to recognize Dr. David Goldman,
2 Dr. Elisabeth Hagen and Bonnie Kissler from the FSIS
3 Office of Public Health Science, for their hard work
4 in coordinating this meeting.

5 And I want to thank all of the speakers on
6 today's program for taking time from your busy
7 schedules to share your valuable experiences and
8 insights with us.

9 As you can tell from the meeting materials
10 that you've already received, we have quite an
11 ambitious agenda.

12 Thank you all again for being here, and I
13 look forward to a day of stimulating discussions. We
14 have an opportunity to work together to find viable
15 solutions to meet our shared goal of protecting the
16 public's health. Thank you.

17 (Applause.)

18 DR. HAGEN: Thank you, Mr. Almanza. Before
19 we get started with our first panel, I thought we
20 would just do a couple of bits of housekeeping. As
21 far as I know, the restrooms are only located on this
22 side. I walked around this side to see if they were

1 on that side as well, but I believe that they're just
2 located all the way down to the end of this section
3 of salons. We will have a couple of breaks
4 throughout the day but please feel free obviously to
5 get up and step out as needed.

6 We will try to keep on schedule. We are
7 scheduled at this time to do lunch at 12:30. So
8 we're really going to try and keep on schedule this
9 morning.

10 Any other bits of housekeeping I need to go
11 over Bonnie?

12 MS. KISSLER: No.

13 DR. HAGEN: Okay. All right. Our first
14 section of the day is going to be about state and
15 local public health programs, what their experiences
16 are and challenges with outbreak response and
17 investigation, and our first speaker is Ms. Dorothy
18 Gonzales.

19 Ms. Gonzales has worked for the Genesee
20 County Health Department for 19 years in various
21 environmental health investigative, coordinating and
22 program management roles. The past several years,

1 she has managed the Food Safety Program overseeing
2 food service evaluators, training, quality assurance
3 and foodborne illness investigations. She is
4 involved in food safety work groups with NACCHO and
5 the Michigan Environmental Health Directors
6 Association. She's also part of the Genesee County
7 Health Department Continuous Quality Improvement and
8 Public Health Accreditation Teams.

9 Dorothy received her Bachelor of Science in
10 Biology and Public Health Education from Central
11 Michigan University and is currently attending
12 graduate school in a master of public health program.
13 She became a registered environmental health
14 specialist in 1994. Dorothy has received special
15 recognition awards from Southeast Michigan
16 Environmental Health Association and the Flint
17 Watershed Coalition.

18 Ms. Gonzales.

19 MS. GONZALES: Thank you.

20 (Applause.)

21 MS. GONZALES: Well, good morning,
22 everyone. You see I'm still toting coffee around.

1 I'm not quite awake yet. (Laughter.)

2 As Elisabeth said, I'm the Food Safety
3 Program Manager at a local Public Health Department.
4 So I'm here to give you a local perspective and
5 outbreak collaboration, and I'd like to thank you for
6 the opportunity to speak on this subject of our
7 challenges with multi-jurisdictional outbreaks.

8 A few statistics about where I'm from. I
9 am in Flint, Michigan. We are mid-state in a lower
10 peninsula. Our population of our county is about
11 439,000. We have 160 staff members at 3 different
12 locations throughout the county, and our food safety
13 program, we manage 1500 food service facilities, and
14 those are all restaurant type establishments. We
15 don't inspect or investigate any retail grocery.
16 That's something that our Michigan Department of
17 Agriculture counterparts do. I have 10 inspectors, 2
18 plan review folks that do all of the new restaurant
19 and change of ownership types of things. I have a
20 coordinator that keeps a lot of balls in the air and
21 a couple of clerical staff.

22 And, of course, Michigan is surrounded by,

1 you know, all the fresh water in the world basically.
2 So we have it pretty good there.

3 The challenges I want to talk about today,
4 and they're mostly challenges. I've got a good
5 success story in here, too, but they're mostly
6 challenges that we face at the local level.

7 From a local health department perspective,
8 outbreak collaboration is a big challenge for us. We
9 tend to work on our own little silos, in our own
10 little counties, our own little district health
11 departments. We do things according to our own
12 county protocols, and we don't think about the rest
13 of the state or regional outbreaks so much. We think
14 about what's going on in our own little county.

15 We really don't have any procedures in
16 place to work with federal level folks. If something
17 federal comes along, I have Lisa on speed dial.
18 She's our state outbreak coordinator. So we tend to
19 rely on Lisa to liaise with the Federal Government.
20 We don't do a whole lot of that at the local level
21 right now.

22 Communication I think is probably a

1 challenge for us. I communicate really well within
2 my division and my department. We have a whole
3 protocol for investigating foodborne outbreaks,
4 getting my epidemiologist involved early, getting my
5 communicable disease nurses involved. We have a
6 great protocol that works fabulous for us, but we've
7 never been challenged to use that in conjunction with
8 a regional outbreak with maybe three or four other
9 local health departments. We've never had to do that
10 so far in our region. So I don't know how well that
11 would work. Yea, thank God, Lisa says. We haven't
12 had to do that.

13 In federal protocols, at the local level, I
14 can tell you, I know virtually nothing about federal
15 protocols regarding outbreak response and
16 investigation. I get recall notices when they're
17 press releases, and I listen to what Lisa tells me to
18 do. I don't, I don't have a lot of protocols in
19 place, and we're not real familiar with protocols
20 with national outbreaks, national recall notices.
21 Locals aren't versed in label reading and packaging
22 and that sort of thing.

1 Local collaboration. This slide might be
2 better titled local non-collaboration because
3 anecdotally I've heard that local health departments
4 within the State of Michigan have had problems with
5 other local health departments across county lines.
6 If you have folks that are ill in one county and then
7 the establishment, the -- is in another county, if
8 the establishment is in one county, we've heard that
9 they'll say, well, you just investigate the whole
10 thing. It's your establishment when really most of
11 the ill people are in another local health
12 department. There should be some collaboration going
13 on, and there isn't.

14 I've also heard that there's several local
15 health departments involved in a regional outbreak.
16 One health department wants to be in charge and
17 they're really not the legal investigative agency.
18 They want to maintain control, and they'll say, well,
19 we'll just do our own thing with our people and they
20 don't participate with the other region. We're not
21 getting the information, their meal histories.
22 That's happened in the past.

1 So local collaboration is mostly non-
2 existent. We need some help with that definitely.

3 Other local experience, this was brought to
4 my attention by some epidemiologists in Minnesota,
5 and we also have this kind of a problem in Michigan.
6 How do you accurately and in a timely manner identify
7 the appropriate people from each agency that need to
8 be involved. You know, I have Lisa on speed dial, my
9 state person, but I don't have a list of agencies in
10 the contact people. Yeah, I have a list of my local
11 health departments. I can get a hold of them but
12 who's the person I should really be talking to at
13 that agency.

14 I know in Genesee County where I'm from, we
15 use environmental health sanitarians to investigate
16 our foodborne illness outbreaks and most of the other
17 counties, almost all of the other counties in
18 Michigan use communicable disease nurses. They look
19 at it as an illness, and they're doing illness
20 investigations. The sanitarians are only involved
21 when they go to the facility and do the investigation
22 of the food safety plan. So we're kind of a little

1 unique in that regard. So I wouldn't know who to
2 call. I would be calling environmental health
3 directors.

4 Another thing that Minnesota has come up
5 against is some of their larger chain food services
6 have their own quality assurance folks, and they may
7 take a complaint from a constituent or a customer and
8 then attempt to investigate internally and don't even
9 -- they just circumvent the whole local health
10 department which is kind of, you know, against the
11 law. (Laughter.) And, you know, then someone finds
12 out about it and, you know, the local health
13 department tries to get involved after these people
14 have done who knows what. You know, what kind of a
15 protocol are they following. We have not come up
16 against that in Michigan, or I haven't. Have you,
17 Lisa?

18 MS. HAINSTOCK: A few times.

19 MS. GONZALES: A few times. Great.
20 (Laughter.) We don't do things like that in Genesee
21 County.

22 Another local experience that was brought

1 to my attention, Dickinson-Iron District Health
2 Department. It's in the Upper Peninsula. The recent
3 outbreak with the *Salmonella* and the Honduran
4 cantaloupes. Michigan was not in the original recall
5 notice for that, and later that day, they had some
6 staff members, they were at some kind of a seminar
7 and found out from another local health department
8 that some had come to Dickinson County and went to a
9 hospital and they did some investigation and indeed
10 they were there, and we didn't even know that they
11 were in Michigan yet. This is something that
12 actually worked out because the company that had the
13 cantaloupes that delivered them there actually called
14 the hospital, and they were discarded. So we didn't
15 have to worry about anybody ingesting them, but we
16 think it was real slow communication to locals, and
17 we're frustrated with that sometimes. We want real
18 time like you guys have.

19 Another experience that a couple of our
20 counties have had, Saginaw County and Oakland County,
21 participated in the food defense surveillance
22 assignment in 2007, and part of that exercise, it was

1 designed to evaluate all stakeholder communications
2 and identify gaps in areas of increased risk during
3 recall initiative that span all levels of food safety
4 jurisdiction and the regulators were asked to conduct
5 a routine inspection, discuss the alert with the
6 proprietors and collect trace back and trace forward
7 information.

8 Well, we are not real confident in reading
9 labels and packaging and knowing lot numbers, from
10 what establishment, we don't have a clue. We need
11 some definite training in that regard. That was a
12 big issue for our locals there.

13 And the second issue was there would seem
14 to be some forms that the Government, the feds use to
15 collect this trace back, trace forward information
16 and we've never seen them before. We didn't know
17 what they were, and they were told to kind of design
18 their own form to get this information to the feds,
19 and that was a little disconcerting for some folks.
20 So we want all your forms, too, all your good forms
21 that (laughter) that you guys use. I think, you
22 know, we need a template. We need something to help.

1 And Genesee County participates when our
2 State Department of Agriculture asks for locals help
3 in conducting recall effectiveness checks. We
4 usually jump right on the band wagon because we have
5 lots of facilities and we've participated in a couple
6 of statewide recalls, Abbott's Meats and Mark's Meats
7 and there were some *E. coli* issues with some ground
8 beef. And we also participated in the Davis Creek
9 Meats and Seafood out of Kalamazoo, Michigan. That
10 was a national recall, and a site visit was required
11 and the State did fax us some forms to use, but our
12 problem was 7 out of 10 facilities had not heard of
13 the recall and they had product in their facilities
14 to be discarded.

15 So I went back and called my State
16 counterpart and said, okay, give me the rest of the
17 list for Genesee County because I'm a little alarmed
18 if we're finding this much of this ground beef. I
19 want to go get it out of the rest of my facilities,
20 and I was told no. This is a voluntary recall and
21 this is protected information and you can't have it,
22 which didn't go over well with my directors and my

1 health officer either.

2 So this is my point here. Voluntary
3 recalls are not good public health. Local health
4 departments need to get those lists. We need to get
5 food out of the mainstream as quick as possible, and
6 I know it's a law, and I know you guys can't do that
7 just by deciding to do it, but we are really pushing
8 for this. This would be one of our priorities,
9 training and giving us a list so we can go do our
10 work.

11 Finally, a bright spot. We have a local
12 collaboration -- this is a success story. This was
13 really a great bunch of information I got from -- the
14 Metro Atlanta Area has five health districts that
15 encompass eight counties, and the epidemiologists in
16 this area got together and created the Infectious
17 Disease Case Management Across Jurisdictions
18 Protocol. They got the Georgia Department of Public
19 Health involved. Everybody agreed on a protocol to
20 take care of foodborne illnesses across jurisdictions
21 in their Metro Atlanta area. This is a great
22 starting point. I, of course, immediately e-mailed

1 this off to Lisa and we want to work on something
2 like this for Michigan. It's been in place since
3 2004. Five different health districts participate.
4 It lists very simply, you know, if the ill person,
5 you know, the contact, the initial case is one
6 district, they're in charge of the investigation. If
7 the food service is located in another district,
8 that's the person that has to go do the investigation
9 there. If people are ill in other districts, they do
10 the questionnaires, but everything goes back to that
11 first district where that initial case was, and
12 that's who does the final report and that's who
13 collects all the information and has to get it off to
14 the State Department of Health. It's a great
15 protocol. It's simple. It's straightforward. I
16 love it. And it's something that I'm sure they
17 wouldn't mind passing around. Is anybody from
18 Atlanta? Heidi. Hi, Heidi.

19 So to sum up, what us local little country
20 bumpkins need, we need training on recall trace back
21 of product. We are not confident in reading
22 packaging and forms. We need some help with, give us

1 some basic forms and we can work with that. I know
2 that you did come out with a great document in 2001,
3 Multistate Foodborne Outbreak Investigations,
4 Guidelines for Improving Coordination and
5 Communication. This is a great starting point. I
6 read this a couple of years ago when I took over this
7 job, and I reread it before I came here, and there's
8 a lot of good information in here, but I think we
9 need some -- locals, we're not just going to do it on
10 our own, you know. We need some help. And we need
11 some -- federal protocols and your communication
12 strategies and what you would expect us to do, how
13 you'd expect us to communicate with you if we have a
14 huge outbreak, where something is in every county,
15 everywhere.

16 And I know this afternoon we're hearing
17 from the CIFOR folks, the Council to Improve
18 Foodborne Outbreak Response, and I'm curious to see
19 what they have. I think they're probably coming up
20 with a protocol that may work, and it's very timely.
21 We need something like that. So if you guys could do
22 some regional training for us, I think the locals --

1 you would be overwhelmed with people that would be
2 interested in attending, and helping us with agency
3 contacts and setting up some sort of collaboration
4 protocol, we're right on board with that. We would
5 love to have that kind of stuff.

6 And if you don't have any questions --
7 anybody?

8 DR. HAGEN: We're going to do questions at
9 the end.

10 MS. GONZALES: At the end. Okay. All
11 right. Thanks.

12 (Applause.)

13 DR. HAGEN: Thank you, Dorothy. That was
14 great. I mean, I think we're already headed in the
15 right direction here. We've already got a couple of
16 concrete suggestions about exactly what they need. I
17 see the wheels turning with some of the Epi-Ready
18 people in the audience saying we can do that. So
19 we're already off to a great start.

20 So in our haste to get started, I, of
21 course, actually did forget some of the housekeeping
22 details that I should also let you know about.

1 One, Dorothy just brought up, we're going
2 to go ahead and hold questions until the end of each
3 section just to kind of stay on target with the
4 times. So please write your questions down, and
5 obviously at break you'll have a chance to ask
6 questions of the presenters as well.

7 And the other thing that you should know is
8 that we always do a transcript of public meetings.
9 And so this is being transcribed as well.
10 Particularly when you ask your questions, it's
11 important that you identify yourself and if you are
12 with an organization, who you're with because even
13 though we may know who you are, we want to have that
14 information on the transcript, and we do post those
15 transcripts to our website.

16 As well, I believe our plan is to post all
17 the presentations on our website after the meeting.
18 So that should happen pretty quickly after the
19 meeting is done.

20 Okay. So moving onto our next speaker,
21 we're going to have Dr. Bill Keene come take the
22 podium next and talk about things from a state

1 epidemiology perspective.

2 Bill Keene has been a communicable disease
3 epidemiologist of the Oregon Public Health Division
4 since 1990. As a generalist, he provides
5 consultation and support for most disease of public
6 health interest running a gambit from rabies to
7 malaria to measles to hepatitis.

8 He has worked on hundreds of outbreak
9 investigations with a special interest in enteric
10 diseases. He now coordinates Oregon's enteric
11 disease outbreak investigations and also develops
12 databases, questionnaires and other tools for use in
13 general disease surveillance and investigations. He
14 has written or contributed to numerous articles about
15 outbreaks in enteric diseases and has been an adjunct
16 professor at Oregon Health and Science University
17 since 1991.

18 He's also interested in international
19 public health, and in recent years has traveled
20 frequently to Asia on various assignments and Iran,
21 India, Pakistan and Indonesia and other countries on
22 behalf of the WHO and the U.S. National Academy of

1 Sciences.

2 He's a graduate of Yale University and the
3 University of California at Berkeley, and this is my
4 favorite part of Bill's bio. His Oregon license
5 plate is O157:H7. (Laughter.)

6 Dr. Bill Keene.

7 (Applause.)

8 DR. KEENE: Thank you. One of the
9 challenges we face giving talks to these groups is
10 that many of the people who are in the audience were
11 at the last meeting we were at giving a talk. So
12 trying to use different slides is sometimes something
13 we struggle with. So I'll see how well I can do.

14 Anyway, I'm from the State of Oregon and
15 was asked to describe some of our perspectives on
16 outbreak investigations in general and multistate
17 outbreaks. I've used this before. When you ask for
18 anybody's perspective, it sometimes is a little
19 distorted. So our perspective in Oregon is not the
20 same as you might have in Florida, New York,
21 Missouri, they're all back east to us. And so when
22 we talk about these issues, we have our own ideas,

1 and not everybody in our own office shares the same
2 perspective on matters, too. So this is kind of a
3 personal perspective on some of these issues, and
4 we'll see how it goes.

5 Foodborne illness, I'm not going backwards.
6 This is actually an attempt to look again at our
7 State seal which goes back and even at the founding
8 of our State, these issues were on their mind. We
9 had cattle right on top of the food supply
10 (laughter), and they have birds flying overhead. So
11 even at that time, some of the issues that we
12 struggle with today were recognized and enshrined in
13 our State seal.

14 This is a Jack-in-the-Box Restaurant in
15 Washington State, our neighboring state, and as many
16 of you know, the Jack-in-the-Box outbreaks in 1992
17 and 1993 were watershed events that catapulted a lot
18 of food safety issues onto a higher plain, a higher
19 plain of Government, a higher funding, a higher point
20 of industry awareness and attention. It wasn't new.
21 It wasn't by no means the first outbreak of either *E.*
22 *coli* O157:H7 or O157 attributed to ground beef, but

1 it was one that really caught a lot of attention both
2 in the media, industry, regulatory agencies and in
3 the public health community at large.

4 So the finding that undercooked hamburgers
5 were the source sank in, and a lot of people got that
6 message, particularly in the general public who
7 hadn't before, but there's a long history of just
8 these outbreaks even in my own State, Sizzler's Salad
9 Bar, cross-contamination issues, swimming associated
10 outbreaks, a lot of what we call foodborne diseases,
11 not really spread by food and the term is often used
12 very, very loosely. And those of you who don't do
13 this for a living should keep that in mind when
14 you're reading reports about what is foodborne
15 illness.

16 Raw milk, a recurrent source of O157 and
17 many other infections, doesn't show up too well with
18 the lights on, but even wild animals are a source of
19 some of these pathogens.

20 Needle tenderized meat has been a current
21 source of how you can turn a steak or a roast into
22 ground beef before your very eyes. And more recently

1 concerns increasing about fresh produce and other
2 products. But the history does go back further than
3 Jack-in-the-Box.

4 This is a chain A restaurant in Southern
5 Oregon that was the first identified source of an *E.*
6 *coli* O157 outbreak, and so we do have this history in
7 our State and it's shared.

8 We have lots of interesting outbreaks but
9 if you look at the history of public health, not only
10 in the United States but around the world, a lot of
11 it started with enteric disease, epidemiology and
12 outbreak control, going back to cholera in London and
13 many outbreaks in this country, thousands and
14 thousands of them.

15 It was at the core of public health
16 department's creation, or at the core of a lot of
17 environmental health efforts, in the beginning of the
18 19th Century and continuing until this day.

19 Those pictures were all from various *E.*
20 *coli* O157 outbreaks but as again I'm sure most of you
21 know, there are many, many agents that cause these
22 kind of diarrheal and enteric diseases. These are

1 just some of the bacteria, the more common bacteria
2 we're concerned about. Also parasites and viruses.
3 There's lots of these microbes out there. Some of
4 them have animal reservoirs, some of them are person
5 to person only. They have different characteristics
6 but generally from the person's point of view, it's
7 often very difficult to tell them apart or from a
8 clinicians part of view, very difficult to tell them
9 apart in an individual person because the range of
10 reaction to these is from asymptomatic carriage to
11 fulminant disease and death and everything in
12 between. So when a person comes in, there's no way
13 for a clinician, if somebody has a very mild case of
14 A or a very severe case of B, without the proper
15 laboratory testing.

16 So a lot of what we do, we rely on disease
17 reporting, and again, just to recap how this system
18 works, and my examples are from Oregon, but this is
19 not wildly different from the way it works in most
20 states. These are state specific rules. They're
21 rules that apply to both physicians and laboratories.
22 There are requirements both for named diseases. So

1 *Salmonella* is on the list. Hepatitis A is on the
2 list. Gonorrhoea is on the list. But there are
3 requirements for reporting of general categories like
4 any kind of outbreak perceived as such or any kind of
5 unusual disease that doesn't fit in the usual disease
6 spectrum of the state.

7 We get these reports from physicians. We
8 get the reports from labs, and I should say generally
9 we get them from labs. Physicians are required to
10 report but rarely do, and that's essentially never
11 enforced. These data come, depending on the states'
12 mechanisms, they come to local health departments.
13 They come from local health departments to state
14 health departments. Sometimes they come
15 electronically directly to the state health
16 departments. And they stop there and again those of
17 you not in the business should understand that the
18 basic health reporting functions and legal authority
19 is at the state and local level. And only at the
20 state and local level do they have the identifying
21 information, the names, addresses and phone numbers
22 that allows people to pursue these reports. CDC does

1 not do outbreak investigations unless they're working
2 with a local or state health department. They have
3 no way to contact people unless somebody calls them.

4 What goes to the federal agencies are de-
5 identified data. So there are six *Salmonella* cases,
6 they know the county, they get the date of birth or
7 the month of birth, something like that, but they
8 don't have any way to contact these patients, and a
9 very important part of our system is, and again it
10 varies somewhat from state to state, is not only this
11 information about the disease goes to the public
12 health agencies, but if it's a bacterial infection
13 like *Salmonella* or *E. coli* 0157, some of those
14 isolates, maybe all of those isolates depending on
15 the state will be forwarded to a public health
16 laboratory, the state public health laboratory as a
17 reference lab for subtyping, and although this
18 subtyping is of no interest or no value really to
19 clinicians or patients, it doesn't affect their
20 treatment or what's going to happen to them in the
21 course of their illness. These data are very
22 important to us trying to make connections between

1 cases. So from an epidemiologic point of view, it's
2 very important. So getting those isolates is key to
3 what we do at this stage.

4 Well, anyway, this shows some of our data
5 and it's going to jump backwards I think as soon as
6 it stops.

7 We get these case reports and then there's
8 a variable degree of follow up. In our state, we try
9 and interview all the persons reported with those
10 enteric diseases, and local health department nurses
11 contact them. They call their parents if it's a kid
12 and ask questions, who are you, where do you live,
13 when was your specimen collected. They ask a certain
14 litany of exposures, and it's on the exposure front
15 that practices differ most widely among states, how
16 much data they get and when they collect it. We make
17 an effort to identify other people at risk. So if a
18 person works as a food handler, their child in
19 daycare, there may be some special considerations
20 that are explored.

21 And then again, the local health department
22 person is focused on preventing additional cases,

1 providing personalized health education based on
2 their story. So if they say they drink a lot of raw
3 milk, they'll get the raw milk lecture. If they have
4 iguanas at home, they get the pet reptile lecture.
5 And this is all wrapped up with admonitions to wash
6 your hands and go forth and good luck, not spreading
7 it to other people. And then again there may be some
8 specific restrictions depending on their situation.

9 And these are just data in the aggregate.
10 We look at these trends. These are Oregon trends.
11 We pull these data nationally, and then we all try
12 and say, oh, it's going up because people aren't
13 paying attention to HACCP or it's going down because
14 the price of gas is going up and we try and explain
15 this with some degree of success, generally not much
16 I think.

17 This shows our cases not for Oregon this
18 time but for 10 FoodNet states, pooling data across a
19 large number of sites. And I've divided the cases
20 here as to whether or not they're parts of outbreak
21 or not. And what this tries to show is that for *E.*
22 *coli* 0157 and *Salmonella*, the vast majority of the

1 reported cases are not known to be parts of
2 outbreaks. So it's a tortoise and hare race, and
3 every time the tortoise wins, the sporadic cases make
4 up the vast majority. So you're going to see for
5 O157, it's only about 15 percent of the cases that
6 are known to be outbreak related and for *Salmonella*,
7 it's closer to about 6 percent.

8 So when we do these investigations on
9 sporadic cases, we end up not knowing where they got
10 their source. They have lots of potential exposures.
11 They went to lots of restaurants. The kid's in
12 daycare. He's got animal contact of multiple kinds.
13 All of these are potential sources and most people
14 have exposures that they didn't think about, they
15 didn't tell us about, and we didn't think to ask them
16 about. But it's only when we get these outbreak
17 cases that we have some chance of being able to
18 identify a source.

19 So there are reasons to investigate
20 outbreaks that give them an importance that belies
21 their small numbers.

22 Number one, and the most obvious one, is we

1 can often or I should say occasionally stop ongoing
2 transmission. If there's a meat product that's part
3 of large consignment from a single lot and it's
4 frozen, it may have a very long shelf life. So
5 identifying a hot lot and getting out a recall on
6 that can prevent lots and lots of cases from
7 undercooking or mishandling down the road. If it's a
8 short shelf life product, or it's a product that's
9 contaminated close to the point of consumption, just
10 by food handler not washing their hands, a very
11 common scenario, generally these outbreaks are over
12 long before the public health system even hears about
13 the cases.

14 So we don't really stop anything. We take
15 credit for stopping them but it's already happened.
16 What we can sometimes do is, even if we're too late
17 to stop transmission, is we can put out information
18 often in a local community that would say a
19 particular agent is in the community, and this will
20 improve the likelihood of getting a good diagnosis
21 and appropriate treatment for people. More often,
22 even that's not feasible.

1 What we can do with outbreaks is identify
2 risk factor for sure. So when we trace this outbreak
3 to swimming, we trace that outbreak to spinach, we
4 can be pretty sure that that was the source of a
5 given number of cases. And those kind of
6 conclusions, because they're more sure and we're more
7 confident about them or more convincing to a lot of
8 people who need convincing, be they in the general
9 public or in the industry or regulatory agencies.

10 So outbreak data are good. They sometimes
11 stimulate research. We'll come up with unusual
12 findings that will prompt people in academic centers
13 or elsewhere to do something. Gee, why does that bug
14 seem to survive in mayonnaise. It shouldn't. And we
15 learn things about bugs.

16 And then in the aggregate, these data are
17 used by some of the people in this room and elsewhere
18 to help develop sensible prevention strategies. Do
19 we need to focus our attention on hand washing? Do
20 we need to focus it on preventing contaminated meat
21 getting into the sales stream? Where's the biggest
22 bang for the buck? Because it is a matter of

1 tradeoffs. There's a lot of money in food safety and
2 there's a lot of money in foodborne illness but
3 there's also a lot of money spent on preventing it,
4 and we want to make sure we're getting the most
5 efficient return on those kind of investments.

6 So again outbreak investigations, although
7 they're a small part of the disease picture are
8 disproportionately important for a lot of reasons.

9 The media interest in outbreaks should not
10 be undersold. One of the things we can do with a lot
11 of media coverage is get out public health messages.
12 The reason we can tell people to cook ground beef to
13 a high temperature and to wash your hands, we don't
14 get funding to take out advertisements for that. We
15 have to get free advertising, and we get it by having
16 outbreaks unfortunately. That's where we can get
17 people to get on TV and put out these general
18 messages. People don't pay attention a lot of the
19 time without it.

20 Furthermore, the loss of lawsuits and the
21 loss of sales and the damage to brand names that can
22 occur is another way of getting industry's attention.

1 It often doesn't happen even though more cases are
2 piling up from some of these sources in sporadic
3 cases because they're not really tied to specific
4 people. The impact is not nearly as great. That's
5 quite understandable.

6 And lastly, these outbreaks stimulate
7 political interest because people want to be
8 responsive to problems, and political interests
9 changes things, changes things in the regulatory
10 environment.

11 This shows a number of diarrheal outbreaks
12 in Oregon over the last 10 years, including this part
13 of 2008, and you can see there's a steadily
14 increasing trend, and we're on a pace this year to
15 get somewhere between 200 and 250 of these outbreaks
16 in my little State of under 4 million people this
17 year alone. That's a lot.

18 But if you look at them, you see that close
19 to half of them are spread by the person-to-person
20 route, and foodborne infections make up really only
21 make up about a third. There's another group that's
22 sort of a mixture. It might have been foodborne. It

1 might be person to person. They're indeterminate
2 from what information we get, and then there's a very
3 small proportion that are waterborne, a small
4 proportion due to animal contact, and a few that are
5 investigated so poorly, we can't even make that
6 guess. But foodborne outbreaks don't even make up
7 the majority of our diarrheal outbreaks.

8 Again, here's the same numbers. This just
9 shows the foodborne ones only, and you see that that
10 upward trend is not quite so dramatic. What we're
11 seeing really that is driving it is a lot of what we
12 can call Nursing Home Norwalk outbreaks and overall
13 picture. And if we look at foodborne infections,
14 it's a little flatter. It bounces around more but
15 it's not such an obviously trend.

16 If we look at those foodborne outbreaks
17 though, we still see that half of them are caused by
18 Norwalk-like viruses. That's by far the most common
19 cause, and the next biggest one after that is
20 *Salmonella*. Things like *E. coli* O157 and *Listeria*
21 are very small in the number of outbreaks, and that's
22 not the same as the number of people affected by the

1 outbreaks but actually it works out pretty similarly
2 if you do the math that way.

3 If we take another measure of how important
4 these various agents are and we look at deaths, again
5 this is deaths in Oregon over a 10 year period from
6 enteric agents. I'm weaving one of them out so far.
7 You see *Salmonella* is responsible for a quarter of
8 those deaths and the total here is only 87. It's not
9 that many over a 10 year period. *Listeria*, the next
10 biggest one, but driving this thing again is Norwalk.
11 And again our deaths are occurring largely in non-
12 foodborne outbreaks. They're occurring largely in
13 nursing homes and again, they are people with serious
14 medical problems.

15 But, in fact, one of these agents we don't
16 pay a lot of attention to, and certainly not in a
17 foodborne setting necessarily is Norwalk, and it
18 kills quite a few people.

19 Let's talk about those multistate outbreaks
20 then. We've had a lot of them. These again, the
21 same graph you've seen. These are our foodborne
22 outbreaks bouncing between 20 and 60 or so in a year.

1 And this shows how many of them are multistate. Not
2 very many. About 10 percent. And fewer still if you
3 look at how many involve regulatory agencies, the FDA
4 shown in kind of a pale yellow that looks about the
5 same as green from here, and the USDA ones even
6 fewer. So it's a small proportion.

7 Now these get a lot more work up generally,
8 and they get a lot more attention. They consume a
9 lot more time but it's a small proportion even of the
10 foodborne outbreaks.

11 What starts these investigations at the
12 local level? Well, the most common source is people
13 call the health department say in part of an
14 outbreak. I mean it's that simple. We went out to
15 dinner and a bunch of us seem to have gotten sick.
16 My daughter got married last weekend and I'm getting
17 calls from everybody that was at the reception that
18 says they're sick, that kind of thing is still the
19 classic scenario for an event centric outbreak and it
20 still is bread and butter particularly at the local
21 level.

22 Physicians every once in a while do call

1 and say that somebody came in with a disease and they
2 mentioned that a bunch of other people were sick in
3 their household or people that they're associated
4 with, and that starts outbreak investigations.

5 Then we have what we could call local
6 surveillance anomalies. By local, I mean at the
7 state or local level where we notice from laboratory
8 reports of our surveillance reports, we're seeing
9 more cases of *Salmonella* than we would expect. We're
10 seeing more cases of O157. They all have the same
11 serotype. So again, it's a combination of laboratory
12 subtyping data that we're getting within our state
13 and our own knowledge of regular patterns that say
14 this is unusual. We're seeing something out of the
15 ordinary.

16 Then we'll get notifications from our
17 colleagues in other states. We'll get an e-mail
18 message from Washington saying, are you seeing a lot
19 of *Salmonella* Heidelberg? We are. And sometimes the
20 answer is yes and sometimes it's no, and sometimes
21 these notifications are not from our next door
22 neighbor but because of improved communications and

1 e-mail, we'll get it from anywhere in the country.
2 Or we might even read about something in Canada or
3 another country.

4 And, of course, PulseNet, which you'll hear
5 more about, has been very valuable in letting us link
6 bacterial outbreaks to each other. As we get those
7 subtyping data and pool them nationally, and improve
8 our ability to share the subtype, something that is
9 still not nearly as good as it could be, we get a lot
10 of our clusters starting that way.

11 We start by reviewing the information we
12 have. We know how old they are and where they live.
13 We have some clue as to their ethnic group. All
14 these things, and we know when the cases occurred
15 sort of. So this gives us some sense if these all
16 popped up over a weekend or it's something that's
17 been grinding out over the last few months and we've
18 just recognized it. All these clues go into us
19 trying to make guesses as to, you know, profiling the
20 suspect so to speak. It's something that only
21 affects kids. It's something that seems to be
22 affecting mostly Vietnamese adult women. Things like

1 that are more or less obvious although that doesn't
2 necessarily tell you what the food is, but it starts
3 to give you some ideas to pursue.

4 Now depending on the state, we'll have some
5 information about exposures. We might be able to
6 find out that they all ate at restaurant A or that 80
7 percent of the first 6 people we hear about reported
8 eating at a McDonald's Restaurant the week before
9 they got sick. Now that may reflect how popular
10 McDonald's is or it may be something that's worth
11 pursuing, and so we'll take that on merits.

12 We may have exposure information that's
13 about food consumption patterns, and we can look
14 through that for common foods or they all went to the
15 same event, or they were all in the same city for
16 some reason.

17 We'll also at the same time be looking for
18 additional cases because usually we're starting with
19 one or with two or three people, and we need more
20 than that to have a lot of confidence most of the
21 time. So we're calling labs in our state. We're
22 calling hospitals looking for people that may be in

1 the pipeline so to speak, but they haven't actually
2 reached our public health reporting system in the
3 usual way yet. We'll be calling our neighboring
4 states, and we'll be putting notices on e-mail where
5 it's saying are you seeing this elsewhere? So
6 finding additional cases is extremely important to
7 get investigations moving quickly, and then we'll be
8 generating hypotheses about what it could be.

9 This is one kind of questionnaire we use in
10 Oregon a lot. If we don't have sort of an obvious
11 suspect, we have a thing that lists about 4 or 500
12 different kinds of foods. It's in effect sort of a
13 Hail Mary pass. They've got to have something in
14 common. If we ask them about everything, then we can
15 just see what they do have in common. And so we use
16 these long interviews, and they are long, taking
17 about 45 minutes or so. This is an example of a
18 fragment of one page and where people responded when
19 they were asked, yes, they've been eating bagged
20 prewashed spinach. That was a very easy outbreak to
21 identify the source of. It really just took a few
22 hours of work once we had a short list of cases and

1 began to interview them. Very, very easy. It
2 depends on the outbreak, of course, but some of these
3 are not at all difficult to find when you apply some
4 disciplined approach to it, and you have enough
5 cases.

6 When we have multistate outbreaks, and
7 we're working on these kinds of things, those of you
8 who don't do this, again this is a message for you,
9 you should understand that there is not always a
10 clear hierarchy. These are not centralized
11 investigations necessarily. They're often, in fact,
12 I would say usually have a leader that emerges
13 however temporarily at one or two states, but they're
14 not centralized. There are lots of agencies that are
15 involved in these investigations and don't expect
16 that to change.

17 No matter what happens at the federal
18 level, that's not where the early action is in
19 outbreaks. It's at the local and state level, and I
20 don't think we're going to get rid of the states in
21 the near term.

22 So you'll always have to deal with multiple

1 state agencies that are more or less cooperating on
2 these investigations. Whoever is in charge will try
3 and collect and disseminate the information, or at
4 least should, and agencies sometimes have little bit
5 different perspectives and different timetables and
6 this causes some tension or -- well, causes some
7 tension. (Laughter.)

8 The methods for these investigations
9 involve organically and depending on who's involved,
10 it's still very much a person driven business. It's
11 not very systematic in the sense of if you took out
12 some key people, the people would change quite a bit.
13 It's an interesting business.

14 But one thing we've seen so far and we're
15 working to try and get beyond this, to have
16 successful investigations now, it seems like you
17 usually need to have a critical mass of cases in one
18 or a couple of states, and if you have cases
19 scattered everywhere, it generally does not work very
20 well because nobody really gets motivated enough to
21 get stuff organized to move quickly.

22 So we're trying, and C4 is an example, to

1 help develop some more standardized methods that will
2 allow us to get beyond this person centric, we've got
3 four cases in Minnesota, so that's all we need,
4 solution to the problem or generalized solutions.

5 State and local health departments
6 fortunately, unfortunately, but certainly obviously
7 vary a lot, and they vary a lot in their capacity,
8 how many people they have, how interested they are in
9 this particular problem. They may be more interested
10 in running WIC Programs and immunization clinics.
11 Hard to imagine.

12 Foodborne disease may not be a priority for
13 them because they may have nobody that works there
14 that does that. What kind of follow up they do
15 varies a lot and the amount of funding they have to
16 do this is different. There are different legal
17 structures. Lab capacities differ. This is very
18 confusing I think to people in industry when you have
19 these outbreaks that affect you because you're
20 interacting with different people that seem to have
21 kind of similar titles or similar positions but
22 they're not really necessarily coming from the same

1 place.

2 To turn it around, when we work with
3 companies and industries in multistate outbreaks and
4 these are generally commercial product outbreaks, the
5 companies vary a lot. And some have been very good
6 to work with, very open and easy to work with and
7 quick to give us information that we need. Some are
8 not so great. Some people make very poor choices in
9 outbreak investigations and that complicates things.
10 One thing we've learned is that a lot of companies
11 like to have direct contact with epidemiologists and
12 sometimes the state level people are more willing and
13 able, both from a legal and I think a philosophical
14 point of view, to provide information that federal
15 agencies may not be able to share or at least willing
16 to share.

17 So I'm going to stop because I think we're
18 running out of time. The pace of these
19 investigations varies a lot and epidemiology does
20 take time. Just identifying that you have a problem
21 takes a while, and for some of these infections like
22 *Salmonella* or O157, it's usually at least two or

1 three weeks after the first exposure at a minimum
2 before a health agency could even have a chance of
3 realizing that there's a cluster. So that's just not
4 going to change.

5 Then if the cases are sufficiently
6 clustered, we can move relatively quickly but if
7 they're not very clustered, this, this early stage
8 may drag on for weeks or even months as cases
9 accumulate, and we're not always proud of that but I
10 mean that's a fact.

11 Generally, though, the end game of a lot of
12 outbreaks moves them very quickly, often within
13 hours, and people are sometimes caught off guard by
14 something that goes from a suspect you hear about to
15 people putting out press releases hours later or the
16 next day. It can move very, very quickly and we
17 don't have time necessarily to keep everybody that
18 would like to be in the loop.

19 We work with regulatory agencies, mostly
20 with FDA, more commonly with FDA but sometimes with
21 USDA. Our experiences have been generally fairly
22 good, more innocuous I should say. USDA -- since

1 this is a USDA sponsored meeting, and I was asked to
2 comment on it, it's okay. (Laughter.) It's not
3 great but it's okay. We don't have that much
4 interaction with you in outbreaks about things that
5 are controversial.

6 Generally local health departments, we
7 identify outbreaks, we identify vehicles, we turn
8 this information over. Sometimes we sort of cut the
9 cord at that point, and it's totally handed off.
10 Sometimes we're very involved in the follow up of how
11 the product became contaminated, what should be done
12 about it. That may be a function of who's doing it
13 and how interested they are. It may be a function of
14 where that next step occurred. If it happened to
15 occur in the same state as where you're located, we
16 tend to be more involved obviously. If it's in
17 another state, we're not able to travel there unlike
18 the federal agencies. This was, well, a ground beef
19 associated outbreak that Washington identified
20 through an early cluster of cases. Everybody
21 reported eating this very uncommon kind of specialty
22 kind of ground beef that was very expensive. So

1 everybody remembered it (laughter) and it wasn't
2 difficult. What was difficult was figuring out when
3 the problem occurred, until we learned that we had an
4 Oregon case that matched this and fortunately, the
5 Oregon case uniquely did not throw out their garbage.
6 They stored it on site for months on end and then
7 they would haul it off to the dump. So we sent a
8 local health department person to go through 15 bags
9 of trash that they had on a trailer looking for the
10 packages. They said they're in there somewhere
11 (laughter) and, in fact, they found the packages and
12 that gave us the production codes that everybody knew
13 we wanted and that's very helpful. So again
14 sometimes you get this information. We do understand
15 the need and the desire of regulatory agencies to get
16 that information. Sometimes it just doesn't exist
17 but when it does, we'll try and get it for you. This
18 package incidentally was positive for the pathogen.
19 Not only do we get the codes but we got the bug out
20 of the pathogen, too. They're hardy.

21 I should stop before I get into trouble.
22 We have complicated relationships with federal

1 agencies. We acknowledge and admire and take
2 advantage of a lot of the technical expertise that
3 these agencies have. A lot of them have done real
4 work before they ascended to their current positions
5 and are very knowledgeable about certain segments or
6 broad segments of the Agency, segments that we know
7 very little about really other than as general
8 consumers.

9 They have an incredible -- to send people
10 out and get data. Once the decision to commit to an
11 outbreak investigation is made, you know, there can
12 be dozens or hundreds of people deployed, and we
13 can't do anything like that in our states.

14 Regulatory agencies, however, are not very
15 good at sharing information. They're very good at
16 getting information and responding to it, but they're
17 very, very poor about sharing it, and that may be a
18 legal restriction or it may be institutional. It's
19 probably something of both. They can be very slow to
20 get going, and not terribly slow in a grand scheme of
21 things, but slow from an epidemiologic perspective.
22 They're very centralized. It's very hard for say FDA

1 people in our region to do things to support an
2 outbreak investigation without getting the blessing
3 from Washington, D.C. It's just the way it works.
4 That's the way they're set up which seems surprising
5 to us. Epidemiologists are very decentralized.

6 As you'll hear more of, I'm sure, there are
7 very -- although they can get a lot of people into
8 the field, they have such limited budgets that they
9 have to pick and choose their battles and that
10 sometimes is frustrating to us, and sometimes they're
11 not so good at coordinating their media messages.

12 But anyway I will stop because time is of
13 the essence, too. And thank you for your attention.
14 We get lots of these outbreaks, so we'll have many
15 opportunities to work together in the future and
16 improve.

17 (Applause.)

18 DR. HAGEN: Thank you, Bill, for all of
19 those very honest and valuable insights, and really
20 that is why we asked Bill to come talk because we
21 knew that he would be very candid.

22 Our next speaker is Lisa Hainstock from the

1 Michigan Department of Agriculture to give a little
2 bit of a state regulatory perspective.

3 Lisa holds a Bachelor of Science degree in
4 environmental and occupational hygiene from Northern
5 Michigan University and has worked in environmental
6 and public health for the past 18 years. She has
7 worked for a number of years at a local health
8 department level as a sanitarian, then worked with
9 the Michigan Department of Environmental Quality as a
10 regional non-community public water supply
11 consultant.

12 Since 2002, she has worked for the Michigan
13 Department of Agriculture as a food safety specialist
14 and serves as an adjunct instructor at Michigan State
15 University's National Food Safety and Toxicological
16 Center. The main focus of her work at MDA is
17 functioning as a liaison between local, state and
18 federal regulatory and public health agencies during
19 foodborne outbreaks and recall management.

20 Lisa Hainstock.

21 (Applause.)

22 MS. HAINSTOCK: Can people hear me?

1 UNIDENTIFIED SPEAKERS: Yes.

2 MS. HAINSTOCK: Oh, great. Okay. As my
3 colleague, Dorothy Gonzales, says, essentially I work
4 as the state liaison in outbreak coordination and
5 recalls within the State of Michigan. Dorothy aired
6 a little bit of our dirty laundry. We're working on
7 it, but we still haven't got it quite right but let's
8 go ahead and get started.

9 I'm just going to talk from a couple of
10 different perspectives today. One is the state
11 regulatory perspective, and I'll try to keep things
12 very brief. I'd like to talk a little bit about the
13 collaborative relationships we actually have been
14 able to create in Michigan and in the other states.
15 Some of the common challenges because I think that's
16 what we're all here to talk about, and also the
17 future. What are some of the things we might want to
18 consider because mom always said, don't make
19 complaints if you haven't got possible solutions.

20 I'm speaking mainly from a Michigan
21 perspective today but in polling some of my other
22 colleagues around the country, at the state

1 regulatory level, I have found that many of us share
2 the same issues, the same questions. And so even
3 though I am speaking from a Michigan perspective, I
4 think many of us would accept that this is probably
5 more of a nationwide issue.

6 From a statewide regulatory perspective,
7 essentially we often function as a funnel for
8 information between the locals and the federal
9 investigators just like Dorothy said. And much of
10 that is, of course, just kind of the nature of the
11 beasts, the way our governments are set up. And so
12 as such, we kind of walk on the fine line of between
13 being a really good partner and being a choke point,
14 whether that be a real choke point, all of the
15 information coming to me and then me having to then
16 distribute that out or a perceived choke point
17 meaning that perhaps our local investigators are
18 feeling that we are holding things back, and in some
19 cases we actually are.

20 Also one interesting thing I found when I
21 spoke to some of my colleagues in other states at the
22 regulatory level is that I asked them about the

1 perspective on outbreaks, and to a person, they all
2 talked in terms of recalls. And that's because at
3 the regulatory level, many times the multi-
4 jurisdictional outbreaks for us ultimately do end up
5 as a recall issue.

6 So this is kind of the basic set up, a
7 little bit about in the State of Michigan, and from
8 what I understand, a number of other states as well,
9 the local health departments, of course, they do
10 coordinate with the state regulatory agencies as well
11 as the state public health.

12 One thing I'd like to draw your attention
13 to is the connection between the state regulatory and
14 state public health departments. Even though we do
15 have our issues, particularly at local health
16 departments, we have people who don't want to share
17 their toys, I really am very grateful that in
18 Michigan I share an extremely close relationship with
19 my counterparts at the State Public Health
20 Department. Again, we have each other on speed dial.
21 We contact each other at least three or four times a
22 week to keep ourselves and keep each other up to

1 speed on things that might be brewing. We've got a
2 cluster of this illness in this particular region.
3 We're kind of looking at maybe some of this
4 particular product. Have you gotten any complaints
5 on it. Or I get information from the federal
6 partners about positive things coming across on
7 recalls, and I can talk with my federal partners, get
8 information about whether PFGE is available and let
9 my state public health agency counterparts know, yes,
10 the PFGE is in PulseNet. It says that there hasn't
11 been any illnesses associated, but can you take a
12 look and see if we have anything that matches, and we
13 actually have had success in the past of finding that
14 we do have cases that ultimately turned out to be
15 available or to be associated with recalls.

16 We also have a pretty good working
17 relationship with our industry in the State of
18 Michigan. Anytime we have recalls that have been
19 announced for Michigan, we automatically send out
20 notifications to our Michigan Grocers Association,
21 Michigan Restaurant Association, and a number of
22 other people at private entities to let them know,

1 hey, this is something that we know we have in
2 Michigan, can you start taking a look in your
3 department or your agency.

4 They've also been very good, for the most
5 part, sharing distribution lists with us because as
6 you know, we've all talked about the issue of trying
7 to get information from the feds and occasionally
8 there's a very long time lag between the time that an
9 outbreak is announced and the time that a recall is
10 announced, and we ultimately get that information.

11 There's been a few other relationship
12 building efforts as well, too, and I see national
13 associations here, and I should have also included
14 our state associations. The national associations
15 such as AFTO, NACCHO, ASTHO, a number of the other
16 ones, have been very good about trying to make sure
17 that the states are seeing local perspectives, and I
18 think for many of us, we need to always keep that in
19 mind is that the locals have got a lot to offer and
20 since they are the ground troops in the course of
21 many of these multistate outbreaks, we need to make
22 sure that they're at the table, that their voices are

1 being heard, and so I really appreciate the efforts
2 that have taken place there.

3 FIRST, many of you might not have heard of
4 it, it's called Foodborne Illness Response Strategy
5 Training. Believe it or not, that was actually the
6 prequel as it were to the national Epi-Ready Program
7 and that was developed in Michigan. I still remember
8 back in the early 2000s when CDC and NEHA came to
9 actually see us put on FIRST training, and then it
10 was adopted as a national standard, and that, of
11 course, has been very good at building relationships
12 between environmental health and the communicable
13 disease and laboratory --

14 The health alert networks, all of the
15 states do have health alert networks of some form,
16 and in many cases, different states actually are able
17 to communicate on their HAN alert systems with other
18 states, and I think that that's a very good thing,
19 but I think we've got a long way to go there.
20 Michigan actually uses a MI FOOD Yahoo group, where
21 anyone can join and the Michigan Department of
22 Agriculture actually manages the Yahoo group, but we

1 were able to rapidly communicate with our partners in
2 public health and community health and environmental
3 health on food related issues. Everything from
4 interpretations of the food laws to announcements on
5 recalls or potential outbreaks.

6 Emergency action procedures, how many of
7 you remember the 2003 blackout? How many of you were
8 affected by that? Anyone? A large portion of
9 Southeast Michigan, specifically the Detroit area,
10 lost power for several days in Michigan, and we had
11 counties, that some counties were closing their
12 restaurants and the counties that were immediately
13 across the street were allowing restaurants to
14 continue to operate or different issues where we had
15 multi-jurisdictional outbreaks where different
16 counties were doing different things that were
17 creating difficulties.

18 So what we did is we worked with our
19 several local health departments, with the Michigan
20 Restaurant Association and the Michigan Department of
21 Agriculture to put emergency action procedures
22 together. People were saying we couldn't reach the

1 health departments to ask what we should do. We
2 couldn't reach the Department of Agriculture to ask
3 what we should do. So I said, you know what? Let's
4 work together. Let's come up with a plan for what
5 you should do next time. So if you're in an
6 emergency, a power outage, an outbreak, this is
7 something you can go to. So you don't necessarily
8 have to run to us and stand there with your hands
9 open saying help us please. Here's the help that we
10 put together. We're very proud of this actually
11 after looking at this now as a national standard as
12 well. So I'm very proud of the fact that Michigan
13 has been a forerunner of this.

14 The national and state exercises, of
15 course, that Dorothy mentioned, I think that those
16 have gone a way to starting to build some
17 relationships, open lines of communication and also
18 have been helpful in identifying where those lapses
19 in communication are occurring.

20 And the last thing are the real life
21 experiences. I think what most of us can say with a
22 reasonable assurance, with in the last couple of

1 years, we've gone through some pretty rough patches
2 between peanut butter and spinach and a number of
3 other things. We've learned some hard lessons, and I
4 think that many of us have taken those lessons to
5 heart. So those have been some really good
6 relationship building efforts as well.

7 Here's a success story that was not
8 necessarily just specific to Michigan, but I think
9 Michigan's experience was quite unique. How many
10 remember the *Salmonella* and orange juice outbreak? I
11 think it was 2006. Okay. Michigan had several cases
12 of the *Salmonella Typhimurium* that were linked to the
13 PFGE to other states cases as well, and the
14 epidemiology provided by our partners at the state
15 and local health department level, led us to believe
16 that we were looking at an orange juice issue. The
17 problem was that it was orange juice under a variety
18 of names.

19 Within several days after I received that
20 notification from Community Health, I was able to
21 marshal our efforts at Michigan Department of
22 Agriculture who were able to go out to various stores

1 where things were sold under store labels and within
2 I think 48 hours, they were able to trace it back to
3 a manufacturer in Florida who was manufacturing under
4 a number of brand names as private labels.

5 So using that, we were able to work with
6 our federal partners and very rapidly get that
7 information out to the other states. So they were
8 able to look at that and start trying to do trace
9 back to associate with that.

10 What was interesting in this particular
11 case is the manufacturing company in Florida actually
12 called me within two or three days and said our store
13 X in Michigan that we make product for said that one
14 of your inspectors was in and was asking questions
15 about our orange juice. What's going on? And I was
16 rather taken aback because at that point I didn't
17 realize that they had no idea that their product was
18 associated with an outbreak. And so I was kind of
19 hemming and hawing but I said, well, you know, we've
20 been looking at particular cases. There seems to be
21 some association with orange juice that we've been
22 looking at, and one of the products implicated, and I

1 said one of the products as we hadn't yet ruled out
2 anything else, appears to be your product. And my
3 first question then was, have you spoken with your
4 state regulatory agency? Have you spoken with the
5 FDA? You need to get on the phone with them right
6 away because I knew that there was other information
7 going at the state level and federal level, that they
8 just simply weren't aware of.

9 So that was one of those instances that I
10 think things worked really well for us. We were
11 rapidly able to respond. There was a national recall
12 sparked, and we were able to pull product off the
13 shelves relatively quickly.

14 Common challenges, because I think that's
15 what we're all here to talk about today, is where are
16 we falling down?

17 State regulatory and public health. Here
18 it is. I just lied to you, no actually I didn't, I
19 told you that we have a really good working
20 relationship with our public health partners, but we
21 still stumble up against that issue of HIPAA. My
22 public health partners at the state and federal level

1 still have difficulty sometimes sharing information
2 because they're afraid of HIPAA issues. They're
3 afraid if they give it out to us, that automatically
4 we're going to, I don't know, maybe put it out in the
5 paper or something like that, or we're not going to
6 protect it apparently and, you know, we do have State
7 FOIA laws that actually do prevent that, but I think,
8 you know, there have been some relationships that
9 have been damaged around the country through things
10 getting out when they shouldn't have, you know, case
11 in point is Cyclospora in raspberries and the
12 California strawberry issue, and I think we would
13 need to work hard to build those relationships back
14 up, and we need to build that trust.

15 Another one is Epi-X and some of the other
16 toys. I had absolutely no idea there was anything
17 going on with peanut butter until the CDC came out
18 and said Peter Pan peanut butter, FDA came out and
19 said massive recall, and all of a sudden it was like
20 you felt like you came in, in the middle of a movie.
21 Now had I possibly had access to Epi-X, which for
22 whatever purpose I'm still having difficulties

1 getting on, I think it's because I don't have the
2 word health anywhere in my title or the title of my
3 agency. I don't know what that is. I had no idea
4 that there was something going on.

5 Now I'm a professional. We're all
6 professionals. I think if we know that there's
7 something that's still in an investigation
8 standpoint, this is not for public release, but it
9 would have been nice to know before the ceiling fell
10 in on us.

11 Sometimes state versus state. I don't
12 necessarily know who all of my counterparts are in
13 other states. Same thing that Dorothy is saying, she
14 doesn't know who some of these people are, and we
15 really need to work hard on trying to make sure that
16 there's some central location that we can go to, and
17 if you know of one, please let me know, where we can
18 go and say that's the person I need to talk to. Who
19 is my counterpart? I know that there's some efforts
20 maybe with FoodSHIELD and some of the other things
21 that have been brought up, but I still haven't seen
22 it.

1 And, of course, all of us I think are
2 saying, you know, lack of travel funding is creating
3 some real issues. In our association, in our
4 experience, we need to keep our networking up. We
5 need to make sure that we have faces with names, to
6 build relationships so I can pick up and say, you
7 know, hey, Paul, hey, Mike, in State X and he
8 automatically is not trying to learn who I am while
9 we're in the middle of a crisis. That lack of travel
10 funding is really creating some issues because as
11 people are retiring, those networks are being lost.

12 The states and the feds, okay. I'm working
13 right now on an outbreak where I'm talking with my
14 state public health partner who said CDC, we've been
15 on calls with CDC but FDA isn't there. And I said
16 why is that? Well, I think FDA's kind of figured
17 that they know what the problem is. So they're no
18 longer participating in any calls. And so as a
19 result, I'm not getting any information from my
20 federal partners because they're not participating
21 consistently through some of these things. So I keep
22 feeling sometimes there's these secret meetings.

1 Same thing with CDC, that they'll meet with my public
2 health partners but, you know, us as regulators are
3 being told that there's something, you know, that
4 there's a meeting going on. We'll tell you when we
5 think you need to know.

6 I know we've talked a lot about outbreaks
7 today, and I keep kind of going back to the recalls
8 thing, but again for us, it's not one really without
9 the other. There's a lot of frustration during
10 recalls, and I empathize completely with Dorothy
11 Gonzales. Why can't we have distribution lists? And
12 she has no idea how difficult it was for me to try to
13 jimmy around to give you the information we actually
14 gave you because we do have a signed MOU, but the
15 question was, is that it was beyond our resources to
16 be able to respond, and I had to talk really nice and
17 really fast with our federal partners to say can I at
18 least give them some name so they can help us, and
19 they kind of hemmed and hawed but I think in that
20 situation they kind of said, well, just be really
21 careful about the information and that can get very,
22 very frustration with MOUs.

1 Jurisdictional issues, if we have an
2 outbreak that's involving an MDA regulated facility,
3 but also its regulated by our federal partners, we
4 have to sit down and try and work those things out as
5 to who's going to be the lead. Most of the time that
6 works pretty smoothly for us but occasionally we have
7 had some issues where we've kind of butted heads
8 because I'll say, no, wait a minute, this is one of
9 our facilities. Yes, but it crosses state, you know,
10 product crosses state lines. So even though we
11 haven't been in a facility for five years, we're
12 going to be in charge. That's a little difficult to
13 swallow.

14 And you'll notice I have a logo down there.
15 It says Federal Bureau of Investigation. Several
16 years ago, in Michigan, we had an intentional
17 poisoning of people with a nicotine-laced base
18 pesticide in ground meat. This was one I think that
19 was a case study in what not to do because we had
20 issues where the actual industry partner called the
21 Michigan Department of Community Health. This was
22 right after the holidays and said we're pulling a

1 recall. We've had these complaints. We've already
2 submitted samples to a private lab, and we honestly
3 were not aware of the fact that nobody had contacted
4 the local health department. So they were not yet
5 aware of the fact they had people who were poisoned
6 in their own jurisdiction, and that really was an
7 issue that we found out the hard way. We need to
8 make sure those phone calls are made right away.

9 We also had other players come into it that
10 really had absolutely no idea how public health
11 investigations go, and that was the FBI. I don't
12 know how many obvious opportunities many of us have
13 to work with law enforcement. Have any of you ever
14 worked with law enforcement in outbreaks? Were they
15 good or bad?

16 (Inaudible comment.)

17 MS. HAINSTOCK: Okay. What -- did --

18 (Inaudible comment.)

19 MS. HAINSTOCK: Okay. Anybody else?

20 (No response.)

21 MS. HAINSTOCK: We found out, one, our
22 terminology was entirely different. To us a case was

1 a case of illness. To them, a case was the actual
2 criminal investigation. So when we kept talking
3 about cases, they were hearing something different
4 because we had never actually sort of talked about
5 the jargon that we use.

6 Secondly, FBI swept in and said we're in
7 charge, and this is the way it's going to be, not
8 realizing that public health and the state regulatory
9 agencies have a role to play in this so we can figure
10 out what's going on with this particular issue, and
11 we really had some very difficult issues involved in
12 just trying because here we are, we were exchanging
13 business cards over the bodies of the sick literally.
14 I mean, well, not literally but I mean at the time
15 when we were trying to work together as a group, we
16 didn't know our partners and they didn't know us.
17 And one thing that I could recommend is that when we
18 get into these national exercises, we really should
19 be starting to always treat these, even if it's one
20 where it's considered to be accidental, get law
21 enforcement at the table and getting media at the
22 table because they can be your friend or they can be

1 your foe.

2 Communications and info sharing, and I show
3 this as a double-edged sword. Sometimes, and I think
4 as a regulator, we often find that the time we find
5 out there is an outbreak or we find there's a recall
6 and we get distribution lists, we often feel it's too
7 little too late. It's really hard to -- I think in a
8 lot of situations, feel like you're making an
9 effective response especially during a recall because
10 it's like if this happened four weeks ago, the
11 average time I was told between an outbreak and a
12 recall is 40 days. That's a long time for a lot of
13 product to be consumed by people. And then we're
14 called to task by our legislature in our states or
15 even at the federal level, why is it taking you so
16 long? And I think we really need to reassess that.

17 And decision, is somebody going to do
18 something? Falling back to the situation, I think
19 that Bill said, where we're feeding information to
20 the federal agencies, we're not getting anything
21 back, and we don't see anything happening and we're
22 wondering, are we wasting our time? Are we, you

1 know, am I sending trace back information and it's
2 just going into a black hole? Has somebody even
3 talked about this yet at the federal level? And I
4 think that that's really frustrating for many of us.

5 Media, sources of information,
6 unfortunately I think all of us could say that the
7 first time we've heard about some outbreaks is by
8 reading it in the newspaper which is rather
9 unfortunate but it is just a truth, but it is, also
10 the media is a double edge sword in and of itself,
11 too, because it can also be used by us to get
12 information out.

13 Rapidly changing situations that affect our
14 response. I know that with I think the latest -- we
15 have a large canning facility in the State of
16 Michigan which shall go unnamed, which resulted in a
17 very recent large recall that multiplied
18 exponentially in size, and I think most of you know
19 what I'm talking about. Information was going so
20 fast, and this was when we were trying to work with
21 our federal partners, it was moving so quickly that
22 we were trying to get help with local health

1 departments. We would say, okay, look in these
2 facilities or we think it's out in the school
3 systems. They would go out and do actions and then
4 the next day we would get another recall that said,
5 oh, yeah, by the way, it's not just green beans, it's
6 Mexican chili beans and it's this and it's that, and
7 I'm not sure how you can get around that. Sometimes
8 it's just the nature of the beast.

9 And lastly, well, maybe not lastly, I can't
10 quite see it there, technology. We've got this
11 wonderful technology. Jack -- and I were talking
12 this morning about when we were first trying to work
13 on recalls before the advent of computers and things,
14 you would have to get your information, copy it down
15 accurately and then call people individually and make
16 sure that they were copying it down accurately, lot
17 codes, use by dates, that they weren't transposing
18 numbers and that, of course, obviously is just, in
19 this day and age of rapid information, it just
20 doesn't work for us anymore.

21 We have a lot of technology available to us
22 and while we do actually use it effectively, I think

1 there's a way that we can use it even more
2 effectively. I mean one of the -- I think one of the
3 best and the worst things that I ever got was this
4 BlackBerry because now I can't use the excuse, well,
5 you know, I didn't get your e-mail. I've been out of
6 the office for three days. I better be checking my
7 e-mails because I have, you know, it's here now. And
8 confidentiality, distribution lists, the 500 pound
9 guerilla, the one that we all have to deal with.

10 The issue of state and federal MOUs is
11 really confusing. It's difficult, and it's really
12 difficult to tell if it's a help or if it's really a
13 hindrance.

14 I have a pretty good working relationship I
15 think with my federal partners in Michigan and
16 they're pretty good about sharing distribution
17 information with us, but same thing, frustration at
18 Dorothy's level, what we can do with that
19 information, we are so limited and I think even just
20 giving out the little bits and pieces of information
21 we can to the locals on a "need to know basis," it's
22 effectively tying our hands in responding

1 appropriately to these issues.

2 The speed of distribution lists, by the
3 time the distribution list go from the company to the
4 federal agencies and then it's farmed out to their
5 regions and then they determine what they're going to
6 when it comes to us, it's all time that's being lost,
7 you know, days or sometimes weeks go by before we
8 find out about it. And in the interest of public
9 health, it seems as if commercial interests are
10 taking precedence over public health response. And
11 that's extremely frustrating for states. Again,
12 we're that funnel of information, and sometimes we
13 are a choke point because we can't pass it on, and it
14 shouldn't be that way.

15 Interestingly enough, in the
16 Hallmark/Westland recall, I saw an article that
17 actually showed where the State of California put
18 distribution lists right on the web, and so I called
19 California. I said how can you do this? Is anybody
20 from California here? It's okay. You can raise your
21 hand. We won't hurt you. I thought, wow, this is
22 really cool. How did you get around this? And they

1 said because we don't have a MOU with the federal
2 agencies. They actually passed a law that required
3 that companies give distribution in their state
4 directly to the State of California, and it's up to
5 California how they use it. And in that particular
6 instance, they put it right on the website. I was
7 like -- I was amazed and shocked and in awe because
8 it was, oh, my gosh, I could get this out to my
9 locals, go here, here's where your facilities are. I
10 know that that's an issue but it has been discussions
11 at the FoodSHIELD. Say we put it on a secure site
12 where the state and local agencies can get in and
13 look at it, but it's not for all and sundries to look
14 at, is that a happy compromise? Maybe so.

15 The states sharing with local health
16 departments again, that's a stumbling block for every
17 single time.

18 So here's suggestions. Like I said, don't
19 make complaints unless you've got ideas.

20 The first one is can we include some non-
21 government partners in outbreak response or recall
22 response. Academia, I've actually had offers from

1 the University of Michigan's School of Public Health
2 to assist us in some of these issues with trying to
3 coordinate information, trying to contact companies
4 or trying to do effectiveness checks for recalls.
5 They do have the capacity to manage that data, to get
6 that data to us quickly. In some cases, such as with
7 Castleberry last year, it was more I think than any
8 single agency in the state could handle on its own.
9 And that would have been nice.

10 Also Michigan State University, we do have
11 what's called the reportfoodpoisoning.com, and it is
12 a nice website that is unfortunately very underused
13 where people can go and actually put their name,
14 their contact information, and a little bit of
15 information about when they got sick and what they
16 may have eaten. It's not the be all and end all. It
17 doesn't collect Epi information, but it's a starting
18 point for screening purposes when you're dealing with
19 an outbreak.

20 What we've tried to do, and unfortunately
21 with mixed success in Michigan, is talk to local
22 health departments about, you know, when your office

1 hours are closed, and you know you're dealing with an
2 outbreak, putting something on your voice mail that
3 says, if you're calling to report illness associated
4 with X outbreak, go to this website and put some
5 information in and what it does is it generates
6 information to the locals that gives a name and a
7 number to call them back. More times than not
8 unfortunately, people either just lose interest in
9 calling the health department or they try to get
10 through when all the phone lines are full, and they
11 get frustrated and so they don't make that contact.
12 And with multi-jurisdictional outbreaks, when you're
13 dealing with large numbers of people, you need to get
14 all the information you can as quickly as possible.

15 So again, it's a plug for reporting food
16 poisoning. It's a system I think that can be taken.
17 It can be used and changed.

18 Industry, again we're working very hard in
19 our State to build relationships with industry. I
20 have all of my industry contacts with Meyer
21 Corporation and Kruger and Spartan Foods and any
22 number, right on my BlackBerry. I know exactly who I

1 need to talk to. So I can talk to them at anytime.
2 We feel very comfortable with sharing as much
3 information as possible, and they know that they can
4 trust the information that I'm giving them because
5 I've sat down, I've talked to them. There's a face
6 with a name.

7 We've actually been very successful in
8 including them in planning exercises at the state
9 level. And in actually formulating our protocols
10 like our EAPs and some of other outbreak and
11 emergency response issues. And as well as some of
12 even our policies. They're very actively involved in
13 the recent change in our food laws. We adopted the
14 2005 Food Code, and we had industry at the table.
15 And including them in the state emergency operation
16 center in the course of a real -- God forbid we get
17 another Castleberry. Getting the people at the table
18 who need to be there. The information doesn't need
19 anymore barriers.

20 And, of course, reaching out to the little
21 guys, the ones who don't belong to the associations
22 and doing what we can for them.

1 Okay. Here's some of the common systems
2 and protocols that are actually in use but maybe
3 underused. One is CIFOR. I'm not going to go into
4 that. I don't want to steal anyone else's thunder
5 but the Help Alert Networks, all the states do have a
6 Help Alert Network, and I find it very useful in our
7 State for getting information to my public health
8 partners, but some of the state systems, Help Alert
9 Networks actually link. They can talk to each other,
10 and some of them don't.

11 Now in certain situations when you're
12 dealing with a multistate outbreak, it would be nice
13 to be able to get that information out in a much more
14 timely fashion to the right people. Then I don't
15 have to rely on a calling card with, you know,
16 everybody's little business cards in a thing and
17 calling people one at a time to get information to
18 them or from them.

19 Putting out things like traveler's alerts.
20 A couple of years ago unfortunately Michigan State
21 University had their commencement in the spring. A
22 very popular, high end restaurant had hundreds and

1 hundreds of people visit that restaurant within that
2 commencement week, people from all over the country
3 and from all over the world, coming to see their kids
4 graduate. It ended in a massive norovirus outbreak,
5 and that would have been nice where we could have put
6 something out nationwide and said we had an outbreak
7 in Michigan associated with Michigan State
8 University's commencement, you know, if you have
9 cases that have history of travel to Michigan and
10 have reported illness, we have something going on,
11 folks, but your HAN Alert system again, since it
12 doesn't all talk to each other, we lost an
13 opportunity there.

14 We actually tried to add our industry
15 representatives to our HAN system, our Michigan
16 Grocers, Michigan Restaurant Association, and a
17 number again of other private companies. So when we
18 need to get information to them quickly, I can do a
19 one stop thing.

20 Epi-X, does anybody understand why I still
21 can't get on there? Why can't I get on Epi-X? Maybe
22 somebody doesn't like my face, but --

1 MS. GONZALES: You're on a bad list.

2 MS. HAINSTOCK: Huh?

3 MS. GONZALES: You're on a bad list.

4 MS. HAINSTOCK: On a bad list. I don't
5 have health in my agency title. We need to be able
6 to get on these systems. Again, what it does though
7 is it comes with the responsibility of not taking
8 action until it's the appropriate time. Just being
9 able to be kept aware of what's coming on, so the
10 peanut butter emergency doesn't plop on our heads
11 again.

12 And FoodSHIELD. FoodSHIELD I think has the
13 capacity to be a really terrific one-stop shop, and
14 I'm not going to take any thunder away from North
15 Carolina. I think that they may be talking a little
16 bit about FoodSHIELD later, but I'm not sure, but I
17 think this is one of those ones where we can be
18 talking with our partners quickly in real time and
19 across disciplines, the lab and the environmental
20 disciplines quickly. Have all the links to FERN
21 labs, to eLEXNET, the Homeland Security Information
22 Network, all in one stop shop. There's just too many

1 sources of information spread across the board too
2 widely, and there's just no way of knowing where they
3 all are.

4 Training, you know, using it as a training
5 tool, to get information out quickly, say if we have
6 another multi-jurisdictional response like a
7 Castleberry or a New Era or something else, getting
8 training to our local partners quickly about here's
9 forms, here's how you use them, an excellent
10 opportunity there.

11 And also an event management tool,
12 something that is, you know, that you can do web
13 reporting in real time. You can upload your audits
14 directly to a central collection. So again, we're
15 not having the states then trying to gather all the
16 bits and pieces and then funnel it to the federal
17 agencies because at this point in time, with the
18 nature of the emergencies we're dealing with, we're
19 just -- we don't have the luxury anymore of wasting
20 time that we are currently doing.

21 So with that, I think I'm just going to get
22 on with things so we can get moving, and I'll be

1 available for questions during the panel discussion.

2 Thank you.

3 (Applause.)

4 DR. HAGEN: Thanks very much, Lisa. We are
5 running a little bit behind schedule but I think what
6 I'm going to try to do is still fit in the remaining
7 two presentations from this section since they really
8 kind of go together with the local and state
9 perspectives, and then we'll take our break more at
10 about 10:15. So please feel free to get up and take
11 a break if you need one before then.

12 Our next speaker is going to be David
13 Bergmire-Sweat who is representing the Association of
14 State and Territorial Health Officials. David earned
15 his Master of Public Health from the University of
16 North Carolina, School of Public Health, in 1993.
17 Since then, he has worked in public health at the
18 state agency level for the Texas Department of State
19 Health Services and then North Carolina Division of
20 Public Health, in academia with the North Carolina
21 Center for Public Health Preparedness at the UNC
22 School of Public Health in Chapel Hill, and with the

1 national non-profit organization, the American Social
2 Health Association in Research, Triangle Park, North
3 Carolina.

4 He has more than seven years experience
5 working as a field epidemiologist and is currently
6 the Foodborne Disease Epidemiologist with the North
7 Carolina Division of Public Health.

8 (Applause.)

9 MR. BERGMIRE-SWEAT: Thank you, and I'll
10 try to be brief, and I want to emphasize that North
11 Carolina today is not responsible for me being here.
12 I'm here on behalf of the Association of State and
13 Territorial Health Officials or ASTHO as you may
14 know.

15 About ASTHO, ASTHO is the non-profit
16 organization that represents -- it's the membership
17 organization for all of the state health officials
18 for the 50 United States, the 6 territories, Guam,
19 Micronesia, Northern Marianas Islands, U.S. Virgin
20 Islands, Puerto Rico, American Samoa, plus the
21 District of Columbia. Those are the 57 that are the
22 member health agencies or health officials that

1 comprise the membership of ASTHO.

2 And what ASTHO's vision is, is we want to
3 have all of our populations and all of our
4 jurisdictions, you know, we want to see healthy
5 people living in a nation that's free of preventable
6 illness and injury, and I think that this vision
7 statement is really important when we get to some of
8 the communications issues. It's come up several
9 times that one of the biggest problems in this area
10 of improving communications that could possibly
11 benefit from some sort of a change would be the
12 ability to share distribution lists from the federal
13 agencies to the local level. That's the most
14 important thing. That's probably the most important
15 thing. Because we are trying to prevent illness and
16 injury and in order to do that, knowing -- being able
17 to microtarget who are the people at risk is probably
18 the most important piece of information we could get.

19 As far as our mission within ASTHO, of
20 course, we want to transform the public health
21 practices within the states and territories to help
22 our members improve the health and wellness of the

1 populations. That's the mission of ASTHO.

2 So we have a saying in public health that
3 when you've seen one health department, you've seen
4 one health department. (Laughter.) We do in the 57
5 state and territorial health agencies, they're
6 organized in a number of different ways, and I was
7 trying to figure out the right analogy and I haven't
8 quite figured out the right analogy but in a food
9 safety meeting, you might say when we're approaching
10 Thanksgiving, you can ask people do you want dressing
11 or do you want stuffing. It's basically the same
12 thing but not really, and we all are doing the same
13 things essentially. We all have many of the same
14 functions but how we get there and, you know, the
15 flavor and texture and the way we organize things may
16 be a little bit different. They can be freestanding
17 health agencies. They can be parts of umbrella
18 agencies. The authority you will find at state
19 health agencies, sometimes centralized, sometimes
20 decentralized, sometimes it's mixed or shared.

21 The size of health agencies varies and this
22 presentation will be available to you and you can

1 read the small print at your leisure but, you know,
2 some of the state health agencies are very small,
3 1500 employees or less. Some, very few, have over
4 4500 employees and, you know, very extensive budgets.
5 So staffing levels are different. Resources are
6 different, and who they are comprised together with
7 at the state level can be different from one place to
8 the next, but virtually all of the state health
9 agencies do have a role in food safety or multiple
10 different roles in food safety.

11 And as Dr. Keene pointed out earlier, when
12 we talk about foodborne illness, we're really -- are
13 we talking about the illnesses that are shared and
14 people are exposed through food, or are we talking
15 about the pathogens that people get. Sometimes
16 they're foodborne. Sometimes they're not. But, you
17 know, when we think of food safety, we're also
18 thinking about enteric disease prevention generally
19 and that's why we're involved with drinking water
20 regulation, environmental health programs, food
21 safety, health facility regulation and inspection, a
22 variety of other issues, some of which touch on the

1 area of food safety in one way or another.

2 Now the principal functions that all the
3 state and territorial health agencies all are
4 involved in, in some way, is disease prevention
5 programs, disease detection or surveillance, counting
6 cases, outbreak response. That's typically a
7 universal function of state health agencies, and then
8 policy development, either statewide or territory-
9 wide level policies within a jurisdiction and then
10 nationally typically through our national
11 organizations like ASTHO and in our collaborations
12 with the federal agencies in helping develop or shape
13 policy. Those are all essential functions of the
14 state health agencies when it comes to food safety
15 and health protection.

16 And those health agency offices that are
17 involved in food safety have a variety of roles.
18 Certainly there's the executive leadership role, and
19 that's the one the governor is most familiar with or
20 the people who handle budgets at the legislative
21 level, you know, they're interacting primarily with
22 the heads of the agency, and the heads of the agency

1 have specific roles, but then we have environmental
2 health programs, epidemiology programs and in most
3 instances, the state public health laboratory is part
4 of the state health agency in some way.

5 So at the executive leadership level, the
6 state, you know, the state health official is
7 ultimately the decision maker, the final say for what
8 is going to go forward as action or policy from that
9 state. They typically are appointed by the governor,
10 and they report to the governor. So this is the
11 cabinet level person. They also are frequently the
12 state spokesperson. This is who goes and represents
13 all of our health issues at the legislature. This is
14 who goes on TV when they're wanting to take credit
15 for what we've done right. This is who goes on TV a
16 lot of the time when something is not going right.
17 And they also serve as a key liaison with the other
18 states and with the federal agencies.

19 On the environmental health side, our
20 programs are really involved. This is the restaurant
21 inspections. This is the sanitation inspections, the
22 septic system inspections and license and permitting,

1 and all the different things that go on and comprise
2 environmental health, the regulation aspects, the
3 permits and licenses, certainly food service
4 establishments and food processors are heavily
5 involved with our environmental health programs, and
6 typically there's a food education component. Now
7 it's very frequent for it to be housed in the
8 environmental side but it may be in other parts the
9 agency, you know, depending on where they put health
10 educators and how they organize it, it can be --
11 there can be some variability but everybody has some
12 sort of a role in this education and outreach.

13 When we come to the epidemiology, you've
14 heard a great deal about epidemiology already. So
15 I'm not going to spend a great deal of time on this
16 but I do want to mention about the surveillance and
17 detection piece. I mean one of the focuses of this
18 meeting is outbreak, you know, multi-jurisdictional
19 outbreaks and communication during those outbreaks.
20 But the bread and butter, every day what we do in
21 epidemiology really is we establish what the baseline
22 is. We're counting the cases. We're determining

1 what is normal so it is possible to recognize when
2 something abnormal is going on. You cannot recognize
3 an outbreak if you do not know what is normally every
4 day going on. When we do recognize outbreaks or we
5 have disease of special significance for some reason
6 because they are unusual or they pose a significant
7 public health risk to some population, we're involved
8 in the investigation, we interpret the data that's
9 collected, coordinate the interventions that are
10 necessary to prevent the further spread of illness
11 and then dissemination of information.

12 But I will admit that sometimes, you know,
13 when epidemiology contributes to the barrier, I'll
14 own up to that because I'm going to mention some
15 other barriers later, but one of the places where we
16 sometimes get in trouble as epidemiologists, is just
17 because we want to disseminate the information in a
18 particular way. We want to publish very frequently,
19 and sometimes I have run into situations where the
20 desire to keep information close until we can
21 complete the -- all the studies and get it written up
22 and getting it accepted to journal for publication

1 before we go fully public with all the data that we
2 have. That can be a barrier, and it is a problem,
3 and I have run into epidemiologists who are of that
4 mindset, but I will say that is the exception rather
5 than the rule. Most epidemiologists are pretty good
6 about sharing their information. They understand the
7 importance of doing so in a timely fashion.

8 And, of course, public health laboratories,
9 I'm not going to speak a great deal about this
10 because the next presentation is going to go into
11 this in great detail but the State Public Health
12 Laboratories are really important and they're very
13 important today because of some of the changes that
14 are going on in the commercial labs. We're seeing
15 more and more tests get approved that are not
16 culture-based tests. They are toxin probes or some
17 sort of a rapid read test that just identifies some
18 sort of a marker presence, absence of a pathogen and
19 then they're done with it at the commercial level.
20 They don't do the further culture work that used to
21 be done. And so without those culture isolates to do
22 Pulse Field gel electrophoresis on and do other sorts

1 of testing. We wouldn't know the difference between
2 a *Salmonella* Heidelberg and a Montevideo or a
3 Paratyphi B or something else. And so the State
4 Public Health laboratories now are taking on a
5 greater role of importance in obtaining these
6 isolates that CDC wants, that USDA wants, that we
7 want, so that those isolates can be further worked
8 and serotyped and pulsed so that we know more about
9 them, and so I want to definitely put kudos out there
10 to APHL and the State Public Health labs because I
11 think they are more important today than they ever
12 have been before.

13 The point of this slide I guess is really
14 just to emphasize that there's very few state health
15 agencies where all of the health programs are -- I
16 mean all of the food safety programs are held within
17 the health agency. In almost all of the states and
18 territories it's some sort of a shared responsibility
19 usually with Departments of Agriculture and sometimes
20 also with Departments of Environment and Natural
21 Resources, sort of your state level EPA type of
22 organizations.

1 So at the state level, we're very used to
2 collaborating because we have to collaborate all the
3 time on something, you know. Very few of our
4 agencies have complete control of an issue.

5 And this just mentions that these are some
6 of the other types of partners that we have that we
7 regularly work with.

8 Okay. So this slide, as I said, there's a
9 lot of different ways we can put it together though.
10 The state where I currently work, North Carolina, is
11 like a majority I guess of the states in the country
12 where it's a decentralized self-authority. I'll just
13 speak to the way we have it in North Carolina since
14 I'm the most familiar with it.

15 We have 100 counties, 86 local health
16 departments, plus we have the Qualla Boundary which
17 is the Cherokee Reservation in the mountains.

18 So in that kind of a situation, some of the
19 very small population, rural counties, have banded
20 together and created a health district that is a
21 multi-county health district. Mostly we're talking
22 about an individual county as its own health

1 department. And they are autonomous. Okay. We have
2 the same relationship in Raleigh with the Forsyth
3 County Health Department in Winston-Salem, that the
4 Centers for Disease Control has with the State of
5 North Carolina. They are autonomous. They don't
6 work for me.

7 And then we have other states like Florida.
8 I know Roberta Hammond is here. Arkansas State, I'm
9 very familiar with, where it is a centralized
10 authority and all of the local health departments are
11 extensions of the same health department that's got a
12 headquarters in the State Capital. So in Florida and
13 Arkansas, that's the way it is, but in North
14 Carolina, it's not that way. And then we have other
15 states. Oregon and Idaho and Nevada, up in here from
16 this area, and Wisconsin and I think in the D.C.
17 area, we may have what is called a shared authority
18 and I don't really know how that works. Bill could
19 speak to it in the panel if you want to ask him. And
20 then in the other states, like Texas, it's something
21 called mixed, and Texas is a state I'm very familiar
22 with where, you know, we have some 30 or 40 local

1 health departments in the populated counties but then
2 in all of the places where there's more cows than
3 people and more rattlesnakes than people, the Texas
4 Department of State Health Services is the local
5 health department. But in the City of Houston or
6 Harris County, for instance, you have multiple local
7 health departments that are autonomous and in the
8 City of Houston, you have a health department that
9 gets direct federal funding, doesn't have to come
10 through Austin.

11 So there's a lot of different ways that
12 public health can be put together but we're all
13 essentially trying to do the same things.

14 Okay. The next two slides are probably the
15 most important ones.

16 The point of this slide, I think there's
17 several things. I'm not going to go through this
18 flow chart. You can be grateful for that, but what
19 we do have is it illustrates that there's a lot of
20 things that happen before we get to the step that a
21 contaminated product is actually identified through
22 an investigation. Okay.

1 First, you have to have some sort of
2 exposure, people have to get sick, you know, a lot of
3 other things have to happen first and investigations
4 have to get to a certain point, right, before you
5 realize, oh, my gosh, these people are eating peanut
6 butter and they're all getting sick from the peanut
7 butter. It takes a long time to get to that point.
8 Well, what's the next thing that happens though?
9 Well, we probably try to tell somebody over here, and
10 the first question or the piece of feedback that
11 frequently comes back is you mean you've been working
12 on this for six weeks and you haven't told us?
13 Right. And it's, well, you know, as Bill pointed
14 out, over 90 percent of the time, our investigations
15 are going to be about sporadic events. Seldom do we
16 prove outbreaks.

17 When we're working outbreaks, it's a subset
18 of the ones we work that we ever solve, and so I
19 don't really think you want to know about the 90 plus
20 percent of the time that we're investigating
21 something that's not going to be important to you,
22 right. You don't. You don't want all that e-mail

1 traffic. You don't want all those phone calls. But
2 it does create frustration. People feel like they're
3 caught off guard when all of a sudden you figured
4 something out and you're just now telling me and they
5 know you've been working it for a while. There is a
6 sense there of frustration and that that's a problem,
7 but I'm not, I'm not sure that everybody understands
8 all the work that goes into getting to that point,
9 and how much of the time it's like going fishing, and
10 you don't catch it. You just don't catch the fish.

11 But this is one of the big challenges
12 because when we do know, I mean when we do have
13 something that's important and we figure something
14 out on the Epi side or in the lab side, the next
15 steps are where the communication really becomes
16 super important.

17 And when I boil the question of
18 communication down, this is what I think it means.
19 Who knows what, when and who can do something with
20 it? Right. Do you have a piece of information? Is
21 that information going to be important to somebody?
22 Can you get it to the right people? Do you know how

1 to get it to the right people? Do you know who the
2 right people are to get the information to? I think
3 those are the key questions in communication. I
4 don't think it's an institutional situation of
5 there's some memo or some policy or some culture that
6 says we're not going to share our information. Most
7 of the time. It could be true some of the time, but
8 I don't think that's true most of the time. I think
9 most of the time it's I don't know who needs to know
10 this. I don't know which agency cares about what I
11 know. And, I don't know that they would -- I mean I
12 may know something that's not important to me but it
13 is important to you, and I don't realize it's
14 important to you. So I don't know to share it with
15 you. Those sorts of things I think create the bigger
16 problems.

17 And I think another big problem that we
18 need to address, CST, the Council of State and
19 Territorial Epidemiologists and CDC earlier this
20 year, published a report that looked at what's going
21 on in the public health workforce. And in the 1980s,
22 which I don't know that any of us would look back to

1 the 1980s and say that was the hay day of public
2 health but, you know, we have about 220 public health
3 workers per capita in the United States. Today we're
4 down to about 158 public health workers per capita,
5 and 25 percent of our workforce is within 5 years of
6 being eligible to retire.

7 Okay. So right now, a lot of the who
8 knows, who needs to know is housed in institutional
9 memory. It's in somebody's head. It's in, you know,
10 go talk to Jean Marie because he's been here for 30
11 years and he knows all this stuff, but what happens
12 when he leaves? Right. And we, we need a better
13 system to give people guidance on who needs to know
14 and what do they need to know because we're relying
15 an awful lot on institutional memory of people who
16 are in place but those people are not always going to
17 be in place, and new people coming in, there will be
18 new people and they're going to be confronting
19 situations. They need to know what to do, and so I
20 think that's one of the challenges.

21 And the flow of information, we have issues
22 in all the direction in all the levels. Who has it

1 and who needs it is the big question, and it's true
2 that there are problems with this at every single
3 level. There are times when locals have recognized
4 something that they don't tell the state about.
5 There are times when individual doctors have seen
6 something that they should tell someone about that
7 they don't. There are times when federal agencies
8 know stuff that they should share and they don't, and
9 times when state agencies don't share information up
10 and down the chain. It happens in every direction at
11 every level. It is true.

12 We need to understand better, strengthen
13 our understanding of our roles and responsibilities
14 and make sure that that's communicated.

15 So some of the efforts that ASTHO is
16 involved with, to try to help this situation, CIFOR,
17 which I'm not going to speak at a great length about
18 because Tim's going to talk about that in a little
19 while, but this is something that ASTHO is proud to
20 be a part of. There are 10 member organizations
21 within CIFOR, the Council to Improve Foodborne
22 Outbreak Response, and we are one of them, and I'll

1 just let Tim talk about the rest of it because he's
2 got a whole presentation on that.

3 ASTHO also has an environmental health
4 policy committee that met in New Orleans in May of
5 2007. I'm reading this because I want to get it
6 right, and it's a strategic planning committee that
7 is trying to focus our policies and priorities in
8 environmental health and choose five topics for us to
9 focus on, and one of the things that was chosen for
10 ASTHO to focus on at that May 2007 meeting is food
11 safety, to address that decision that was made. A
12 committee, a task force was formed that's headed by
13 the state health official from Nebraska, Dr. JoAnn
14 Schaefer, and that task force is trying to shape and
15 advise our policy and make sure that our member
16 organizations understand what the best practices are,
17 improve our control programs.

18 We have a joint workshop coming up that's
19 sponsored by the Robert Wood Johnson Foundation in
20 George Washington University. That will be held in
21 July with NACCHO, the National Association of City
22 and County Health Officials, and the focus of that

1 workshop is going to be looking specifically at those
2 interactions that occur between local health
3 departments and state health departments and also a
4 cross between different local health departments. So
5 the same kind of meeting that this is for all of us,
6 there's a similar meeting being planned just for
7 those state and local officials in July.

8 We collaborate with USDA, and we are on the
9 planning committee and supporting actively the 50
10 state meeting that's being sponsored by FDA later
11 this year. So there's a number of different places
12 where ASTHO is touching food safety and has an
13 intention to be involved in food safety, education of
14 our membership, understanding the best practices,
15 dissemination of information and shaping policy that
16 we're actively involved in right now.

17 So where do we need to go. You know, our
18 perspective is we need new and innovative ways to
19 address those barriers. I think one of the new and
20 innovative ways we can address the barriers is by
21 identifying them and eliminating them, you know,
22 identifying the language in loss, identifying the

1 language in MOUs that says you can't share
2 distribution lists in taking it out. Let's change
3 those laws. Let's share that information. That's a
4 new and innovative way, and that's a barrier gone.

5 You know, we need to increase the
6 communication and coordination, of course, and that's
7 why we're all here today. We have a lot of work to
8 do because there's a lot of bugs out there. I mean
9 Bill showed us there's a lot of bugs out there, and
10 it's just going to keep coming back, and we're going
11 to have to keep dealing with it. One way, that's job
12 security, but in another way, you know, it's a lot of
13 people getting sick, and one of the things I think a
14 lot of people don't appreciate fully is these
15 pathogens kill people. I mean that is a problem.
16 These pathogens kill people. When Bill was showing
17 his data about deaths, how many of you really
18 expected to see the proportion of deaths over a 10-
19 year period attributable to *Salmonella* infections.
20 It's pretty tough when you're talking to the parent
21 of a two year old who died from *Salmonella*. That's
22 preventable, and it's a preventable death. And we do

1 a lot of that at the state level.

2 So we care about this very passionately and
3 we want to see the situation change as best we can.
4 And I also want to put in a commercial here. We're
5 having a joint conference with NACCHO in Sacramento,
6 California, in September. My understanding is that's
7 a pleasant place to be at that time of year, and if
8 you are available to come and join us, we hope you
9 will. Thanks.

10 (Applause.)

11 DR. HAGEN: Thank you, David. We're going
12 to have a slight change of schedule because we are --
13 if you can come back up here, Mr. Boxrud, we are
14 running a bit behind, and the coffee is here, and I
15 think everybody could use a little stretch. So we're
16 going to take a quick break just until 10:30.

17 Please do use the time at the breaks if you
18 can to introduce yourself to some of the people that
19 you don't normally associate with. We'll see you
20 back here at 10:30, and if I could have everybody
21 from the next group of speakers come on up here, so
22 we can kind of strategize about how to catch up on

1 time a little bit.

2 (Off the record.)

3 (On the record.)

4 DR. HAGEN: Let's get started with our next
5 session. We had a couple of questions at the break
6 about when, when to come to the microphone and make
7 comments or ask questions. We're going to save all
8 of that for the end of the morning session. So we
9 will have ample opportunity before we all break for
10 lunch to make comments and ask questions. So we're
11 still in order but just have changed things around
12 the break a little bit.

13 Our next, our next panelist is going to be
14 Mr. Dave Boxrud, and he's going to be discussing the
15 role of public health laboratories and the
16 perspective from that point.

17 Dave Boxrud is a supervisor for the
18 Molecular Epidemiology Unit at the Minnesota
19 Department of Health. He has been a participant in
20 the formation of the pathogen-specific foodborne
21 disease surveillance system at the Minnesota
22 Department of Health, and this system has detected

1 scores of outbreaks over the last 15 years which have
2 helped to reduce the number of human illnesses and
3 promote changes to food handling practices.

4 Dave has also been the co-author of many
5 journal articles documenting infectious disease
6 outbreaks. Mr. Dave Boxrud.

7 (Applause.)

8 MR. BOXRUD: Thank you. I'm going to be
9 talking specifically about how we do foodborne
10 disease surveillance on *Shigella*, *Salmonella*, *E. coli*
11 O157 and *Listeria* in Minnesota. So even though I may
12 not mention these by name later on in the
13 presentation, there are the predominant isolates that
14 I'm talking about.

15 Anytime you have an outbreak detection,
16 there are a whole lot of steps that are going into
17 it, and here I've written down some of the steps that
18 in just three cases from being exposed, going to the
19 doctor, culturing. There's a whole lot of steps and
20 even when you get an isolate at the Department of
21 Health, and you have to do the subtyping and then
22 your epidemiologist has to interview them, and that's

1 just for one single person, to detect a clustering in
2 several people. So it's a long process, and due to
3 time, I'm only going to be able to talk about some of
4 these processes where we have more of a direct
5 control over.

6 So we attempt to do all of our activities
7 in real time, meaning as soon as possible at the
8 Department of Health.

9 First of all, I'm going to talk about
10 isolate acquisition. This is our disease report
11 form, not our form, our reporting -- well, it's a
12 poster that gets sent out to all of our clinical
13 laboratories in the states, and it's a little hard to
14 see, but all of the diseases in red, it's required by
15 the state rule that they send an isolate to the
16 Department of Health, and at the bottom I highlighted
17 the footnote and it says the submission of the
18 clinical material is required and this starts to
19 address the issue of non-culture based detection
20 methods. So hopefully when clinical labs, as they go
21 to more and more non-culture based methods, will be
22 able to at least receive the material and perhaps we

1 can culture the isolates from the material.

2 Now I'm going to talk about our Pulse Field
3 specific areas, namely the subtype analysis and the
4 subtype reporting. We do real time on all of the
5 usual PulseNet organisms. Real time means as fast as
6 possible and I will talk a little bit more about
7 specifically how we do our Pulse Field. So it's your
8 *E. coli*, *Salmonella*, same group I mentioned before,
9 and we also do *Neisseria meningitidis* groups B, C and
10 Y because we feel it's such an important and
11 dangerous disease. And then we have several isolates
12 where we're looking more at studies and long term
13 studies and so we look at MRSA and -- cases of group
14 A strep and pertussis and then anything else our
15 epidemiologists want us to look at which they seem to
16 like to do a lot of things.

17 So I want to talk about how we do PFGE.
18 This is a traditional PFG flowchart. It's sequential
19 testing and I would say many states do this where
20 they receive the isolate in their department of
21 health, set up biochemicals on them and let them grow
22 overnight. The next day the enterics lab begins the

1 serotyping and when the serotyping is completed,
2 which can take anywhere from hours to several days,
3 then the Pulse Field is started on the isolate which
4 takes another day. So in best case scenario, with
5 this method, it's a three day method. Worst case
6 scenario, it can be several weeks.

7 In order to save time, we do a concurrent
8 method where we receive the isolate, set it up on
9 biochemicals and a TSBA plate, let it grow overnight.
10 The next morning, our enterics lab starts the
11 serotyping. At the same time, we need to begin Pulse
12 Field on the isolates. So we're doing serotyping and
13 Pulse Field at the same time. And oftentimes we have
14 Pulse Field results before the serotyping lab has
15 completed their serotyping. So in this scenario, we
16 almost always have results within two days.

17 Now this greatly reduces the amount of time
18 before we have subtyping results but we are aware
19 that it does increase the cost because oftentimes we
20 have to throw out organisms. It's not the most cost
21 effective way of doing business but we feel that
22 because we're reducing the amount of time, that it's

1 worth our while. It's worth that extra money.

2 When we get our Pulse Field results, then
3 we compare it to our local database and determine
4 whether we have any matches. If we find that there
5 are recent matches, we'll call our epidemiologist
6 right away and let them know about it so that they
7 can start and investigation.

8 Then we'll look at, if you have a cluster,
9 we'll look at the national database and see if our
10 cluster is matching anything in the national database
11 and we can report that information to our
12 epidemiologists. Then we document the cluster
13 through several different ways, both internally and
14 we can put this information on the CDC web board
15 which is a communication system, the PulseNet
16 communication system that all of the public health
17 labs have access to. And then we'll enter that
18 information into our LIMS system.

19 And our LIMS system produces this automated
20 daily report which is an automatic printout of any
21 serotype or Pulse Field in that was added into our
22 LIMS the previous day.

1 I took a note because I had something to
2 say on this but -- oh, I know what it is. This
3 information is sent out in an e-mail to our
4 epidemiologists or it can be sent out as a hard copy
5 too, and it's also sent out to all of our laboratory
6 people that are interested in this, and I'm going to
7 spend a little bit of time walking through this daily
8 report. It's broken down into four different pieces.

9 The first piece is essentially looking at
10 all of the isolates that were reported the previous
11 day. So it gives the specimen accession number, the
12 person's name, city, age, the agent, and then also
13 the subtype. So this helps our epidemiologists to
14 see exactly what was reported from our post field
15 labs the previous day, and in this case you can see
16 that there's three cases that are highlighted that
17 all have the same subtype and then 31.

18 The next part of our daily report is a
19 moving frame subtype history. So it takes anything
20 that have been entered into our LIMS system the
21 previous day and it compares to what has been entered
22 in for the last 30 days, and any similar patterns or

1 serotypes are clustered together.

2 So in this case, the cluster of three that
3 we had entered in the previous day, when we look over
4 our database over the previous month, we find that
5 there's seven matches. So if our epidemiologists for
6 some reason weren't notified of this cluster before,
7 they should be aware of it at this point.

8 The third part of the daily report is to
9 try to give a historical perspective on the subtype
10 information that we've put into our LIMS system. So
11 for the MN31 subtype which is highlighted here, you
12 can see in March of 2003, it was seen seven times,
13 only once in February and zero times in January. And
14 then you can compare it to calendar years 2002, it
15 was seen one time and then 2001 it was seen two
16 times. So it helps our epidemiologists to have some
17 sort of perspective on how frequent the pattern is
18 seen.

19 And the last part of the daily report is a
20 summary of the national clusters that we're seeing
21 over the last three months. So these are clusters
22 that were added to the PulseNet web board which I've

1 already said is a communication system. It gives the
2 agents when the alert date was, the state that was
3 involved with it, and then if we have any sort of
4 matches to this pattern and the Epi association with
5 this. Our epidemiologists really like this because
6 it gives them a summary of what's going on in the
7 nation in a really easy-to-read format.

8 And now I'm going to talk about the
9 epidemiology section, and I'm not an epidemiologist,
10 and this gets a little slippery for me. So I'll do
11 my best with this.

12 I'm going to talk about the case
13 interviewing and the cluster investigation. Some of
14 the things we do in our epidemiology section in
15 Minnesota is perhaps a little bit different than what
16 is done in other states. We have a foodborne illness
17 hotline and here, to the right, is an example of
18 that. That's on our website. So anyone that has a
19 foodborne illness can call in and report that.

20 We have a centralized epidemiology system
21 which I believe is quite rare. It's been talked
22 about before. So all of the case reports for the

1 entire state go to the Department of Health. We do
2 real time comprehensive interviews. I'm going to
3 talk more about this later. This is also called the
4 trawling questionnaire, and we do dynamic cluster
5 investigation. Again I'll talk about that later and
6 we utilize student workers also.

7 So here's a two by two table that
8 epidemiologists frequently use and they use this to
9 measure the association of illness with exposure, and
10 with this table, they can find statistics
11 association, for instance, on the odds ratio and a
12 high odds ration would indicate a high association
13 between a specific exposure and an illness.

14 Well, PulseNet does a good job with
15 identifying the cases involved in a cluster. So
16 that's where our subtyping comes in, and our
17 epidemiologists, they are looking at the exposure
18 information through the investigation process and the
19 interview content, and we feel that this is a really
20 vital part of the process, and when you look at the
21 two by two table, success is really dependent on both
22 sides. So we spent quite a bit of our resources on

1 getting as good exposure information as we possibly
2 can up front.

3 So we have an enteric disease interview
4 form which is asked of all of the cases of the
5 PulseNet organisms as soon as we possibly can. It's
6 about 11 pages, and it takes about 15 to 40 minutes.

7 We do a large number of organisms including
8 all of the PulseNet organisms but also other
9 organisms such as *Campylobacter* and crypto (ph.) and
10 many others. And in this interview, we get
11 information on the demographics, the symptoms and the
12 treatment information, specific exposures like have
13 they been to a farm or do they have reptiles, and
14 then they spent a lot of the interview form on
15 getting a seven-day restaurant history, a five-day
16 meal history where we go through every meal and what
17 they ate and how it was prepared, and a seven-day
18 food consumption history.

19 And as you could imagine, this would take a
20 lot of resources, and this is where our student
21 workers come in. Teen diarrhea is the group that
22 we've hired to address all of the resources. So the

1 interviews are farmed out to this group of graduate
2 students from the University of Minnesota graduate
3 school that are in the public health section. And
4 they do the interviews. They spend a lot of time
5 with this and, of course, they work and they're
6 coordinated by foodborne disease epidemiologists.
7 And so we get cheap labor which is really good, and
8 they get some really good real life experience and
9 oftentimes they get their master's thesis or master's
10 project through work and, if they're really good and
11 things work out, they may be able to be hired on
12 full-time.

13 So I'm going to give an example of a
14 dynamic cluster investigation that we did a couple of
15 years ago. So what a dynamic cluster investigation
16 is, is essentially it's a flexible interview form.
17 So when we see a novel exposure that we think perhaps
18 might be involved with an outbreak, we'll add it to
19 our interview form and so any subsequent cases
20 involved with this cluster will be added about this
21 specific exposure. And also we'll go back and add
22 previous cases, we'll ask previous cases about this

1 specific exposure.

2 And I'm going to talk about this,
3 *Salmonella* monophasic group B outbreak from Banquet
4 potpies, and a nationwide cluster was identified in
5 early June of 2007. And in September, a case control
6 study was started by CDC specifically looking at
7 chicken, breaded chicken products and eggs.

8 So we interviewed our first case on
9 September 10th, with our normal trawling
10 questionnaire, and we found nothing outstanding with
11 that interview. A couple of weeks later, we had a
12 second case. We interviewed them on September 27th.
13 This person was a special needs person. So we
14 actually interviewed the caretaker, and it was felt
15 that we didn't get a particularly accurate history on
16 this person, and again we found nothing outstanding
17 with this interview.

18 On the night of October 3rd, we interviewed
19 the third case, and I don't know why epidemiologists
20 are interviewing people at night but maybe that's the
21 only time they can get a hold of people, but when we
22 interviewed this case, we found that they had

1 consumed Banquet potpies. Not only did they consume
2 them, but they consumed them every day the week
3 preceding their illness for lunch. So we thought
4 that was interesting (laughter), and interesting
5 enough, to add to our trawling questionnaire. So we
6 added information about the potpie exposure.

7 We went back and re-interviewed case 2
8 specifically about the potpie exposure and also about
9 frozen foods because frozen foods, the case control
10 study had shown some association with this cluster,
11 and we found at case 2 had also eaten potpies. Later
12 that afternoon, we were able to interview our fourth
13 case and found that they had eaten potpies, and that
14 evening we re-interviewed the first case and found
15 that they had eaten potpies. So in a period of days,
16 a period of one day, we were able to determine that
17 all four of our cases had eaten potpies.

18 Of course, we thought that was very
19 significant. So at 4:00 p.m. that day, we sent out
20 an e-mail notifying CDC and all the other states that
21 were involved with this case control study that we
22 had three potpie eaters and we requested that they

1 add this information to their interviews. By that
2 evening, other states specifically West Coast states
3 were reporting consumption of potpies. A couple of
4 days later, ConAgra stopped the potpie line, and the
5 next day the advisory was posted by USDA, FSIS and
6 CDC, and two days later, there was a recall and
7 several states were able to isolate *Salmonella* from
8 the potpies and currently there's over 400 cases in
9 41 states involved with this outbreak, and this
10 outbreak, although there were many people working on
11 it, it was really this dynamic cluster investigation
12 which really kind of spurred on the idea of potpies
13 being involved with this.

14 And here's a map. You can see the states
15 in Black. Our states that didn't have any cases, and
16 it's relatively few states that were not involved
17 with this at all.

18 So now I'm going to talk about the
19 laboratory epidemiology partnership that we have in
20 Minnesota. We take a team approach to all aspects of
21 foodborne disease surveillance. We have
22 collaborative funding. Both groups are co-authors of

1 grants, and we share the funding based on our needs
2 from the grants, and we've seen in quite a few other
3 states when one group controls the funding, they tend
4 to have the power and the other group becomes
5 somewhat of a service to the first group, and so
6 there's not a real equality between the groups. So
7 we really strive to have that equality.

8 We do a lot of education sharing. Any new
9 foodborne epidemiologists comes down to our Pulse
10 Field labs and learns how we do things and vice
11 versa. We spent some time with our foodborne
12 epidemiologists and learned how they do things and
13 what is important to them.

14 The daily report is a really good example.
15 That report was made both by our laboratories and
16 epidemiologists together. We sat down and discussed
17 the issues and how we wanted to figure out how to do
18 this report and what sort of information was
19 important, and also the physical proximity in our
20 state were fortunate enough to have a laboratory and
21 epidemiology section, not actually in the same
22 building. Here's our lab building, and there's the

1 Epi building, but they are attached by a skyway. In
2 fact, we just moved in the new buildings about two
3 years ago and that was one of the prerequisites from
4 moving into the new building is that we needed to
5 have direct access to the other group.

6 Now I've talked a lot about our system for
7 how we do things but really a system is only as good
8 as the results that you get from it. So I looked at
9 all of the Minnesota foodborne disease enteric
10 outbreaks from 2000 to 2005, and again these are only
11 outbreaks of our PulseNet organisms. So I mean this
12 won't include norovirus or clostridium or anything
13 like that.

14 And I was able to break these outbreaks
15 down into two categories. One is a reported
16 outbreak. The reported outbreak would be an outbreak
17 where essentially it's solved before you started.
18 Someone calls into the foodborne illness hotline and
19 says that they went to a wedding and they have a
20 foodborne illness and they know five other people
21 that went to the wedding and have the same illness.
22 Those are pretty easy outbreaks for our

1 epidemiologists to determine the source.

2 The other kind of outbreak is a pathogen-
3 specific outbreak, and this is an outbreak where the
4 subtype analysis is critical. So a typical outbreak
5 will determine if there's a cluster by the Pulse
6 Field patterns and that information will be relayed
7 onto our epidemiologists who will do the interview
8 forms and hopefully eventually find exposure.

9 So during this time period, we found 10
10 reported outbreaks with the PulseNet organisms and we
11 found 28 pathogen specific surveillance outbreaks,
12 and included in those outbreaks was millions of
13 pounds of products that were recalled, 10 multistate
14 outbreaks and a whole wide variety of vectors and
15 sorts of outbreaks that were involved including
16 frozen steaks, ice cream, frozen stuff chicken
17 products, on down the line. And because of those
18 outbreaks we're able to address some of the
19 underlying problems associated with the food. I
20 won't go into all of those, just for time's sake, but
21 hopefully the idea is that we can address the
22 problems so we don't have the same outbreaks again in

1 the future.

2 Now over the last couple of years, I've
3 been part of a group that's been involved with what's
4 called the Regional PulseNet Conferences and these
5 conferences bring together a Pulse Field laboratorian
6 and foodborne disease epidemiologists and an
7 administrative official from each state. So we get
8 together and talk about the issues that we're seeing
9 in all of our states. So I've got a really good
10 background on how every state does their
11 surveillance, and we've been able to find some
12 barriers that are common in almost all health
13 departments, and specifically with their foodborne
14 disease surveillance, and I would say the number one
15 barrier is money. The lack of money really controls
16 all aspects of foodborne disease surveillance, and I
17 know a lot of states would really like to try to do
18 things some different ways, but they simply don't
19 have the resources.

20 Some other barriers that we identified was
21 isolate submission. Some states do not receive all
22 of the isolates from their clinical laboratories.

1 Out-of-state reference labs can be difficult because
2 some of the clinical labs send their isolates to out-
3 of-state reference labs and the public health lab
4 never receives the isolates. I mentioned physical
5 proximity between laboratory and epidemiology.
6 Different laboratory strategies and non-centralized
7 epidemiology has been talked about quite a bit
8 earlier. Administrative support is a big deal, and
9 experience, there's a really high amount of turnover
10 in PulseNet, specifically on the laboratory side.

11 So, in summary, real time pathogens
12 specific surveillance enhances our ability to detect
13 foodborne disease outbreaks and laboratory Epi
14 communication and collaboration is vital to effective
15 foodborne disease surveillance.

16 (Applause.)

17 DR. HAGEN: Thank you very much, Dave.

18 For our next panel, we're going to have a
19 true panel discussion. There are a couple of
20 questions that we're going to ask our federal
21 partners to address. We're going to try and make up
22 for a little bit of lost time here, and since the

1 three organizations, FDA, CDC and FSIS are the
2 cosponsors of this meeting, we're also going to go
3 ahead and eliminate their biographies. None of them
4 seem to be offended. The fact that we're eliminating
5 them does not suggest anything about the importance
6 of these three people or their prestige in their
7 organizations but that was Ellen Morrison's
8 suggestion. I think it's a good one.

9 So I will at least introduce who our
10 panelists are and their titles.

11 Dr. David Warnock is the Director of
12 Foodborne, Bacterial and Mycotic Diseases at the
13 National Center for Zoonotic, Vector-borne and Enteric
14 Diseases at the Centers for Disease Control.

15 Ellen Morrison is the Director of the
16 Office of Crisis Management in the Office of the
17 Commissioner at the Food and Drug Administration.

18 And David Goldman is the Assistant
19 Administrator for the Office of Public Health
20 Science, at the Food Safety and Inspection Service
21 and he's also my boss.

22 Okay. So we're actually going to turn the

1 first question over to David Warnock. We thought
2 actually Dave Boxrud's presentation kind of set the
3 stage nicely to talk about kind of the shared volume
4 of information that now needs to be processed
5 particularly now that we're identifying more and more
6 clusters through PulseNet and relatively few of those
7 lead to positive identification of a vehicle and a
8 regulatory action but there's still an awful lot of
9 information. How is CDC dealing with handling that
10 peer volume of data and how do you prioritize your
11 efforts in terms of identifying the outbreaks among
12 these many clusters that are identified.

13 DR. WARNOCK: Thanks, Elizabeth. I think
14 the presentations so far this morning presented very
15 different perspectives and my perspective is very
16 different from people at the local level and the
17 state level, and I think the first point I'd like to
18 make is that, you know, 90 percent of foodborne
19 outbreaks are being handled at the local or state
20 level.

21 In our annual summaries, we are reporting
22 somewhere in the region of 1200 or so foodborne

1 outbreaks each year, and that translates into about
2 10 a month roughly. So of those -- translate into
3 100 per month, excuse me. And that breaks down, we
4 actually investigate somewhere in the region of 100
5 outbreaks per year ourselves. Most of those are
6 multistate dispersed outbreaks. So any, any given
7 week of the year, we're investigating anywhere
8 between two and four multistate outbreaks or
9 outbreaks that are being reported to the regulators,
10 to USDA or to FDA. So that's quite a heavy, ongoing
11 workload for a relatively small staff.

12 Now, as should be apparent from the
13 previous presentations, the local and state level,
14 still the commonest way that you find out about an
15 outbreak is from a concerned citizen. That's very
16 different from our experience. We either find out
17 from a state health department or we find out from
18 PulseNet. And, you know, the picture for us has
19 changed dramatically over the last decade from the
20 predominant type of outbreak that we would be
21 involved with a focal outbreak. Now, it's much more
22 likely to be the multistate dispersed outbreak, and

1 we are assisting the state or we're endeavoring to
2 coordinate among states to expedite the
3 investigation.

4 So PulseNet on the one hand, it's been a
5 tremendous asset. We now detect clusters that we
6 would not have recognized as clusters in the past,
7 and even today with a slow burning outbreak, as an
8 example, *Salmonella* Tennessee, in peanuts, for
9 several months was a very slow burning investigation.
10 A few cases here and there. No clusters in any state
11 and even when the first clusters were identified, in
12 different states, really no leads to go on. When
13 everything came together, events happened very fast
14 but it was a very, very slow accumulation of
15 information, several rounds of hypothesis generation,
16 going back to states and asking them to conduct more
17 and more targeted interviews with cases until the
18 answer became obvious enough and convincing enough on
19 the basis of case control statistics, to be able to
20 say to the regulators this is real, this is something
21 we can give you sufficient evidence now for you to
22 act upon.

1 But we've got to the point I think with
2 PulseNet where we're almost at information overload.
3 Last year PulseNet received over 60,000 patterns
4 nationally. And that's a huge amount of data to
5 store and to analyze and increasing the ability to
6 look back through the information that's been
7 gathered is constrained by the amount of information
8 that we have. And oftentimes now, it's human
9 intuition rather than the ability of the computers to
10 solve some of these problems for us. The recent
11 instance of *Salmonella* Agona in malted cereal, that
12 became obvious very quickly, firstly because the
13 manufacturers had spotted the problem and recalled
14 lots of the product. From our point of view, it was
15 obviously because somebody who was here 10 years ago
16 said, ah, it's the same organism. Let's check and
17 see if it's the same PulseNet fingerprint. It was.
18 We can't rely on the hardware or the software to do
19 that for us. Often it's the liveware.

20 How we're being driven at the federal
21 level, we're now driven by PulseNet rather than by
22 epidemiologist led investigations, and the ability of

1 epidemiologists to keep up with the number of
2 clusters that are being detected is increasingly
3 being challenged.

4 DR. HAGEN: Thank you, David, and I know
5 that we deal with this at FSIS, too, and I don't know
6 if David Goldman, you'd like to make a comment. We
7 follow a lot of these clusters that don't necessarily
8 get us anywhere on the food history. If you could
9 make a comment.

10 DR. GOLDMAN: Sure. I would characterize
11 it this way. PulseNet is a blessing and a curse, to
12 reiterate what David just said. But I think it's
13 important to point out that whereas what David
14 suggested was when the epidemiologists either at the
15 state level or the federal level have done the work
16 and have drawn some conclusions about what the
17 vehicle was in a particular case, on a daily basis
18 there are communications that go on and, you know,
19 PulseNet as a database but the PulseNet web board
20 that was described a little bit by one of the earlier
21 presenters, is really a valuable tool for us and
22 probably for FDA as well because it's sort of a

1 PulseNet chat room where people share ideas and
2 thoughts and sometimes hypotheses about the
3 connections that may exist in a cluster, and I think
4 it's a valuable way for the epidemiologists both at
5 the state level, the federal level and in the
6 regulatory agencies to kind of get a jump start on
7 some connections that might lead to identification of
8 a cluster as an outbreak and therefore something that
9 we could take action on.

10 So we do have in our agency a staff that is
11 trained in PulseNet. They're trained on the software
12 that is used to analyze the PulseNet patterns and
13 clusters and also they have the relationships with
14 the PulseNet staff and can make those human
15 connections as David was pointing out, you know,
16 making the phone call or go over there. That staff
17 happens to be luckily located in Athens, Georgia. So
18 it's just a short way from Atlanta, and there are
19 frequent meetings and discussions that go on that
20 help us move things more rapidly along than otherwise
21 might be the case.

22 The other thing I want to point out is an

1 innovation that has just come to pass recently, and
2 that is there is a collection of Pulse Field patterns
3 for foods that has existed for sometime. We now
4 through an agreement between the Department of
5 Agriculture and CDC have connected those two systems,
6 one called VetNet and PulseNet, so that we have again
7 these training staff members who can look at both
8 systems simultaneously and make connections. And in
9 one particular case, with a very unusual serotype of
10 *Salmonella*, I think it was -- it proved valuable in
11 recognizing a possible vehicle for an investigation,
12 in the early stages and helped the epidemiologist on
13 the ground in Massachusetts in this case to focus
14 their epidemiologic investigations. So I think
15 there's a promise for this kind of activity between
16 the database and the patterns themselves and the
17 epidemiologists so that we can move things farther
18 along more quickly.

19 DR. HAGEN: Thank you. And I don't know if
20 you had anything to add, Ellen or --

21 MS. MORRISON: Well, I think it's
22 interesting to see the first time I remember PulseNet

1 being used in connecting outbreaks was probably 1997
2 with the sprout outbreaks where you recognize the
3 pattern matched in different states and the epi was
4 matching. I think the cautionary principle I think
5 about it just assuming that everything matches
6 because it is a matching PulseNet pattern rather than
7 having the epi also there. So we were always sort of
8 under the teaching of CDC that epi and the patterns
9 had to match, and I think as David just said,
10 catching up the patterns with the epi is a challenge
11 today because they're so much quicker to be putting
12 the patterns into the database rather than the epi
13 investigation catching up to it. It can lead to case
14 finding but I still am very cautious when a federal
15 agency is asked to simply take action simply based on
16 the pattern alone, without epi there.

17 DR. WARNOCK: Could I add to that? I think
18 it's very critical to remember that PulseNet is a
19 cluster detection tool. It's not an outbreak
20 detection tool. You have to, once you've got your
21 cluster, you then have to conduct the epi
22 investigation to determine whether or not there is

1 linkage between the cases, epi linkage and that, in
2 fact, you have an outbreak. People often assume that
3 these are one in the same thing. They're not and
4 part of the problem is actually making the sort of --
5 the judgment whether it's local, state or federal
6 level in public health as to which clusters deserve
7 further investigation to establish whether or not
8 they're outbreaks.

9 DR. HAGEN: Thank you, David. The next
10 question that I have for the panel really gets at how
11 well we all share information among ourselves during
12 outbreak investigations or illness investigations.
13 So I guess I would start with Ellen, if you would
14 take the first shot at this. When FDA first hears
15 about foodborne illness outbreak or a handful of
16 illnesses, when do you, you know, what do you
17 consider as you think about contacting other federal
18 partners? When do you decide when to share that
19 information and what might be some of the constraints
20 and, if you could address it from the perspective of
21 when you hear about it from a state or from CDC but
22 also sometimes I know at FSIS we hear about things

1 from industry first through different mechanisms. So
2 if you could kind of take a shot at that.

3 MS. MORRISON: Okay. We hear about it from
4 all sorts of different ways and we have 20 district
5 offices across the country. So they are in touch
6 with the local and state folks, and I would encourage
7 further communication in that regard based on the
8 panel discussion earlier this morning.

9 Just because we hear about illnesses, we're
10 very quick to share information. One of the offices
11 in the Office of Crisis Management is Emergency
12 Operations and we run the emergency center at FDA.
13 Hanging onto information is not concept from that
14 perspective.

15 So we pass on a lot of information before
16 we come to a necessary conclusion about it. If we
17 hear it from our district office, we ask them to go
18 back and talk to the state health department and see
19 what information we get. We have liaisons and the
20 liaisons for FDA and CDC are here, and I think that's
21 been a very important -- to us in direct connection
22 with CDC but we talk to the CDC all the time, on a

1 daily basis, about what they're seeing on the radar
2 screen as we call it, as opposed to what is actually
3 going to implicate a food that FDA regulates. So
4 there's a lot of information in the system all the
5 time, and we are always also paying attention to the
6 School Lunch Program. So we have direct connection
7 with the Food and Nutrition Service as with FSIS and
8 APHIS for that matter.

9 So we all have 24/7 numbers of everybody
10 and we're sharing information just in case something
11 might be in the School Lunch Program. We've found
12 information coming in likewise to us from USDA, Food
13 and Nutrition, from FSIS. The information, we don't
14 care where it comes in from, it's coming in. The
15 important part is sharing that information and not
16 sitting on the information, and we're often going
17 back to CDC and saying what are you seeing on a
18 national basis for what we've just got a reporting
19 from X state. And to see, you know, where is the
20 nexus of information. We have access to Epi-X as
21 well and the FDA, and we're watching things closely
22 but we have to wait for an association with an FDA

1 regulated product.

2 And I forgot if there was another part of
3 that question. The constraints of sharing
4 information we can certainly talk about ad nauseam no
5 doubt but the federal requirements for us to share
6 trade secret or commercial confidential information
7 are prohibitive, and unless we have memorandums of
8 understanding for confidentiality reasons, we cannot
9 share that information. We do have an MOU even with
10 CDC and they're in our department of HHS. There
11 isn't any reason why we can't share all information
12 within our department, but I think I share the
13 frustration that I've heard this morning with the
14 ability to track down products in a recall situation,
15 and the fact that somebody may be sitting on
16 distribution information that you'd like to know at a
17 local level to do the best thing, I think is a big
18 concern but again we cannot just share that
19 information unless you're a FDA commissioned official
20 or there's a MOU with the state entities. So I think
21 -- do you want to make any comments?

22 DR. WARNOCK: Just following on from what

1 you've said, we can each share information with the
2 other but we tend to be on the sharp end because
3 oftentimes it's the states or the locals who are
4 asking us what we know that the FDA or the USDA have
5 told us and as Ellen has said, that there are very
6 strict limits on the information we can pass on, but
7 I think, you know, one of the great things is that we
8 do have liaisons from FDA and FSIS actually embedded
9 with our division and they are there and oftentimes
10 they will hear us thinking out loud, and they are
11 part of the hypothesis generating process that we
12 use.

13 DR. GOLDMAN: I'll just add a couple of
14 things. First, there is no preconceived or
15 considered reluctance to share information among the
16 federal partners. I mean we don't -- when we get
17 information, at FSIS and probably the same with each
18 of the other two agencies, we don't go through this
19 calculation about whether or not to share. It's more
20 a matter as was described a little bit earlier that
21 there is a lot of information that flows in and out
22 of our agencies on a hourly basis. It's more a

1 matter of deciding what is useful to our federal
2 partners and therefore then when to share that
3 information rather than any -- again any reluctance
4 to share information. I think we have outstanding
5 relationships among the federal family and certainly
6 our relationship with CDC is somewhat different than
7 the FDA's relationship because they're our sister
8 agency and we don't have that same blood relationship
9 if you will but we do have -- I mean we have very
10 good relationships among the federal partners. The
11 function of the liaisons is critical to that. We
12 have a staff member who has been in that role for
13 some number of years, Kristen Holt. She's in on all
14 of the twice-weekly discussions in the epidemiology
15 and enteric diseases branch that talks about what,
16 you know, a few cases that have been reported from a
17 state or two. So we know very early on from our CDC
18 partners when something is bubbling along, and
19 certainly we know very well when it spikes in terms
20 of the evidence that it's gathering to support, in
21 our case to support some regulatory action. So we
22 don't have problems with that.

1 To get back to the question, we sometimes
2 hear from states because we have, somewhat like FDA,
3 we have public health liaisons who have
4 responsibilities for each and every state and
5 territory and they have a responsibility to establish
6 on an ongoing basis over time a relationship with the
7 appropriate authorities in that state. So we often
8 hear from states before we hear from the CDC about
9 something, and in particular when it's a single state
10 that's involved in an outbreak investigation.

11 So we sometimes do have the issue that we
12 don't know whether it's necessary to share that
13 information with the CDC. It's not really our place
14 to. The states have to decide that for themselves
15 but certainly when there are multiple states
16 involved, 90 plus percent of the time CDC is already
17 involved. So that's not really a practical issue.

18 On the other end, when we hear from the
19 industry, sometimes we hear from them first and it's
20 usually for two reasons. One is there's been a press
21 release or a media report as we heard earlier.
22 Sometimes that's when many of us hear for the first

1 time about a case or two or three in a particular
2 locality or state. And the other thing is more and
3 more states are interacting directly with the
4 industry as Bill Keene pointed out, and so sometimes
5 that interaction has already occurred and so our
6 regulated industry will call us and say tell us from
7 your perspective what you're hearing about this
8 outbreak because we've had a conversation with the
9 states and they have drawn some conclusions, and we'd
10 like to balance what we hear from them with what you
11 may know. So we have that somewhat unusual
12 circumstance more and more, and we're learning how to
13 react to that. And then, of course, there are the
14 considerations for sharing that sort of information
15 with our federal partners, and again if there's any
16 question that the product or the food vehicle has not
17 been identified, we obviously will share that with
18 the FDA because they have an interest as they do
19 early on in trying to help solve the problem as well
20 as take whatever appropriate action there may be, and
21 then we have the other issue of sharing that with the
22 CDC and again, if we have these regular

1 communications with the CDC, that's usually not an
2 issue for us at all. So I think that addresses the
3 question.

4 DR. HAGEN: You had another comment, David?

5 DR. WARNOCK: I was just going to add that
6 unlike my two colleagues here, I do not represent a
7 regulatory agency and that gives us a certain freedom
8 in talking to industry and increasingly we do try to
9 talk to industry to learn more about their processes
10 and how their staff go out on field visits to learn
11 the background about modern production methods so
12 that we can interpret what's going on in outbreak
13 situations more intelligently.

14 MS. MORRISON: I'd like to make another
15 point about information and distribution. If the FDA
16 is going on an investigation of a company when we
17 know there's a problem and potential recall, I think
18 to a large extent, the district offices are asking
19 their state counterparts to go with them, and that's
20 generally probably the ag side, not necessarily the
21 health side of the states because those are the ones
22 that do inspections. But in a joint investigation

1 like that, then the state has the same information
2 that the FDA has in terms of distribution.

3 So I'm not trying to think ways around
4 things. I'm just trying to say that in joint
5 investigations, the same set of information is held
6 both at the state and federal level and that's also I
7 think very helpful, and we found that to be the case
8 in many of the recent outbreaks, and I was around for
9 the Malt-O-Meal in 1998. I'm not going to be around
10 10 more years now at least with the FDA anyway, but I
11 think that it's helpful to have historic memories of
12 incidents that happened before, and I think in our
13 own situation, gathering that information and
14 actually remembering it is not necessarily something
15 we can readily access. We have to be the ones that
16 remember it, and I think that we're all striving with
17 an incident management system process that actually
18 keeps historic data so that you can say, did we ever
19 see this before. I'm not relying on the person that
20 was there 10 years before. So that's another
21 challenge that was brought up this morning at the
22 state representatives.

1 DR. HAGEN: Any closing comments from the
2 three of you? Anything else that you want to --

3 MS. MORRISON: I would just like to say a
4 federal regulatory is not like a bad comment, David.
5 Thank you very much.

6 DR. GOLDMAN: I would just add one thing
7 because we didn't address this, I mean I didn't
8 address this issue about legal constraints but like
9 Ellen said, we do have constraints surrounding
10 business confidential information. However, when we
11 have our federal, within the federal family, that's
12 not usually an issue and, in fact, the identity of
13 the producer if we've gotten to that point is usually
14 immaterial to the discussion. It's really a
15 discussion about what's the cause of contamination
16 that led to illnesses and how can we fix it. So it's
17 usually not a constraint when it comes to discussions
18 among ourselves. There are obviously some
19 considerations when we start to involve as many of
20 these conference calls do, other parties from the
21 state level. More and more we have calls from the
22 feds, the state representatives and the industry, and

1 so we do have other considerations but we are kind of
2 developing the ground rules as we go and keeping in
3 mind the single legal constraint that we have and
4 that FDA has as well.

5 DR. HAGEN: Well, thank you to our
6 panelists. We're going to do -- we're going to make
7 a quick scene change here. Stay in your seats.
8 We're going to ask Dane and Caroline and Terri to
9 come on up front. And at the end of the morning
10 session, we're going to have all the speakers either
11 on the stage or in the front row, so don't go too far
12 back in the room so that everyone will be available
13 to answer questions.

14 Okay. So switching gears a little bit, we
15 are next going to hear a perspective from industry.
16 Mr. Dane Bernard is going to be our speaker on that
17 topic.

18 Dane is currently the Vice President of
19 Food Safety and Quality Assurance at Keystone Foods
20 LLC, having joined the company in 2001. He's
21 responsible for global programs on HACCP and food
22 safety for Keystone. Prior to joining Keystone, he

1 was employed as Vice President of Food Safety for the
2 National Food Processors Association where he had
3 worked since 1973.

4 Mr. Bernard received his Bachelor of
5 Science Degree in Agriculture from Purdue, and a
6 Master's Degree in Food Science from the University
7 of Maryland. He is a registered specialist in food,
8 dairy and sanitation microbiology with the American
9 Academy of Microbiology. He has done extensive
10 testing of food processing systems, supervised
11 research in many areas of food safety and has
12 authored or co-authored several technical articles.
13 He's been an instructor and lecturer on principles
14 and applications of HACCP and has assisted in
15 formulating HACCP plans for the U.S. food industry.
16 He has been an invited expert to five international
17 consultations sponsored by the Food and Agricultural
18 Organization and the World Health Organization
19 dealing with certain aspects of HACCP and other food
20 safety issues. Mr. Dane Bernard.

21 (Applause.)

22 MR. BERNARD: Thank you, Dr. Hagen.

1 Dr. Hagen informed me that I could say anything I
2 wanted as long as I could say it all in one breath.
3 (Laughter.) So I guess I'm done.

4 Well, let me just kind of cut to the bottom
5 line since I'm going to be skipping through some of
6 these slides.

7 There have been, you know, a lot of
8 outbreaks that have happened. We in industry talk to
9 one another. One of the things I worked with, with
10 Jennie Scott, when I was at the NFP was assisting
11 people with recalls, and there were enough to kind of
12 get a gauge on what was going on but one consistent
13 thing that comes through is a frustration on the part
14 of industry with some of -- the pace of things and
15 getting information back. And I believe some of my
16 industry colleagues have told me that there have been
17 instances where multistate outbreaks have happened,
18 and that if all the information had come to them or
19 had come forward to a central coordinator, those
20 outbreaks could have been diagnosed quicker, the
21 recalls could have been instituted quicker. They
22 could have been instituted in a more target way and

1 the public health could have been protected better
2 than it was. And so I think that's the bottom line,
3 is if we get this right, if we get some dialogue
4 going beyond this meeting to get this thing together,
5 this is a common goal. There's no reason that it
6 should take two to three days longer to get a recall
7 going and leave the public health at risk simply
8 because the communications are not adequate to
9 support that goal. So that's the bottom line.

10 So in industry, our first priority is not
11 to have a recall obviously. If you have one,
12 especially one involving a multistate outbreak, it's
13 a shared goal. Get the product identified, get it
14 off the market and get it done as quickly as
15 possible. Voluntary/mandatory is not really the
16 issue here. That's about having to make the
17 decision. That's a debate for another day. This is
18 about how you get to that point quickly and how you
19 get implemented and get it done.

20 So whether it's voluntary or not really
21 doesn't make any difference. Once the decision is
22 made, this package comes to your doorstep as industry

1 and says, okay, get it off the market. So now it's
2 ours or at least it's a shared responsibility to get
3 that product off the market.

4 In order to do our part, we've got to get
5 information from those that have it, and hopefully
6 it's there. And to put it into two buckets. This is
7 the categories of information that we need to get the
8 process rolling.

9 First of all, we need information to be as
10 specific as we can get it regarding the production
11 codes and the identity of the product.

12 This is a label that I pulled off the USDA
13 website. It's a very recent recall. There are a
14 couple of things on here that if you can, and this is
15 not rocket science, if people are out investigating
16 recalls and they can get a label, get it. The
17 circled part here is the item number. That tells the
18 manufacturer exactly what was in that package. The
19 UPC code will give us the same sort of information.
20 I've blanked out the establishment number but if it's
21 a USDA, whether it's state inspected, federal
22 inspected, there's a plant number there and for us

1 and those in the industry that multiple plants, it's
2 important for us to know which plant it came from
3 because we may make the same product in two, three,
4 four different plants. So it's important for us to
5 know which one it came from so that we can begin the
6 trace back to know where it went and what ingredients
7 went into it.

8 So a complete label is certainly of benefit
9 especially if it was packaged in the manufacturing
10 facility. Retail labels are important, too, but
11 there's a whole cassette of information that needs to
12 go along with retail labels. As manufacturers who do
13 labeled product, we have or are supposed to have
14 production records that will lead to the ingredients,
15 lead us, link us to the distribution records that we
16 have and will facilitate a pretty quick action on our
17 part. At minimum, if those things are not available,
18 we need information to identify at least one
19 production day. That can get us started. We can
20 look at the commonality between that production day
21 and those that are after it relative to the item,
22 relative to the way it was processed, the ingredients

1 that went into it, et cetera. I think I'm on my
2 fifth breath by now. (Laughter.)

3 But if no complete label is available,
4 well, what's in a name. And since Keystone Foods
5 manufactures ground beef for one thing, chicken
6 products, fish items, all for the quick serve
7 restaurant industry, the ground beef issues are more
8 familiar to me. So that's an example that I'm going
9 to use here.

10 For example, was it ground beef, ground
11 chuck, ground sirloin or ground round? By the way,
12 what goes into ground sirloin? Can anybody tell me?
13 Oh, come now. Sirloin. (Laughter.) Da! And if
14 you're a grinder like us, you may buy your sirloin on
15 a particular day from a particular packer. It may be
16 a different set of orders that you would put in if it
17 was your regular ground beef product. So knowing
18 that helps us to identify not only where it went but
19 what could be in it and what could be the contributor
20 to the problem and how big the problem could be. So
21 we need that kind of information.

22 Lean content, you saw earlier on one of the

1 earlier presentations an example of ground beef, the
2 package, probably nobody noticed, but I noticed.
3 That was a 7 percent lean product. We make ground
4 beef to order based on what the store wants or what
5 the customer wants, and it doesn't come off the
6 animal with 93 percent lean, 7 percent fat. We have
7 to blend things. So if you have that number, and
8 this is just an example. Most products have the same
9 thing, but if you have that number, we can kind of
10 trace back in our records and try to figure out where
11 we bought the meat that we included in it on that
12 day.

13 Weight of product. We don't always produce
14 the same size product on the same day. So, you know,
15 ancillary information is not just trivial stuff. If
16 you don't have the label, if you have an incomplete
17 label, just get whatever information is available
18 because we can oftentimes knit it together and come
19 up with a good idea or at least narrow the field of
20 possibilities.

21 Store cards, loyalty cards. These have
22 been talked about as a good source of information.

1 If you're out investigating things, ask whether the
2 store that you purchased it at where you have a
3 loyalty card, recognize that not every chain, not
4 every store has loyalty cards nor are they able to
5 take that card, scan it and give you the information
6 that you want. It can work not always because of
7 confidentiality of records and those kind of things
8 but bar, if everything works right, you can take that
9 card back, scan it. If the customer is a frequent
10 buyer of a certain product, you can actually peg the
11 day and a lot of the product information from the
12 loyalty card information.

13 So some industry frustrations. Being
14 informed that we think you need to recall a product
15 when the investigation has been going on for weeks or
16 months or whatever it is. We have very little time.
17 Somebody knocks on the door, says this is a problem,
18 you need to recall this. We're going what? Why?
19 What is it? Give us some information.

20 So we have, you know, it's kind of like
21 somebody knocking on your door and saying we think
22 you owe \$1500 from your 2006 taxes, pay up, and you

1 go why? Well, we have that same kind of reaction
2 when we first find out about it. So it's important
3 for us to have some communications ongoing. If there
4 are certain things going on, it would be great if we
5 knew about them. There seems to be a fear that
6 telling industry anything, we'll hide it, we'll do
7 something and they'll never figure it out.

8 But on the other hand, by not telling us,
9 we don't have the opportunity to fix something.
10 We're going to keep doing what we're doing, and if
11 there's a problem it's going to keep coming out. We
12 have the opportunity to hold products if we know
13 about it in advance. We have an opportunity to
14 investigate. We have an opportunity to limit the
15 public health impact of a problem if we know about it
16 as soon as we can find out about it.

17 So not being provided with the necessary
18 information after an outbreak is confirmed, that's
19 another concern that we have. Sometimes no single
20 entity, and you've heard it here, no single entity
21 has all the information. It's just not shared by
22 state and local agencies. You've guys have told us

1 that earlier in the day. It's a frustration for us.
2 Who do we call for information? It is simply not
3 appropriate in this day and age for me to have to
4 know people in every state agency, just as a
5 precaution, so that I can call them up. If they know
6 you and they trust you, you can get information. If
7 it's a cold call and they don't know you, then you
8 kind of get, well, what do I tell this person like,
9 Lisa, you had said earlier. So there has got to be a
10 better way to put all of this together.

11 Information not collected during the
12 investigation. Why didn't you get that label? Why
13 didn't you get that detail of information? That
14 would help us to nail this thing, pinpoint it and try
15 to figure out how to make a very targeted collected
16 recall.

17 So what we'd like to have, single source of
18 truth, who can we call. In our case, we are a large,
19 in fact, a multinational company but here in the
20 United States, mostly meat and poultry products. It
21 would be nice because USDA is going to be calling us
22 and contacting us, and if USDA had the information we

1 needed, rather than us having to go find it
2 ourselves.

3 It would be nice if there were a
4 willingness to share information real time. I said
5 that earlier. Standardization of investigation
6 techniques and training of field investigators.
7 There was a lot of discussion about that this
8 morning. I'll leave that to the experts, but it
9 would be nice if there was some standardization.
10 Also it would be nice if we in industry could have
11 access to that same training, just to kind of
12 calibrate, see what it is that we need to know.

13 Not having this information results in what
14 you've all seen, what we call the rolling recalls.
15 You know, we get partial information. We think it's
16 that. The agency wants us to recall. So we recall.
17 Two days later we find out a piece of information
18 that was already there, resident in one of the states
19 that didn't come forward that says that's the wrong
20 product recall. You need to recall this. So those
21 kind of things just flat don't build confidence in
22 the public in the process, hurt our businesses, et

1 cetera.

2 Recalls are larger than needed. Why is
3 this a problem? You know, people get impatient and
4 you say, well, why don't you just recall the whole
5 month? Why don't you just recall the whole year?
6 Well, there's an economic impact to that. That
7 probably doesn't float everybody's boat but certainly
8 it does ours. If it's a small firm, you can be
9 putting them out of business by issuing a
10 comprehensive recall. We do pay people. A lot of
11 these small towns where we do business, it's the
12 major employer. You're going to have a major
13 economic impact also.

14 If you think about a recall of any kind,
15 we're still in the marketplace. We're recalling a
16 certain amount. We've got contractual obligations to
17 fill. We're going to be shipping product while
18 product is coming back.

19 Now the distribution system that we've got
20 works pretty good going that way but it doesn't work
21 very well coming this way. So now we've got product
22 coming back and going out, and the bigger this recall

1 is, the more likelihood that something that's coming
2 back is going to end up on the wrong truck and go
3 back out. It does happen. It happens fairly
4 frequently.

5 So there are problems with making a recall
6 much bigger than it needs to be and there are delays
7 in the process that can result in more cases of
8 illness. So the longer we delay these things, the
9 more likely we are to have a significant public
10 health impact.

11 So success would be having no more recalls
12 but that's not likely to happen. So getting the
13 information that we need to do it better, to do it
14 quicker is the objective. And that's basically it.

15 By the way, what is that picture? I hear a
16 train. But if you were to see that picture on my
17 computer screen and you got to look at the colors
18 that are in there, you'd recognize that that's really
19 a pretty beautiful picture. You look at it, you see
20 the train but what we're trying to do here is get you
21 to see the big picture, not just the train. Thank
22 you.

1 (Applause.)

2 DR. HAGEN: Thank you very much, Dane, and
3 I should have mentioned when I introduced Dane, that
4 he was actually one of the very early proponents of
5 having exactly this kind of meeting. So we thank you
6 again for that enthusiasm from the very beginning and
7 for being here to talk with us today.

8 We have one last panel before we get to
9 question and answer and lunch, and we're going to be
10 discussing next risk communication and getting the
11 message out to consumers.

12 Our first speaker is Caroline Smith DeWaal.
13 Caroline is the Director of the Food Safety for the
14 Center for Science in the Public Interest, and is co-
15 author of "Is Our Food Safe," a consumer's guide to
16 protecting your health and the environment. She
17 represents CSPI in the media, in Congress and in the
18 regulatory arena on a broad range of food safety
19 issues.

20 Ms. DeWaal is the leading consumer analyst
21 on reform of laws and regulations governing food
22 safety. Since 1999, she has maintained an annually

1 published listing of foodborne illness outbreak
2 reports. She says I can cut it off right here.
3 Okay. Everyone always wants to know, you know, where
4 you went to school in case they know your relatives
5 or friends or something.

6 So Ms. DeWaal graduated from the University
7 of Vermont and Antioch School of Law, and she is a
8 member of the Massachusetts Bar. Caroline.

9 (Applause.)

10 MS. SMITH DeWAAL: Good morning, and you've
11 been a great, patient audience who never asks any
12 questions, but hopefully that will end soon.

13 We are now going to shift a little bit to
14 look at how this system that we've been talking about
15 this morning gets down to the consumer level, and
16 this is a really important question because if we're
17 really talking about products that have gotten into
18 people's homes, with pathogens like *E. coli* or
19 *Listeria* or *Clostridium Botulinum*, these are
20 critically important products, to notify consumers
21 about and to get them to take some actions on. Now
22 you need to show me how to do that.

1 Okay. So this is a partial list of
2 outbreak just since the beginning of the year linked
3 to FDA, a wide variety of products, and a wide
4 variety of pathogens, and you'll see the first one,
5 Honduran cantaloupes in March. That was an example
6 of a rolling recall. We got multiple notices going
7 on over a long period of time. But again getting the
8 information out to the public, especially as we're
9 dealing with some of these very serious hazards, is
10 critically important, and what we need to do from a
11 risk communication standpoint is to talk to consumers
12 about the steps they actually need to take to get the
13 products off their shelves, out of their pantries,
14 back to the stores maybe for a refund because some
15 consumers actually can't afford to throw food out or
16 if you can, to get them to throw it out, but to make
17 sure they don't eat it.

18 Now again another example here, and this is
19 a partial list of a rolling recall with the frozen
20 chicken entrees. A couple of sources, a couple of
21 points I want to just bring out here. We had an
22 example that's been discussed today of a potpie

1 outbreak that happened last year, but what was
2 interesting about the recall is that it didn't
3 initially go out as a recall. It went out as
4 something called a public health alert.

5 Well, what does that mean to the public?
6 Is it recalled? Is it not recalled? We'll discuss
7 that a little bit later also in terms of the concept
8 of a voluntary versus a mandatory recall.

9 But the other thing, information source I
10 want to make people aware of is that we've talked a
11 little bit this morning about how did you hear about
12 different recalls. Well, one source that I found
13 very useful over the last year is Safe Tables Our
14 Priority and Nancy and Donna and some of their staff
15 are here today. They actually have a researcher who
16 trolls the websites of the agencies, and she sends
17 out e-mails. So if you want to get on the stock
18 list, you may get information from them faster than
19 you get it from other sources.

20 I will tell you a couple of my personal
21 experiences. With respect to the Castleberry recall,
22 Clostridium Botulinum, a very serious recall, I first

1 heard about it with a call from FDA, to my home, on a
2 Sunday I believe. It was a Saturday or a Sunday
3 afternoon but they actually called me and said this
4 is serious, we want you to be aware of it, and if you
5 can get information out to the media, that would be
6 great. That's rare. I can tell you that's happened
7 a very few times in my professional experience. More
8 often, and this happened with Westland/Hallmark,
9 Sunday afternoon, you know, 4:30 p.m., I get a call
10 from one of the major news networks, and they said
11 how soon can you be on camera, and literally get
12 changed and we did the evening news that night but
13 that's how I'm hearing about recalls. They had a
14 press conference or press event with reporters over
15 the phone starting at 4:00 p.m. It led the evening
16 news, and I needed to know what I thought about that
17 recall and how I was going to advise the public that
18 quickly. I didn't hear it from the agency. They
19 didn't call my home. But I mean luckily you need to
20 be, when you're talking about risk communication, you
21 need to know the information that quickly and be able
22 to respond responsibly and give the public the

1 information they need to actually make good decisions
2 about what to do with the food.

3 So with that preface, there are three
4 classes of recalls. These are the ones where the
5 Class 1s, where it will cause serious adverse health
6 consequences and death, and luckily for most of the
7 pathogens we're talking about, there's not quibbling
8 between whether they're going to be Class 1 or Class
9 2. Most *Listeria*, *E. coli*, *Salmonella* will go out as
10 Class 1 recalls. Class 2 was the Westland/Hallmark
11 recall. Now note, that led the New York Times and
12 The Washington Post. We're talking top of the fold,
13 front page for the day or two afterwards. That was a
14 Class 2 recall.

15 How do we communicate with the public about
16 that? Really hard. Is it going to hurt me? Is it
17 not going to hurt me? Why is it so important that
18 the press is putting this attention on it, and yet
19 the Secretary of Agriculture is telling me it's Class
20 2.

21 And then Class 3 are the mislabeling that
22 don't involve allergens and mislabeling that may not

1 cause illness.

2 So what are we seeing? And some of this
3 represents concerns more than actual data. I will
4 show you data in a minute but I'm going to tell you
5 the data frankly is much easier to get out of USDA
6 when it comes to recalls than FDA. But we are
7 concerned that there are more recalls actually
8 occurring, and the data, some of this data backs this
9 up. We were really hoping that the USDA recall was
10 trending down, and there was data but now it seems to
11 be going up again.

12 We've talked about the type of hazards, but
13 the fact that *E. coli* is showing up in spinach, the
14 fact that *Salmonella* is showing up on cantaloupes,
15 presents new risk communication challenges,
16 challenges to the public, challenges to getting
17 information out because people don't think about
18 risks from fresh, natural products. In fact, more
19 people are looking for things like raw milk than ever
20 before. So we need to be able to communicate that.
21 What are the actual risks? How serious is this and
22 what should they actually do?

1 The botulism in canned food, I mean that's
2 -- we haven't seen that in a long time, and yet
3 lately we're seeing more botulism showing up in these
4 products, and then *Salmonella* in peanut butter. Big
5 debate on Capitol Hill right now about whether FDA
6 regulations should be risk based because they don't
7 have a lot of resources for inspectors, and we should
8 make it all risk based. And all the members of
9 Congress are going, yeah, but peanut butter was low
10 risk. So that doesn't -- I mean are we actually
11 going to solve our problems and spinach was low risk.
12 Are we going to solve our problems if we have a
13 risked based system for FDA regulated product.

14 But the other challenge that Dane brought
15 out is that the industry has to bring these products
16 back. They have to identify the points in the chain
17 of distribution that they've gotten to, and they've
18 got to be able to tell us. There has been -- well, I
19 will get to that.

20 Here's some of the data on FSIS recalls by
21 year. Here it's broken out by pathogen, and you see
22 *E. coli* O157:H7 as being a real new concern, not new,

1 but we saw a huge jump in recalls last year.

2 I'm going to talk about a couple of
3 examples here about how FDA and USDA actually release
4 the information to the public. With the Honduran
5 cantaloupe, which people, it's fairly recent. The
6 information that went out said that the cantaloupes
7 were distributed for sale in cardboard cartons with
8 the brand Dole and Product of Honduras printed on the
9 side panels. Consumers don't buy cantaloupes by the
10 carton. In fact, consumers never see the cartons
11 that the cantaloupes come in. So this really
12 illustrates the fact that cantaloupes -- when I buy
13 apples, they frequently have a little sticker that
14 tells me the name of the apple and where it came
15 from. We need this kind of information going home
16 with consumers if we anticipate recalls like this in
17 the future. This is really important. Consumers I
18 talk to said, well, I either at the cantaloupe
19 because I couldn't tell or I called the store to try
20 to ask them where it came from, but these are not
21 very efficient systems, and the fact that they can
22 get this kind of information on some fruit but not on

1 others indicates that this is a problem that's
2 solvable.

3 Okay. Westland/Hallmark. Now here is a
4 very complex and difficult recall. It's Class 2
5 because they don't know what was wrong with the cows
6 that we saw in the videotape, but if you watched the
7 videotape, these animals were not fit for human
8 consumption.

9 But I want to illustrate using another
10 example, this issue of the paradox of the voluntary
11 recall. One of my staff members is working on
12 *Listeria*, and she also happens to be pregnant. So
13 she is monitoring pregnant listerves (ph.) pretty
14 regularly, not really as part of her job but just as
15 part of her life. And the issue came up recently
16 about the recent recall involving meat products with
17 *Listeria*, ready-to-eat meat products, and there was a
18 conversation going on, on the listservs about how
19 serious is this? I know I ate this product last
20 week. What should I do? Should I go see the doctor?
21 And some advice came back over the listservs probably
22 from a lawyer by the way, saying, "Oh, it was

1 voluntary. You don't need to worry." That's how
2 consumers, that's how they understand the voluntary
3 recall. If it was serious, the Government would make
4 it a mandatory recall. That's how people think.

5 So we have to get, you know, we can say
6 this issue of voluntary versus mandatory isn't really
7 an issue because the industry's going to do it but
8 when we communicate with the public, it does make a
9 difference, if they think it's just not that
10 important.

11 Okay. Now getting to the product listing
12 issue. So this is what USDA put out. Now this was
13 an exceptional recall. This was a massive amount of
14 product, and there is, we could certainly debate all
15 day, how much of it should have been recalled,
16 whether it should have been recalled. Dane and I
17 started that debate over a glass of wine last night,
18 and here it will continue. But the bottom line is
19 this was a massive amount of product. This is also
20 not a good test case for the new California law where
21 they are required to post this information for the
22 public.

1 But the reality is the information coming
2 out from the agency was bulk packaging information
3 largely. It was not packaging that actually made it
4 into consumers' hands. So as I'm trying to talk to
5 the media about this, what do I actually say? The
6 reality is none of this -- well, very little of this
7 information is ever going to make it into a package
8 going to consumers' homes. The establishment number
9 does not get carried if the product has been
10 repackaged at any point along the chain. The
11 establishment number will likely get lost or not be
12 part of the final packaging going to consumers.

13 Now for product like we saw, an example,
14 earlier that was packaged by the manufacturer in the
15 final package for the consumer, that information
16 would carry forward. But for a lot of this product
17 you have to look at the press releases coming out
18 from the agencies. They're talking about information
19 going to the very next person on the retail chain,
20 and yet that is the information that's going out to
21 the media.

22 So the question I want to ask this group is

1 how do we actually make a system that more
2 effectively communicates to the public what they need
3 to do, what information they need is, to get products
4 that they may have already purchased out of their
5 homes.

6 So I really enjoyed the State presentations
7 this morning and from the local representatives, and
8 in effect, many of them said why won't you give us
9 the distribution list? Well, I remember when this
10 question of distribution lists wasn't really a
11 question. I mean it really seems to have become a
12 policy over the last six to eight years of USDA and
13 now FDA, but the bottom line is, the reason the
14 distribution list can only go to states sign what is
15 called a MOU or what I like to call a gag order
16 because they can't actually tell the public where the
17 meat was sold, is because if you USDA or FDA releases
18 that information, then the companies who are doing
19 voluntary recalls may not tell them in the future.
20 This is all tied back into the fact that the
21 Government itself is afraid that they may not get the
22 information they need. This is a bad policy. I'm

1 not sure it would stand up to a legal challenge, and
2 we've certainly investigated that. And the Under
3 Secretary wants a new rule out of USDA that will at
4 least in part remedy this problem, but if we get it
5 fixed at USDA, we won't get it fixed at FDA. So
6 we've still got a problem.

7 So I would like to see as one of the
8 outcomes of this meeting or meetings like this, a
9 resolution of that issue.

10 Okay. A little more recall data and the
11 recovery data. I love the recovery data. I think
12 they may have stopped publishing it after a while.

13 Okay. This is just another example of a
14 policy issue that's different between the two
15 agencies. In 1998, FSIS supported mandatory recall
16 authority under Secretary Glickman. But FDA said
17 they didn't need it. This is 1998.

18 In 2007, FDA is supporting mandatory recall
19 authority, but FSIS says we don't need it. This is
20 not logical. This is not -- I mean these look like
21 political decisions, not the ones being made, but
22 again let's think back to the issue of communicating

1 with the public. A mandatory recall communicates
2 differently to the public than a voluntary recall.
3 So we need to think through how we're going to handle
4 that. I don't think getting mandatory recall
5 authority through Congress, which we could possibly
6 do this year, will fix any of these problems, but I
7 think it does give us an additional tool when it
8 comes to risk communication.

9 Here are the communication challenges, but
10 I also want to give some good news. So I think I've
11 talked probably about a lot of those in my talk. So
12 let me give you some good news here.

13 We were really impressed that Wegman's
14 recently used their customer loyalty program to
15 actually call consumers and tell them that they had
16 purchased recalled ground beef. This was excellent,
17 and I am hoping it's a trend we're going to see in
18 the rest of the industry. We have been looking at
19 the privacy policies of these customer loyalty
20 programs. Costco says in theirs, and they are a
21 nationwide company, that they are going to use the
22 phone numbers, e-mails and other individual

1 information to notify their customers in the event
2 they purchased a recalled product. But most of the
3 other ones say we're going to use your individual
4 information, your phone number, your e-mail, to send
5 you promotional materials but not to send you recall
6 information. So I think we can fix this problem, but
7 I think it's critically important that we do.

8 I'm jumping around a bit, but I do think
9 that the retail consignee rule would help us move the
10 discussion forward. California did take action by
11 passing a state law. It took us two tries to get the
12 law signed by the Governor, but we did finally get a
13 law, and it's just gone into effect this year. Again
14 the Westland/Hallmark was not the best example of the
15 recalls that it will help on, but it will get the
16 information out. And if that's how we have to go,
17 state by state, we'll do it. Or if we have to sue
18 the agencies, we'll try that. But the retail
19 consignee rule is actually going through OMB right
20 now, and it will affect USDA regulated products and
21 hopefully allow them to get some of this information
22 out.

1 So the states could help by actually
2 supporting that at OMB and helping to move that
3 forward.

4 Civil penalties. I'm going to spend one
5 minute on this. Okay. The other issue I just want
6 to talk about here is the issue that there are some
7 recalls that are done for purely technical
8 violations, and there's an example of a cereal or
9 grain product where a pesticide was used on it that
10 was illegal for use on that product but it did not
11 pose a public health problem, and they ended up doing
12 a market withdrawal of that product. But that's an
13 example where a technical violation could have
14 resulted in a massive recall, StarLink is another
15 example but we won't go there, where civil penalties
16 might be equally effective in actually remedying the
17 situation. This is a great quote. "Civil fines can
18 serve as a deterrent and can be imposed more quickly
19 than criminal penalties or the withdrawal of
20 inspection." They can be appropriately tailored to
21 the nature and scope of the violation as well as to
22 the size and type of the business, but USDA and I

1 will note FDA does not have this authority for food
2 safety.

3 So that's another thing. As we look at
4 recalls, we have to look at, are they appropriately
5 sized? Are they being used as an enforcement tool
6 for a technical violation? If that's the case, let's
7 give the agencies the tools they need to adequately
8 enforce the law.

9 So we would like to give regulators
10 authority to order recalls, mandatory recalls,
11 provide adequate notice to the consumers if they have
12 products and civil penalties. And that's just bills
13 currently pending, and then we're not at questions
14 yet, but at CSPI, we have an important rule. Speak
15 softly and carry a big watchdog. (Laughter.)

16 (Applause.)

17 DR. HAGEN: Thank you, Caroline.

18 It's my pleasure to introduce one of my
19 colleagues, Terri Nintemann. Terri was named
20 Assistant Administrator for the Food Safety and
21 Inspection Service, Office of Public Affairs,
22 Education and Outreach in 2006. She joined FSIS in

1 2003 as the Deputy Assistant Administrator for this
2 Office. Now named the Office of Public Affairs and
3 Consumer Education, the Office Ms. Nintemann leads
4 carries out external and internal communications
5 about FSIS policies, priorities and activities to
6 protect public health. She also directs the
7 development and implementation of consumer education
8 campaigns to assist the Agency in achieving public
9 health goals.

10 Prior to joint FSIS, Ms. Nintemann was a
11 professional staff member and Legislative Director
12 for the Senate Agricultural Committee, served as a
13 Legislative Director for Congressman Dave Camp and
14 was employed for Senator Rudy Boschwitz.

15 Ms. Nintemann received a Bachelor of
16 Science Degree in Animal Science with a minor in Ag
17 Economics, I did not know this, from the University
18 of Minnesota in 1986. She grew up on a beef and hog
19 farm in Southeastern Minnesota. Terri Nintemann.

20 (Applause.)

21 MS. NINTEMANN: Thanks, Elisabeth. Well,
22 good morning. I think it still is morning, so I can

1 still that. It is a pleasure to be here this morning
2 and to share with all of you some of the risk
3 communication that is carried out by the Food Safety
4 and Inspection Service.

5 I'm going to talk a little bit this morning
6 about how we reach the public and consumers, some of
7 the challenges we face and then I'm also going to
8 provide some examples of our consumer education
9 initiatives, and then offer a few thoughts on how we
10 could all work together better.

11 Elisabeth mentioned the Office that I lead,
12 the Office of Public Affairs and Consumer Education,
13 and basically we handle the communication for the
14 Agency both internally and externally with our
15 stakeholders and our employees, and also develop and
16 implement the consumer education campaigns that help
17 us to achieve public health goals.

18 So first of all, how do we reach our
19 stakeholders and the public? Basically most
20 everything you see here on this list, and I'm sorry,
21 some of it probably doesn't show up on the back, can
22 be found on our website. We have a constituent

1 update that we do weekly. On our website, we also
2 offer an e-mail subscription service which we started
3 in I think summer of 2004. We have over 50,000
4 subscribers currently, and we encourage all of you,
5 if you haven't signed up, when you get back to a
6 computer with Internet access, to go under News and
7 Events on our website and click on e-mails
8 subscription. There are over 30 some options, from
9 press releases, from public meetings to directives
10 and notices the Agency does, that you can sign up
11 for, and then you automatically get an e-mail alert,
12 if something new goes on the website. So it's an
13 easy way to make sure you're informed about recalls
14 for example, but there may be other things on there
15 as well that you'd be interested in.

16 We have "Ask Karen" which is our resource
17 and interactive resource of answering questions about
18 safe food handling, 24/7 on the website. We do have
19 hotline which operates during the week from 10:00 to
20 4:00. It's 1-888-MP Hotline, and that is staffed by
21 people who will answer questions both in English and
22 in Spanish. And when the hotline is not actually in

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1 operation, there are recorded messages 24 hour a day.

2 We launched a new item, askFSIS, earlier
3 this year. It's a little bit more industry focused,
4 but there's information about imports, exports,
5 labeling, some inspection issues there, and we just
6 recently launched podcasting as another way to reach
7 consumers and to reach industry, and I'll talk a
8 little bit more about that later. Again, that's on
9 our website. You can subscribe to get those updated
10 podcasts as well, and a couple of other publications
11 that are geared to small plant news, more geared to
12 industry, small and very small plants and then our
13 magazine which we launched a couple of years ago.

14 Well, we've heard a lot about recalls and,
15 of course, that tends to be the result following up
16 on these multi-jurisdictional investigations of
17 illness. And again, just as we've all heard, these
18 are actions by manufacturers or distributors to
19 remove products from commerce that could cause
20 illness or even death, and so we do take this
21 seriously.

22 I want to spend a little bit of time

1 talking about how we communicate recalls to the
2 public and to consumers.

3 First of all, we do start out by trying to
4 figure out what is the information that we have that
5 we can inform consumers and the public about. What
6 is the product, as much information about that and
7 how to identify the product, how the problem was
8 discovered and also what consumers can do. Should
9 they return the product? Should they destroy it?
10 And also some of the recalls we've had over the past
11 year have been for frozen product, and there we want
12 to make sure to emphasize the importance of checking
13 in your freezer for product you still may have since
14 that would not be consumed.

15 I also wanted to start off by mentioning
16 that we do work with our partners. So if we're
17 working on an issue that does involve a number of
18 jurisdictions as well as it could be state and
19 federal partners, we want to work together and
20 coordinate as much as possible and share the
21 information and coordinate the release of the
22 information as well, so we all have the same

1 consistent message to provide to consumers.

2 So once our recall release is written and I
3 have a couple of folks here with me today who do a
4 lot of the release writing, then it gets issued to
5 the media, print, broadcast media, whatever affected
6 states or nationwide. Then next we go ahead and e-
7 mail that out as well to our partners, and we just
8 started doing that probably in the past couple of
9 years, but we do get it out to the Epi-X editor and
10 we also have a number of state and local public
11 health partners that get an initial e-mail alert as
12 well.

13 We post it on our website. We encourage
14 images of the labels or photos of the product as much
15 as possible, again just so you can see what the
16 product actually is, and then we also, as I said,
17 have the e-mail subscription service. That
18 automatically goes out so individuals can get that,
19 and we also have listservs that we provide the
20 releases to.

21 And then finally again our hotline. When
22 it's not in operation, it has recorded messages 24

1 hours a day. So we record messages on there.
2 They're up front when you call in. So you get that
3 information immediately.

4 And we've also been reaching out to other
5 populations as well. We've been translating most of
6 our releases into Spanish, and again on our hotline,
7 we do put the recorded message in both English and
8 Spanish.

9 Well, we've heard a lot about challenges
10 here today and, of course, we have a few, too. And I
11 think you would all agree that the first thing is we
12 want to act quickly, and we want to get out all the
13 accurate and valid information that we have and share
14 that with consumers. And so we do that as quickly as
15 possible but it can sometimes be a challenge when
16 you're in the middle of an investigation as well.
17 You have some information you want to get out, but
18 you know there's still information pending or tests
19 pending that could lead to further information going
20 out later, and again that's a challenge in terms of
21 making sure you're able to get the message out in a
22 consistent way.

1 Caroline mentioned public health alerts.
2 We've been using public health alerts a little more
3 recently in the past couple of years. In cases where
4 we don't have all the information, and may not ever
5 get all the information, to be able to move forward
6 to a recall, we may issue a public health alert.

7 And here are a couple of examples of the
8 situation we might use that in. For example, we can
9 identify what establishment produced the product, if
10 we know what kind of product it was, or we may know
11 what establishment produced it but we can't pinpoint
12 a production lot or specific information about the
13 product. And it is a challenge here. We really
14 strive to strike a balance between what information
15 we have, how we can inform consumers and without
16 creating fear unnecessarily and also without
17 fostering any apathy. So it's a challenge to be able
18 to get that information out, and we do want consumers
19 and the public to take these warnings seriously.

20 I do want to spend just a few minutes
21 talking about some of our consumer education
22 initiatives, and I have another office within my

1 office that develops the information, the educational
2 materials, to foster safe food handling and
3 preparation.

4 Basically, everything we do is based on
5 science. Sometimes that information comes from a
6 risk assessment or other data. We work with other
7 public health agencies and the Partnership for Food
8 Safety Education, and then we come up with
9 communication strategies, taking into account whether
10 we're trying to reach a general audience, a diverse
11 audience or maybe more specific audiences like at
12 risk populations.

13 So here are a few examples. I think
14 probably some of you have heard about some of these
15 but maybe not all of them. We have our new Be Food
16 Safe campaign, where we worked with the Partnership
17 for Food Safety Education, and the four basic
18 messages, clean, separate, cook and chill. We've
19 done some outreach to at risk populations. We had a
20 conference back in 2006. We developed a series of
21 brochures focused at different audiences. For
22 example, cancer patients, older adults, and also

1 starting some follow up to that conference. Again I
2 mentioned Ask Karen and the hotline.

3 And then we've got a couple of initiatives,
4 Thermy, which you can see over there to the right and
5 then is it done yet, which really are attempts to
6 foster more use of food thermometers to make sure
7 that meat and poultry are cooked to a safe internal
8 temperature. And then finally I mentioned the
9 podcasts, and just this past week, we launched the
10 Food Safety at Home podcast series. So we've got a
11 few podcasts out there. We'll be putting them up
12 every Wednesday on the website, and also they're
13 available on the iTunes store as well under
14 Government podcasts. You can look there as well.

15 Then finally I wanted to give you a little
16 heads up about another initiative coming out this
17 summer. We have just taped actually some videocasts
18 that are using American sign language to be able to
19 provide important food safety messages to those who
20 have difficulty hearing, and so we'll be launching
21 that in the coming few months, but I thought I would
22 give you all a heads up on that as well.

1 And then finally, how can we all work
2 together better. What I heard this morning I think
3 from a few folks, probably everybody, maybe not using
4 the same words, but it's a lot of relationship
5 building and working together in advance preparation.
6 And that's probably something that we see as key as
7 well. We've done a few things there within the
8 Agency, like to exercise tomorrow and also food
9 defense exercises that we've been doing at each of
10 our 15 districts, where we involve industry, consumer
11 representatives as well as state and local public
12 health partners and state ag departments as well.
13 Another way to kind of get together, build
14 relationships, but also test out how does the whole
15 communication function work.

16 So finally I thought, well, gosh, there are
17 at least three things that I could encourage
18 everybody here in this room to do that can help us
19 all, just maybe little stuff, that would help us all
20 work together better.

21 Firstly, just alerting your state and local
22 media or your other partners to the fact that there

1 is a recall going on. We do rely on the media to
2 help us get the word out, and we need to rely on our
3 partners, too, and the more everybody is sending the
4 same message out locally within the state or
5 nationally, the more we'll reach more consumers with
6 that important message. Again, I mentioned the e-
7 mail subscription service. You can get those
8 released immediately once they're issued. Also
9 promoting our safe food handling and preparation
10 messages. We have resources on the website and we
11 have other resources that you can call us and we can
12 provide to you as well.

13 And again, we are always open to
14 suggestions and idea of how we can all work together
15 better to reach consumers and reach the public with
16 the important messages that we do have, whether it's
17 recalls or ongoing food safety messages.

18 So I appreciate being here today with you.

19 (Applause.)

20 DR. HAGEN: Thank you very much, Terri, and
21 to Dane and Caroline, for sharing your perspectives
22 and some perspectives that we don't always get to

1 hear when we talk about highly improved outbreak
2 investigations and foodborne illness investigations.

3 At this time I would like to ask all the
4 speakers from this morning who are not currently on
5 the stage to come on up to the front row of chairs
6 here, the front couple of rows and then I still have
7 place cards for David and David and Ellen. If you
8 would like to come back up to the stage, I think we
9 still have room. You all can stay here, and we're
10 going to do our question and answer period now. I
11 know that you're probably hungry and if you must go
12 eat before the questions are answered, go eat. Eat
13 safely. But everyone's itching to ask some questions
14 and make some comments. So we're going to take until
15 just before 1:00 to take comments and questions and
16 then unfortunately one of my rights as the Moderator
17 is to shorten breaks and lunches. So we're going to
18 shorten our lunch period to about 45 minutes. I know
19 that that means you all come back in 60 minutes, but
20 I'm going to say 45 minutes. And at the end of the
21 question and answer period, we'll give you a couple
22 of suggestions about how we might be able to get

1 lunch quickly.

2 So if we could get Dave Boxrud, there you
3 are. And it looks like we have David and David on
4 the end. There are a lot of Daves on the risers. I
5 don't know what happened to the other David. You
6 might just take his place. Are you okay down there?
7 You want to come up?

8 UNIDENTIFIED SPEAKER: I'm fine down here.

9 DR. HAGEN: Did I lose your place card? Do
10 we have Ellen's place card? You all know who Ellen
11 is, right? David's going to be banished to the front
12 row here.

13 Okay. So I think that the easiest thing
14 for us to do will be to have people line up at the
15 microphone. There's David Goldman. We're going to
16 have you come up to the front row, David, to be able
17 to take some questions. And, Bonnie or Toni, I think
18 what we'll do is have people line up for questions
19 maybe at the back mic and then if we want to use this
20 microphone to move among the panel in the front.
21 Okay.

22 So to remind you, not everybody knows who

1 you are, and this is also being transcribed. So if
2 you can please state your name and if you have an
3 affiliation, that also. Okay.

4 MR. CHO: My name is Chung Cho (ph.),
5 Cameron County -- I'm glad to be here. You're
6 talking about the -- related, we may -- related to
7 the fed. Where the food -- interfered, you send all
8 the e-mails about recalls, whether that is from FDA
9 or USDA, I do not know, but we are getting all of
10 those. The issue is we as a local guy, how do you
11 expect to handle all of those? I receive between
12 two, three recalls every day. I have limited
13 inspectors. They just don't have enough time to
14 inspecting the retail foods and restaurants, mom and
15 pop stores, you know, vending machines. We don't
16 have enough days and time to inspect. What do you
17 expect us to do pertaining to recall? We know
18 certain things when state health department say this
19 one has to be priority, your inspectors go out, check
20 that out. Otherwise, we have no way to go out -- to
21 inspect whether that recall was actually taking place
22 in stores. So that's the question I'm asking.

1 DR. HAGEN: So are you asking of the
2 federal officials what is expected or are you
3 directing your question at other state officials?

4 MR. CHO: Yeah, what do you expect the
5 local health department guy is supposed to do, all
6 those recalls?

7 DR. HAGEN: I don't know who wants to take
8 that one.

9 DR. GOLDMAN: I'll start. I don't think I
10 have the entire answer. I'll start the answer but I
11 think what we heard earlier today is that from the
12 federal perspective, we really depend on our state
13 partners to be in touch with the local health
14 officials or local ag officials in their states and I
15 would think the states might want to respond to that
16 in some sense as well. We certainly depend on local
17 officials to help us in what we call recall
18 effectiveness checks, although we do a lot of that
19 ourselves, but a lot of the times the states or local
20 officials have done a lot of that work already once
21 they know a recall has taken place. So we tend to
22 use that information to help us gather the entire

1 picture and put together the entire judgment about
2 the effectiveness of that given recall, but we do a
3 lot of that work ourselves. So maybe that's an area
4 where we could provide you a little better
5 information about how we can collaborate in doing
6 those recall effectiveness checks. I think that was
7 the nature of your question. I don't know if any of
8 the state officials want to add.

9 MR. BERGMIRE-SWEAT: This is David
10 Bergmire-Sweat with ASTHO. I will just share with
11 you very briefly, it's a terrific question and it's a
12 terrible problem. In the State of North Carolina, I
13 think we've gotten, I don't know, flack and
14 recognition and whatever because of the way we did
15 with Castleberry's recall. We basically coordinated
16 with all the 86 health departments in the state, and
17 made it a priority to go out for like 3 to 5 days and
18 -- I'm not sure what's going on. Let me use this
19 mic. We only did that because it was botulism, you
20 know, Clostridium Botulinum. And so we knew because
21 the initial effectiveness check was done by state
22 level people, we found the product on 25 percent of

1 the shelves that we went and looked at, and we only
2 did a very small sample initially and it was very
3 heavily toward the biggest chains. You have the
4 chains that should have the most capacity to get this
5 stuff off the shelf. We were still finding it on a
6 quarter of the shelves on the first day.

7 And, Wendy, if I'm getting any of the
8 numbers wrong, correct me.

9 So once we realized that, and we knew that
10 the mom and pop, the smaller operators were going to
11 have even more difficulty, we made it a priority, and
12 we spent about a week, a week to 10 days of going out
13 every day and we mobilized resources of every health
14 department in the state, and I think we pulled 30,000
15 plus cans of stuff out of stores, going into even,
16 you know, gas stations and convenience stores and all
17 kinds of places, daycare pantries, food bank
18 pantries. I mean it was everywhere.

19 But we don't do that every day. I mean we
20 did it for botulism, but you're right. It's a huge
21 problem and I don't know that any AFTO or ASTHO is
22 prepared to tell you what you should do. I think

1 it's a great question to ask your state health
2 agency, what do they expect of you because they're
3 your major funder. I'm probably tethered. We'll try
4 again.

5 MS. HAINSTOCK: I'll just balance
6 precariously here on one foot. So if I fall down,
7 that's okay, I bounce really well.

8 You know, I'm going to tell you that I wish
9 I could say that we have a really great scientific
10 way of determining when we need local health
11 departments' help or when we don't, and what we have
12 tried to do, at least in Michigan, we have actually
13 tried to prioritize recalls, and so we have actually
14 three tiers. We have the routine stuff where we have
15 the unidentified allergens, the ones where we know
16 there's no human cases of illness in the country, and
17 we basically do not request help in general from
18 local health departments unless, of course, it is
19 deemed such as a significant issue like the Hallmark
20 recall, that it is something that sort of takes on a
21 life of its own.

22 We also have our routine ones, and

1 typically we'll just let our partners know there's a
2 recall. Okay. Here we go. We have our normal ones
3 where we're just asking our own field staff to go out
4 and check during the course of their routine
5 inspections, but occasionally we do end up with the
6 ones where they are highly significant. We know that
7 Castleberry, spinach, peanut butter, those types of
8 things, where we're marshaling all of our forces, and
9 I will communicate with our local health departments
10 and request help, and typically much of that
11 information has to do with the immediacy and
12 significance at the federal level. If they're
13 saying, look, you guys, whatever you can do, we've
14 got to get this stuff off the shelf right now, and we
15 need to respond quickly, and we need to hit it hard,
16 we will then take appropriate action at that point,
17 but to tell you that we have some great scientific
18 way of doing that, it really is case by case, and
19 sometimes a perception of judgment as opposed to
20 again any tried and true methodology. So I don't
21 know if that answers your question or if that holds
22 true for other states.

1 DR. HAGEN: I think Bill Keene was going to
2 offer one more state perspective, and then we'll need
3 to move onto the next question.

4 DR. KEENE: This is definitely not
5 answering your question because it's getting a bit
6 afield, but we don't ask people to do anything
7 because we're epidemiologists, but one thing I would
8 suggest is a way of reaching the consumer who has
9 this product. You know, they've already got it,
10 they've taken it home, they may have split it up and
11 frozen some of it a month ago is we find it very
12 useful to issue our own press releases locally for
13 things that may come out of USDA, FDA that we
14 sometimes may not have been a part of the outbreak
15 investigation. We get a much better bounce in our
16 local media if we're the ones that put something out,
17 and we're able to get on camera or talk to the radio
18 and the TV station. It's just local interest. It
19 gets you more play, and you can look at some of these
20 recent outbreaks, be they peanut butter or potpies,
21 and compare the media coverage in different markets,
22 and it's dramatically different. Sometimes it's a

1 little notice on page 5 of the paper, and sometimes
2 there's banner headlines on page 1, and it's the same
3 story, and they're trying to get the same product not
4 only from retailers and wholesalers but in our case
5 from the consumers. They're not so easy to reach
6 otherwise except through the media.

7 DR. HAGEN: Thanks, Bill.

8 UNIDENTIFIED SPEAKER: Can I just add one
9 thing?

10 DR. HAGEN: All right. One thing.

11 DR. BERNARD: Call it industry lobbying if
12 you will but just to beat the drum on the size of the
13 recall again, targeted recalls, small, you can get
14 them done. The bigger the recall, the harder it is
15 to manage and the more effectiveness checks that have
16 to be done at the other end. So it might be
17 convenient to say, well, let's just take it all, but
18 you're really burdening the system and you may be
19 diminishing the public health effectiveness of that
20 recall by doing so.

21 DR. HAGEN: Can we --

22 MR. CHO: What we do, you know, the

1 sensitive matter we take action immediately. If the
2 size of a recall is humongous, then not only we are
3 checking the store and we post on our website to
4 alert the consumer, anyone wants to know about what
5 we are doing, such as in the tainted toothpaste, that
6 was a really big issue. We inspect in all the Dollar
7 Stores, you know, we confiscate it. We did that. We
8 do have authority to confiscate if that is
9 contaminated or tainted. But still what my issue is
10 every day I got recall list, do nothing, feel dirty.
11 That's what I'm talking about. That we go by
12 priority, you know, certain sensitive issue, it's
13 children's issue, we take action immediately. But
14 all those recalls, you do not expect our local guys
15 do everything we -- That's what I'm telling you.

16 DR. HAGEN: Thank you. I wish we could
17 help you feel less guilty but if anybody can do that.

18 Next comment or question.

19 MS. SAMARATAM: Thank you. Michelle
20 Samaratam (ph.), health officer, health educator,
21 environmental health specialist, Franklin Township
22 Health Department, Somerset, New Jersey.

1 This morning I very much related with what
2 I heard the county and state health departments
3 doing. As one of the most grass roots local health
4 departments, it's kind of encouraging to know we're
5 not alone in our challenges. Also it's incredibly
6 scary to know I'm not alone in our challenges.

7 Two thoughts with communications. One is
8 where's a local health department I get information
9 on outbreaks, and unfortunately it's not coming down
10 through the more official sources. My prime resource
11 is Doug Powell at Kansas State. I get information
12 from him days before I get it from official sources,
13 and then for updates, I'm getting it from a Barth
14 blog (ph.). So as a local health department, we
15 would prefer to get it from a more official source
16 although K State is really good with that.

17 And the secondary thing is when you're
18 talking about how we can communicate with the public
19 in case of recalls, in case of outbreaks, and I very
20 much appreciate the information that FSIS and FDA has
21 on their websites, but I will guarantee you that most
22 consumers have not seen it, mostly because most local

1 health departments have no idea it exists.

2 Now also in the case of that, I'm looking
3 around the room and I appreciate all the colleagues
4 that are here. We need to involve our health
5 educators. I do not believe there's anybody here
6 from any of the national health education
7 associations and on a local level, we are the ones
8 that are most capable of being able to reach the
9 public that is most likely to use a certain product,
10 a certain type of food, and we can do it in a
11 culturally and linguistically acceptable manner. So
12 please do embrace the health educators as we're going
13 forward with communications because we do want to be
14 able to help you with communications with the public.
15 Thank you.

16 DR. HAGEN: Thanks, Michelle.

17 MS. HAMMOND: Hi, I'm Roberta Hammond,
18 Florida Department of Health. I had two questions or
19 two statements. One was the distribution list issue.
20 I think people have the impression that they can
21 never get a distribution list, and it depends on the
22 nature of the outbreak. Often when we're

1 investigating the outbreak, we already had the
2 distribution list before FDA has it. So it's not
3 that FDA has custody and doesn't ever give it out.
4 If we're doing the investigation, we have it or we
5 can get it by calling the company directly. That's
6 one thing.

7 And the other thing I wanted to -- it
8 depends also on if it's a multistate sort of wide
9 distribution type outbreak, like spinach or
10 something, then it's less likely that we would have
11 that information but if it's more localized, we
12 probably would already have it before FDA even gets
13 involved.

14 The other thing I wanted to say is the
15 experience of the local and state, county health
16 departments are not the same across the board. As
17 David Bergmire-Sweat with that nice little map of how
18 the different states are organized, I think that, you
19 know, administratively it depends on if the state has
20 a centralized health department or not as to how that
21 works for them, and with Florida, we are able to work
22 with our counties and have some control over the

1 counties and better communications just by virtue of
2 the fact that we're all in the same agency. So I
3 think the experiences vary from state to state. I
4 think that's all I wanted to say. Thanks.

5 DR. HAGEN: Thanks, Roberta.

6 MR. HEDBERG: Craig Hedberg (ph.) from
7 Minnesota. On this issue of risk communication, I
8 think that I really like the Class 1 recall label and
9 the idea that this is really a public health
10 emergency that we're dealing with, and I think we can
11 all agree that we should talk about that as a recall
12 and that the product needs to come out of people's
13 home and off the market, and sort of take the
14 organizational jargon as to what the authority for
15 promoting a recall is out of the messaging because
16 the message is that it's a recall, people shouldn't
17 eat it, and I think we can all sort of just adopt
18 that as a standard messaging technique as we leave
19 the room today.

20 But the other issue is that I think we as
21 epidemiologists have a real obligation to try to work
22 with industry to make those recalls as specific as

1 possible and getting as much detailed product
2 information up front as we can as Dave Boxrud nicely
3 demonstrated in his presentation, and then engaging
4 in a discussion as the investigation proceeds. So
5 that industry can give us some feedback on how we
6 might refine our search for information to more
7 narrowly frame up those questions, I think will help
8 everybody on the back end then as we implement that
9 recall.

10 MS. KOWALCYK: Hi. My name is Barbara
11 Kowalcyk, and I'm with Center for Foodborne Illness,
12 Research and Prevention. As the mother of a child
13 who died from *E. coli* O157:H7 in 2001, and
14 subsequently had major difficulties dealing with our
15 local and state health departments, and with getting
16 information from regulatory authorities, only to
17 learn three years later that our child's PFGE pattern
18 matched that of a meat recall, this is a topic that
19 is very near and dear to my heart, and I would like
20 to thank the organizers of this meeting for holding
21 this.

22 I have a multitude of questions, but I will

1 limit it to two. One thing that I have found over
2 the years is that there's a lot of discrepancy in the
3 definition of an outbreak. For example, my
4 understanding is that CDC defines three cases as an
5 outbreak and our own personal experience, my son, my
6 daughter and my husband all tested positive for the
7 same strain of O157:H7, but the State of Wisconsin
8 did not consider us an outbreak since it was three
9 related family members. So I would like the state
10 and local departments that are here, as well as the
11 federal agencies, to address the issue of how they
12 define an outbreak which I think is critical when we
13 start talking about how do we improve outbreak
14 response.

15 The second question is, is I'm not really
16 entirely sure why the state and local authorities
17 cannot share the identifying information with
18 agencies like the CDC. I certainly understand that
19 there are HIPAA rules that need to be followed, but I
20 would think that in trying to identify outbreaks
21 where there are limited cases in a multitude of
22 states, it would be very helpful if the CDC would be

1 able to get that information and I was just wondering
2 if anyone could clarify why that information does not
3 get shared from the state and local levels back up to
4 the CDC. Thank you.

5 DR. HAGEN: Okay. So we'll take the first
6 question, was the discrepancy in the definition of an
7 outbreak. Dave or Bill, you're going to handle the
8 state perspective and then perhaps we'll ask
9 Dr. Warnock to answer.

10 DR. KEENE: Well, I can address both
11 questions I guess if you want. What's the first one?

12 DR. HAGEN: The definition of an outbreak
13 in Oregon.

14 DR. KEENE: Well, the outbreak definition
15 is actually flexible. So in our state, if you have
16 three people in one household, we would call that a
17 household cluster. It would not be an outbreak
18 although it might be treated as an outbreak depending
19 on the circumstances or it might not be. I mean it's
20 flexible. The same way two people unrelated, if
21 somebody goes and spend every other day at their
22 aunt's house with their cousins, it's kind of like

1 the same household, but it isn't technically the same
2 household. So we kind of fudge this stuff. We use
3 the definitions flexibly because it doesn't -- in a
4 sense we do our work regardless of whether or not it
5 meets a definition or not. A single household is
6 understandably harder to follow up on because there's
7 a presumption that there are lots of overlapping
8 exposures that are not all food. So they're more
9 difficult to be convinced that this is something
10 other than a -- something that's not possible to
11 pursue, not feasible to get an answer out of but it's
12 all case by case really.

13 The second question, we legally can share,
14 in our state, we can legally share identifying
15 information with any other public health agency if
16 there's a reason to do so. Generally there's no
17 reason to give identifying information to the CDC or
18 FDA or another agency or another state because they
19 don't have to contact them. So there's no reason to
20 violate the confidentiality, there's no advantage to
21 doing that. So we share the information we get from
22 the interviews but they don't actually need to have

1 the identifier itself.

2 MS. SMITH DeWAAL: This is Caroline. Barb,
3 were you able to get the PFGE pattern from the sample
4 that your son submitted back from the health
5 department?

6 MS. KOWALCYK: I believe so. In our case,
7 it took several threatened lawsuits, getting
8 Congressional representatives involved, just to get
9 information from the USDA under the Freedom of
10 Information Act, and it took us about three years to
11 figure out that he matched the meat recall in the
12 same time period in the state in which we were
13 living.

14 MS. SMITH DeWAAL: Bill, my question to you
15 is do you have a policy? If there is an individual
16 who is identified by the state and their sample has
17 gone forward for PFGE fingerprinting, what is your
18 policy about getting that information back to the
19 family?

20 DR. KEENE: I would say we don't make an
21 effort to tell people everything we know, but if they
22 ask us, we generally would tell them. I mean it's,

1 you know, I'm not going to call somebody up and say,
2 hey, I just found out that you match a case in
3 Pennsylvania although we might do that because we're
4 in the context of asking some questions and that
5 would be an obvious lead in. We want to ask you a
6 bunch of questions because you matched somebody in
7 Pennsylvania. But I don't willy-nilly call people up
8 just to give them that kind of subtyping information
9 for its own benefit, but it's information that if
10 they want it, they can get it from us without any
11 difficulty. If somebody says I want my PFGE pattern,
12 we'll give them the pattern.

13 DR. KEENE: What we do, if we have a signed
14 request, a signed waiver request, you know, like from
15 the family if they were requesting it, then we would
16 release it, but if just anybody called up and said I
17 want to know, you know, what's the pattern, you know,
18 on this person, we just wouldn't give it out but if
19 we had a signed request like from the family, then
20 that would be released.

21 MS. SMITH DeWAAL: So is that true most of
22 the state here, that the families themselves can get

1 the information if you've sent it on for PFGE
2 fingerprinting just on request? Because we've heard
3 that they can't. We've heard that families with
4 children who had confirmed O157:H7 cases could not
5 get PFGE fingerprinting. So what I'm hearing today
6 is different and we'd just like to clarify it.

7 DR. KEENE: I think it varies state by
8 state.

9 MS. KOWALCYK: Caroline, I would just like
10 to clarify. We did not get the PFGE pattern from the
11 health department in the State of Wisconsin. As a
12 matter of fact, we were not even informed that my
13 husband and my daughter tested positive until we
14 called the health department over a month after my
15 son had died.

16 DR. HAGEN: Okay. I think unless -- did
17 you want to add anything to the definition of the
18 outbreak, David, from the CDC's standpoint?

19 DR. WARNOCK: No, Bill gave a great
20 definition of the definition. It does depend
21 somewhat on the circumstances and, you know, the data
22 belonged to the states, not to the CDC. We don't

1 collect personal identifiers because we don't need to
2 have them for public health purposes. Much of the
3 information we gather doesn't affect the immediate
4 healthcare of the individual. Public health has
5 different priorities.

6 DR. HAGEN: Next question or comment?

7 MR. DEL TORO: Yes. My name is Miguel Del
8 Toro. I'm here with the law firm of Hogan and
9 Hartson. We represent a number of food
10 manufacturers, food retailers and trade associations
11 for the food industry. And I wanted to first off
12 thank all the participants for coming together to
13 bring together all these different perspectives on
14 the many, many communications challenges faced with
15 these often emergency circumstances.

16 I had a couple of comments I wanted to
17 briefly note, communication concerns that affect
18 industry that we are seeing that often leave a lot of
19 frustration for the companies involved in these
20 processes.

21 First off, just to reiterate the
22 recommendations made by Mr. Bernard and specifically

1 with regards to the importance of identifying a
2 single agency as quickly as possible to be the source
3 of communication with the companies. We see a lot of
4 companies that have a lot of frustration because
5 they're getting conflicting information from
6 different sources and don't know where to turn.

7 We do think that the federal agencies are
8 often in the best position to do this, and we
9 encourage FSIS and FDA to take the lead as quickly as
10 possible and make the initial communications with the
11 companies and the earlier the better.

12 Second, I just wanted to note another
13 concern. That is that a lot of companies come to us
14 very frustrated because the communications they get
15 more and more often are that there has been found to
16 be Epi data linking an outbreak to their product,
17 without a specific finding of contamination in a
18 product. There may be very good reasons for that.
19 It's not always possible to identify a product.
20 However, most of these companies, many of these
21 companies do not have epidemiologists on staff, don't
22 understand epidemiological data, and we think that

1 it's very, very important that the Agency reach out
2 and communicate as clearly and comprehensively as
3 possible the information, the evidence that they're
4 basing their request for recalls on, and that that
5 type of communication can only help build trust with
6 the industry to lead the more effective responses to
7 outbreaks.

8 MS. MORRISON: I think you're right, and I
9 think in talking to companies as we do from the FDA,
10 we often ask the CDC to join us to explain the epi,
11 the cases, the nature of the outbreak and, of course,
12 the FDA perspective of we're probably going to come
13 to your company and the expectation that the
14 companies generally don't have a problem with,
15 they're going to recall their product.

16 But I think there's another point that I'd
17 like to make in one of the recalls that we had on the
18 vegetable snack. The companies are surprised when we
19 call them because this is the first they've heard of
20 it, and I understand that but they will also often
21 say we don't have any consumer complaints on this.
22 But it's really a rare day in my view, in our office,

1 who oversees the national complaint system of FDA,
2 that we will get a consumer complaint on a product
3 involved in an outbreak. We'll get complaints on
4 many things. In fact, I think it's more likely that
5 we're going to get a complaint on a chemical issue,
6 something burned or something like that, because
7 people don't know what made them sick. And so the
8 companies seem surprised that they don't have any
9 complaints and how can their product have *Salmonella*
10 or whatever because there's an expectation that
11 consumers are going to know that their product made
12 them sick, and that's just not the way the system
13 works. If you get sick, you go to your doctor if you
14 even go to your doctor, if you even have a specimen
15 taken, and you'll be noted that you had *Salmonella*
16 but you won't know what made you sick. You'll just
17 think it's the immediate meal or the immediate few
18 meals right next to what you just go after, and
19 that's not necessarily the case.

20 So there's a lot of improvements to be
21 made, Miguel, but certain we understand and that's
22 why many of the recent recalls that FDA has called

1 companies like *Salmonella* in peanut butter and
2 ConAgra and so forth. We've asked the CDC to join us
3 to explain in great detail any questions that they
4 had on the epi data but I will also say that the FDA
5 is prepared to take action on epi alone and not have
6 to have a positive sample. We've done that for many
7 years now.

8 DR. HAGEN: Go ahead. I think David
9 Warnock wanted to respond as well.

10 DR. WARNOCK: I was going to echo that last
11 point that Ellen has made, that oftentimes we don't
12 have an isolate from a product when we notify the
13 regulators and the regulators increasingly are
14 willing to act on that evidence, and I suspect that
15 this is going to be the case more and more because so
16 many of these products have a very quick turnaround
17 time. They're gone by the time we realize there's a
18 problem. There's none left to test and we're very
19 lucky if we have product to test, and we're lucky if
20 we get an isolate from a sample of product that
21 really is the icing on the cake if we have that final
22 bit of evidence but so often we have to just go with

1 the epi and the statistics, and we're very happy to
2 explain to companies and to their lawyers the basis
3 for the recommendations that we're making to the
4 regulators.

5 DR. HAGEN: Okay. I think we're going to
6 hear from several of our speakers this afternoon
7 about the increasing frequency of that type of
8 recall, that type of action that's associated with
9 epi data along with positive product.

10 DR. KEENE: If I could just make one more
11 comment. As much as you would like to hear from only
12 a single agency, I have to remind you that we don't
13 work for the feds, and in some investigations, state
14 agencies or even a large local agency may be the one
15 that is driving the investigation and they may be the
16 one to contact you and you ignore them somewhat of
17 your peril. We'll try to explain the epi, too, and
18 we work with our federal partners, but we don't
19 necessarily work on the same timetable.

20 DR. HAGEN: Okay. We have time for a few
21 more questions.

22 MS. HARRISON: Jean Harrison with Peer

1 Foods. I handle their government relations. And my
2 comment is very narrowly focused to holds and recalls
3 that pertain to school products, both commercial and
4 commodity.

5 A couple of comments. One, it was very
6 confusing to the public and to the school food
7 service community when there was a gap between the
8 commercial product with the Westland/Hallmark that
9 was still okay when the product that was in schools
10 was not okay, and again it goes to voluntary,
11 involuntary, Class 2, edible, inedible, et cetera.
12 Some real confusion and a lack of credibility that
13 spilled back on USDA.

14 The second was the consistent direction
15 that as a further processor and all of us were given
16 to the schools was, well, we cannot give direction at
17 the federal level on disposition of the product
18 because it varied state by state, for environmental
19 rules and the forms vary state by state and maybe
20 even county by county or city by city, and the school
21 would run the risk of not being reimbursed. So
22 bright eyed and bushy tailed at my 53rd call by 10:00

1 in the morning, I say call your local health. They
2 said, I did. They don't know what I'm talking about.
3 They don't have a form. Their form doesn't fit.
4 Well, call the state. Well, now I got, the bottom
5 line is that I am so happy to meet people from local
6 and state health organizations that I understand what
7 you all are up against, and it reinforces to me that
8 those of us who are working on the -- agency, hold
9 and recall, for commodities, how much broader we need
10 to go. That simple statement that sounded so crystal
11 clear, oh, just call your local health department, I
12 got a real awakening about how not simple that is.

13 I wanted to say also that it was
14 extraordinarily helpful. I have to mention the
15 timing, I was curious, 4:20 p.m. on a Sunday holiday
16 weekend, but the multi-agency conference calls that
17 were held with all stakeholders were invaluable.
18 Those of us who were impacted, whether you were a
19 state commodity director, a food service director, a
20 person from industry, et cetera, we got to hear every
21 single state agency. Even if they didn't know the
22 answer, at least we knew they were all in the room

1 together. So I would encourage you to build on that
2 format. It was extraordinarily helpful. Thank you.

3 DR. HAGEN: Thank you.

4 MS. SPAIN: Hello. Mary Spain. I'm an
5 epidemiologist from the State of Vermont, and I
6 handle lots of different pathogens but mostly food.
7 And I have three comments, and I'll make them quick.

8 The first one, we're lucky enough, I feel,
9 we're lucky enough to be a centralized state. We're
10 also centrally organized. We're also very small.
11 But for those local and county health departments out
12 there who don't know about recalls, there's a great
13 resource, www.recalls.gov. Look at it every day.
14 It's a government website. It will tell you all of
15 the recalls that are going on, FDA and USDA, a
16 fabulous resource.

17 Secondly, a very quick comment to reiterate
18 what Ms. DeWaal was talking about in terms of risk
19 communications from the regulatory agencies in terms
20 of, you know, a carton of cantaloupes, blah, blah,
21 blah, number such and such. We really do have to get
22 better at this. I get millions of calls every day

1 from the public, a lot of the public didn't even
2 realize. They thought, oh, I shouldn't be eating
3 this cantaloupe. No, it's the skin that we're
4 talking about. There's a lot more that we can do
5 from, you know, getting the information out there.

6 And then lastly, and this is my main
7 comment, and it's directed to the regulatory agencies
8 specifically, and that is as an epidemiologist, I've
9 had an ongoing huge frustration in that I know we all
10 do a huge amount of work with shrinking resources,
11 shrinking monies, shrinking personnel and turnover,
12 and we all come together. We're all, you know, for
13 the same goal in the end. We're working very hard,
14 but from the regulatory agencies, and I'm talking
15 specifically here about large outbreaks, multistate
16 outbreaks, as an epidemiologist, I get so frustrated
17 by never hearing back at the end of it all, from the
18 regulatory agencies in terms of a summarization, a
19 report, so, you know, with *E. coli* in spinach. So
20 was it the wild hogs? So how did the wild hogs, you
21 know, how did the *E. coli* get into the spinach? Is
22 it true that spinach, you know, has this incredible

1 scientific capacity to grab *E. coli* as we've heard.
2 And then, you know, peanut butter in the Peter Pan
3 peanut butter. So there was a leak in the roof.
4 Well, how does the lead in the roof affect the
5 production line? You know, I as a scientific person
6 would like to know. That would really help my epi
7 work.

8 For instance, the infant snack food, Pirate
9 Booty, so that was a spray on additive. Well, what
10 herbs were in that spray? Where did it come from? I
11 get so frustrated I can't tell you with the complete
12 lack of completing of that circle, and I know that
13 industry needs to protect itself, it needs to protect
14 its methods or its production, I don't know what
15 secrets, but I would love to get more education. So
16 thank you.

17 DR. HAGEN: Last few comments, questions?

18 MR. FLOOD: Thank you. My name is Tony
19 Flood, and I'm with the International Food
20 Information Council, Washington, D.C. Briefly, we
21 are a non-profit. Our mission is to effectively
22 communicate about science-based information about

1 food safety and nutrition related issues. And I just
2 want to thank the young lady that spoke primarily
3 about involving health educators into the mix because
4 I think they are an important part to add to this
5 communication strategy.

6 This question or comment kind of goes to
7 Caroline and to Terri also. My thought is when we
8 talk about effective communication, I think it's
9 extremely important to involve all stakeholders.
10 Stakeholders from the entire food chain and that
11 would include consumers as well.

12 One of the things that we done at IFIC is
13 to get sort of like a read or a pulse on consumer to
14 kind of understand how they actually respond to
15 specific messages about food safety and nutrition
16 related issues. Just as a thought and then a
17 question is, is there any research or consumer
18 research that's out there that actually has just
19 looked at how consumers respond to recall notices
20 whether they be voluntarily or involuntary? And if
21 it is, I was wondering if it's possible that we could
22 have access to that so that we become better at

1 developing communication materials that are based on
2 recall information, and just as a thought of that, we
3 actually just finished a survey. It's called a Food
4 and Health Survey 2008, and this is the first year we
5 actually included some food safety questions in
6 there. We found dramatically that about 7 percent of
7 the Americans that we polled, actually don't use a
8 meat thermometer. So my question is knowing that the
9 consumer, the general public, doesn't use a meat
10 thermometer to check the doneness of their food, how
11 are we aware of the fact that the recall notice to
12 the public, that they're actually following the
13 directions that are set by the agencies. Thank you.

14 MS. SMITH DeWAAL: Okay. Terri and I sort
15 of divided up the answer. The survey that I'm most
16 aware of it's really old, on how consumers responded
17 is actually a follow up to the Schwan's Ice Cream
18 recall. They actually had the best scenario you can
19 image for people going back to the consumers who
20 actually bought the ice cream and telling them. They
21 sent letters, but they actually had people at the
22 door saying don't eat this ice cream. We're going to

1 give you this other carton, and consumers did not
2 necessarily listen to that advice. They continued to
3 eat it. So consumers don't always do what we want
4 them to do, but that's an important element to
5 guiding how we do risk communication.

6 I mean some of the best studies I've seen
7 on risk communication really talk about how you
8 target messages not at the person but at someone they
9 are to protect. For example, if you're trying to
10 communicate with someone about a food product, if it
11 impacts an elderly parent or a child, they would pay
12 more attention than if it's a product that would just
13 impact them. So again you have to look at risk
14 communication messages, not necessarily as aiming,
15 putting the arrow right at the target but figuring
16 out how to aim the message so that it gets the most
17 pickup.

18 MS. NINTEMANN: I'm not aware of anything
19 either on the recall message but the one thing that
20 it did make me think of is one of the items I
21 mentioned was is it done yet? And that was a very
22 specific targeted campaign of ours, that we focused

1 on parents of children I think under the age of 10 in
2 Michigan, and we actually, and this was again to
3 promote the use of food thermometers but do it so
4 that they would be using it to protect their family
5 and the children. And we do have posted on our
6 website information about that because we did have
7 with a partner in Michigan, I think it was Michigan
8 State, who went out and did kind of a baseline survey
9 first before the campaign ran, and then afterwards it
10 did show that there was a change in behavior. But,
11 you know, again that was a very focused kind of thing
12 but we do have that on our website and if you have
13 trouble finding it, let me know and I can get you to
14 the right spot.

15 DR. HAGEN: Last question from Nancy.

16 MS. DONLEY: My name is Nancy Donley, and
17 I'm President of STOP, Safe Tables Our Priority. And
18 for those of you who are not familiar with us, we've
19 been around 15 years now since the 1992-93 Jack-in-
20 the-Box outbreak on the West Coast, that frankly if
21 you went back to that time and if we had had maybe
22 this kind of a meeting before that, wouldn't have had

1 to spread all the way up from the West Coast if there
2 had been better communications between public health
3 departments. It started with the death of little
4 six-year-old Beth Rudolph in San Diego and then did
5 spread as we know widely up the coast.

6 We're a national, not-for-profit public
7 health-based organization that's dedicated to the
8 prevention of illness and death from contaminated
9 foods. And this particular topic is something that's
10 very, very near and dear to our hearts. We've been
11 dealing as I said for 15 years with people who come
12 to us, consumers, every day consumers who come to us
13 and don't know how to navigate the public healthcare
14 system. They have no ideas many times with the phone
15 calls that we handle every day about the -- they
16 would not even think to come to you folks. They
17 don't know the questions to ask. They don't know who
18 to talk to, and it's something that just really isn't
19 understood out there in the public. So many times
20 they're relying on the doctors, and in the cases, if
21 they don't go see a doctor, they come to us and we
22 are out there trying to help them navigate this

1 system. So I'm very encouraged to have this
2 conversation going on today.

3 My son, my only child, Alex, died from the
4 sporadic case coincidentally the same year in 1993,
5 and very, very aware of in sporadic cases that it's
6 very difficult to ever find out what killed your
7 child, and the comment made earlier is, you don't
8 know who to call, companies, anything, because you
9 don't know what made your child sick in many cases
10 unless you can really get down to the crux of the
11 matter. So I'm very, very grateful for this
12 conference. That's my comment.

13 And then I just have one question, and
14 that's for Dr. Warnock. You made the comment that
15 PulseNet is experiencing data and information
16 overload, and I want to ask, is the reason for that
17 is that has funding been pulled away from you on that
18 or are you lacking the resources? Is that the
19 problem?

20 DR. WARNOCK: I think PulseNet has grown
21 and it's an example of a decentralized system that is
22 highly standardized and it is generating more and

1 more useful information. But we don't have the -- on
2 the epi side as you've heard this morning. We have
3 50 states with different ways of doing business, of
4 asking questions, to people who have gotten sick. We
5 have any number of local health jurisdictions within
6 those states and what we have to do I think in the
7 future, is we have to decentralize the epi side of
8 the equation but at the same time we have to
9 standardize it and we have to try and get the sort of
10 instantaneous communication that we've now achieved
11 virtually on the lab side, and only then will we be
12 able to successfully analyze the information that
13 we're now generating from PulseNet.

14 So, the bottom line is, yes, more resources
15 will improve the systems.

16 MS. DONLEY: Thank you. Let us know how we
17 can help.

18 MS. SMITH DeWAAL: What are the agencies or
19 the associations that are needed to do that
20 standardization? Is it AFTO? Is it ASTHO? Are
21 there groups that need to be engaged to do that?

22 DR. WARNOCK: There are different groups.

1 There is CIFOR that you're going to hear about this
2 afternoon that's focused really the state and the
3 local level. There is OutbreakNet, which to an
4 extent is analogous to PulseNet. It's the epi side
5 of that equation but it's an infant compared to
6 PulseNet which is now a very mature, effective
7 system. So hopefully these are areas which will grow
8 and develop over the next decade.

9 DR. HAGEN: Thank you, David. And thank
10 you for all the questions and comments. We're now
11 going to break for lunch. I have 1:02 on my
12 BlackBerry. So I would like you all to be back here
13 at 1:50. I have a couple of suggestions. The Capri
14 Restaurant in the hotel has been alerted for today
15 and tomorrow that we would have a lot of people
16 trying to eat quickly, and they have a limited
17 selection menu that they can accommodate you within
18 that 45-minute timeframe. There are also some
19 restaurants in the surrounding area, and Bonnie
20 wanted me to make an announcement. Someone left a
21 Nokia cell phone at the registration desk. So I
22 think Toni probably has it out there. Okay. So

1 we'll see you back here at 1:50.

2 (Whereupon, at 1:02 p.m., a luncheon recess
3 was taken.)

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1 program, where he also did a fellowship in material
2 child health. He practiced in a underserved
3 population in Utah before joining the CDC's Epidemic
4 Intelligence Service in 1997, at which time he was
5 assigned to Tennessee. He now serves as the state
6 epidemiologist for the Tennessee Department of Health
7 overseeing programs including immunizations, TB,
8 emergency preparedness, foodborne diseases, hospital
9 infections, zoonotic diseases and environmental
10 epidemiology. Dr. Tim Jones.

11 (Applause.)

12 DR. JONES: Thank you. I was going to
13 volunteer this morning to make up time. I can talk
14 fast, but I can't talk backwards.

15 So I'm just going to talk briefly about
16 something that's been mentioned several times this
17 morning which is CIFOR, or the Council to Improve
18 Foodborne Outbreak Response, and forgive me if I go
19 quickly. So I won't belabor many of the challenges
20 that you already heard about this morning but, you
21 know, you've heard alluded to the fact that there are
22 multiple federal agencies, lots of laws, lots of MOUs,

1 governing food safety and this is just from two
2 foodborne disease papers that I was reading, two
3 papers, all these acronyms. This is my job and I
4 don't know what half of those stand for. So heaven
5 help, you know, patients or customers or people out in
6 the community that are trying to call the Government
7 and get help or figure who to address and who to talk
8 to, to address an issue. And you all know the GAO
9 Report that says basically things are messed up, that
10 our system is a patchwork structure, hampers efforts
11 to adequately address food safety risks.

12 An so while we're all trying to get our act
13 together, obviously outbreaks keep going and you've
14 heard about many of the examples of things that are
15 particularly difficult for us to address.

16 So in late 2005, several groups started to
17 have discussions about what we could do to at least
18 take baby steps to address some of the barriers that
19 we've heard about this morning. And in 2006, a
20 meeting was held, an in-person meeting. It was sort
21 of co-convened by CDC, Council for State and
22 Territorial Epidemiologists, NACCHO, and the first two

1 organizations were sort of co-chairs. And multiple
2 agencies were involved, and so, in fact, the list of
3 agencies are basically all of those that have been
4 represented up here on the podium this morning which
5 is good. And many of you in the room are actually on
6 CIFOR which is also a good thing.

7 So the vision of the group is that local,
8 state and federal partners collaborate effectively to
9 reduce the burden of foodborne illness in the U.S. and
10 the mission is to improve methods at the local, state
11 and federal levels to detect, investigate, control and
12 prevent outbreak.

13 The first thing that they did or we did was
14 get an ex-state epidemiologist to talk to the folks in
15 the field and identify gaps and things that we needed
16 to address and again they're basically all of the
17 things that we heard about this morning, public health
18 capacity obviously being a huge one, interagency
19 coordination being one of the things that I think most
20 of us hope this very meeting will help to address.
21 And I'll leave it at that.

22 So one of our first priorities was to

1 identify projects that, when we really wanted to start
2 out not just whining about problems and how bad things
3 were but to do concrete things to work towards
4 solutions. And so we identified four initial
5 projects, all of which are at various stages of
6 completion.

7 The first was a resource clearinghouse.
8 I'll talk about each of these in a little bit more
9 detail in a moment, guidelines for multi-
10 jurisdictional outbreak investigations, performance
11 indicators and then investigation guidelines which we
12 sort of call Guidelines with a capital G. I'll come
13 back to those first projects in a moment but basically
14 this group, since it's inception in '06 has continued
15 to meet in person regularly, at least twice a year.
16 We have sort of a governing steering committee. We
17 are trying, you know, obviously we can only get so
18 many people to come to in-person meetings, but we
19 consider it very important that the representatives of
20 each of the agencies that are coming to these meetings
21 serve as conduits back to their organizations so that
22 we're getting a lot of broad input and feedback on

1 projects. We don't just want this to be, you know,
2 the opinion of two people from CDC and two from FDA or
3 the states.

4 So the first of our projects was basically a
5 repository or a clearinghouse for resources, and I
6 think that this hopefully is a partial answer to what
7 I think the local health departments this morning
8 raised as a need. It's basically a website where
9 local health departments, state health departments,
10 CDC, anyone who has a questionnaire, that they've used
11 in an outbreak, or sporadic cases. So you can put
12 your local health deposition gastroenteritis form, you
13 can put your *Salmonella*, you know, an -- form, any
14 outbreak questionnaire that you've used and we
15 basically post it there so that if you have an
16 outbreak of *Salmonella*, you know, Bultavarin (ph.) or
17 Montevideo and you're looking for a questionnaire, you
18 at least have a model and everyone of the 3,000 local
19 health departments in the country isn't starting from
20 scratch every time we have an outbreak like that.
21 It's getting there. It's on the web.

22 We also hope to put state outbreak

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1 guidelines and manuals, if states have protocols or
2 have developed training resources and done their own
3 tabletops. I mean I've worked on several tabletops
4 and then you realize that so have 10 other states and
5 we're all trying to do the same thing, educational
6 materials, databases and that type of thing.

7 So NACCHO hosts the site. We're still open
8 for donations of questionnaires or any of those
9 materials but you can actually go to the site right
10 now and hunt around and find questionnaires and some
11 of the resources that we talked about and it's at
12 CIFOR.us. So there's a lot of room for it to get
13 better but at least it's up there.

14 The second big project was multi-
15 jurisdictional guidelines. We let out a contract and
16 actually these basically have been developed and are
17 in the stage of being published and distributed
18 amongst the participating organizations. Again, we've
19 talked about a lot of the challenges, how do you
20 detect and investigate them? These are addressed in
21 the guidelines. What counts as multi-jurisdictional
22 guidelines? Lots of different definitions for that.

1 Who do you notify? How do you do it? How do you
2 coordinate and identify roles? Someone mentioned
3 earlier, you know, either no one's in charge or we all
4 think we are and how do you report them which is a
5 constant challenge even just, you know, every year we
6 have a big discussion about how you put outbreaks into
7 the electronic disease reporting system and we all
8 change our minds every other year. So we're trying to
9 get some consistency among sites in multi-
10 jurisdictional outbreaks.

11 One of the touchiest things, what many of us
12 thought was most important, was coming up with
13 performance indicators, and these are basically
14 intended as a way for local or state health
15 departments, environmental programs, laboratory
16 programs, to come up with measures to be able to
17 figure how we're doing it. This was not meant to be,
18 you know, a scoring system so that they could take
19 away grant money if we weren't getting a lot of points
20 or anything like that, but many of us had no way to
21 figure out whether we're way behind the curve, you
22 know, the second worst health department in the

1 country or doing pretty well and what we needed work
2 on.

3 So it's basically meant initially as a self-
4 assessment tool, and I think so as not to scare
5 everybody with the idea, you know, we didn't even put
6 in numeric, you know, how to score yourself. We just
7 are starting out with identifying the categories which
8 at least are going to tell our agencies what kind of
9 data do we need to keep about our programs to even be
10 able to assess ourselves. And then hopefully model
11 states or programs like FoodNet will sort of start to
12 score themselves and set benchmarks, but I think in
13 the long run, in terms of standardization and, and
14 giving us all models for improvement, that this will
15 be very useful.

16 Then we have Guidelines with a capital G.
17 This was a multiyear project. It was intended to take
18 three years. We hope that there will be a product out
19 at the end of 2009. We wanted them to be practical.
20 There are logs of guidelines out there, and we weren't
21 trying to do anything from scratch, but we wanted them
22 to be something that you could have in your hand, pull

1 off the shelf, whether they were at the local,
2 regional, state level and use it as a tool.

3 We again started with a contract with
4 several consultants and have asked for broad input
5 from all of the participating agencies. There's a
6 quite mature draft out that agencies are going to
7 start to circulate internally and present piece of it
8 at conferences coming up in the next months, hopefully
9 to get a final product out, and we realize it's never
10 going to be perfect and satisfy everybody but at least
11 if you get something out there, then you have
12 something concrete that we can continue to build on
13 and improve on hopefully every year.

14 And this is just the Table of Contents as it
15 stands now of those guidelines and we've tried to do
16 some things that I think other guidelines haven't.
17 They include obviously addressing the roles not just
18 of epidemiology, not just of the lab, like many other
19 specific guidelines do but altogether because
20 environmentalists, lab, epi, have to work together.
21 We're not individual groups going off doing out own
22 things. Legal issues are rather a sensitive topic

1 that I have not really ever seen addressed in a very
2 clear manner in other writings, and then the multi-
3 jurisdictional guidelines and performance indicators
4 will be incorporated as part of that.

5 So those were our first four projects. Many
6 of them are well along, and we are now at the stage of
7 entertaining new ideas and starting to initiate some
8 other things and this is sort of the results of some
9 discussion the last few months.

10 First of all, increasing the availability of
11 training which is Epi-Ready and that kind of thing.
12 One that I'm quite interested in is integrating the
13 electronic lab reports from -- well, integrating
14 reports from laboratories and epidemiologists. I
15 think we heard this morning that Minnesota has a great
16 model for that, you know, a daily report. Most of our
17 states don't have that at all, and it makes it
18 difficult to recognize outbreaks quickly.

19 And then probably our most interesting and
20 challenging project is going to be dealing with
21 molecular fingerprinting, PFGE and cluster evaluation.
22 And this was brought up several times this morning and

1 some of us discussed it at lunch, that we've already
2 been asked what's the definition of an outbreak?
3 What's your threshold for investigating an outbreak?
4 And I think you heard quite honestly earlier that it
5 sort of depends on who you're asking and what mood
6 they're in that day and what else they're working on.

7 And so there never really has been a
8 systematic look at, you know, how many matching PFGE
9 patterns do you have to have before a local or state
10 health department will even start to investigate? Or
11 what's the likelihood, you know, how many cases of a
12 matching pattern do you have to have before you have
13 any reasonable chance of finding a satisfying answer
14 and it may vary by pathogen and subtype and all kinds
15 of things. So we're beginning with sort of a
16 retrospective survey and then we would like to do a
17 prospective study of collecting the data that we need
18 to be able to answer that question at least enough to,
19 to guide us to guide CDC and PulseNet in addressing it
20 in a more systematic manner.

21 Standardizing, the kind of hypothesis
22 generating questionnaires that states use, and

1 probably the other scary one is coordinating with
2 industry which is the big group that was not on that
3 list of participants. We wanted to start out, you
4 know, taking bites that we knew we could chew, but
5 clearly industry is an important partner, and we're
6 going to start to include them as well in projects.
7 So I'll stop there.

8 (Applause.)

9 DR. HAGEN: Thank you very much, Jim.

10 Next we're going to hear about another
11 initiative to improve our ability to communicate and
12 process information during outbreaks about Epi-
13 Ready. Elizabeth Bugden will be our speaker.

14 Elizabeth is a food scientist and food
15 safety consultant. She is a NEHA Epi-Ready
16 instructor, a senior training specialist for pasture,
17 pasture training --

18 MS. BUGDEN: Pasture.

19 DR. HAGEN: -- pasture training and project
20 manager for a CDC food allergy project.

21 She worked at Kids First in the Rhode Island
22 Department of Education to create CDC food safe

1 schools to prevent foodborne illness in schools
2 throughout the United States. Elizabeth received the
3 2008 NSF leadership award for food safety education.

4 When Elizabeth was a quality scientist at
5 Ocean Spray Cranberries, she invented ruby red
6 grapefruit juice and headed the technology transfer
7 committee to eliminate risk during product process and
8 packing changes.

9 Elizabeth has a Bachelor's Degree in Food
10 and Nutrition, a Master's Degree in Business
11 Management. Elizabeth Bugden.

12 (Applause.)

13 MS. BUGDEN: Thank you, Elisabeth, and it's
14 a pleasure to be with all of you today and I'm very
15 excited to explain to you about the Epi-Ready team
16 training workshops that are being held around the
17 country.

18 I would like, just if you are an Epi-Ready
19 instructor here in the room, if you'd stand up please.
20 Michelle is standing in the back, CP and has anybody
21 here -- is anybody here an Epi-Ready graduate? Great.
22 Lots of hands. So this program has actually touched

1 quite a few of us in the room.

2 Epi-Ready is a team-based training on how to
3 effectively respond to foodborne disease outbreak.
4 Epi-Ready is also the recipient of the NSF Leadership
5 Award for food safety education. Tom Dickey (ph.) and
6 I were in Washington at the Food Safety Summit to
7 receive our awards, and we've worked collaboratively
8 on so many projects over the last decade. It's great.

9 I'll just give you a program overview of
10 Epi-Ready. It's a team approach. This is our target
11 audience, epidemiologists, environmental health
12 professionals, laboratorians, public health nurses and
13 industry quality assurance folks. And when we have
14 the training, we ask that teams from the locations
15 that we're doing the training, actually come together
16 to the training. It's very effective if everybody on
17 the team comes together and has the experience.

18 We use didactic lectures, group exercises,
19 which prove to be very effective, the group exercises,
20 and we try to share best practices and local
21 requirements.

22 This is the Table of Contents from the Epi-

1 Ready training program. We have six modules. I'll
2 give you a chance to read them. In module 6, which is
3 at the end of the two-day session, we actually have
4 EIS officers who lead an outbreak investigation, that
5 the classes do while they are there. So they have
6 that opportunity.

7 A little bit of the history. This program
8 is definitely collaboration between many partners but
9 the CDC is the funding source, and there were meetings
10 and it all began in 2003, and these are some of the
11 partners. NEHA is just delighted to be working with
12 all of these partners. For instance, Tulane helped us
13 make a video about foodborne outbreak response. Our
14 federal partners, CDC, FDA, USDA, FSIS, these three
15 agencies are really helping to provide and look for
16 sources of funding to continue this project because
17 it's been so successful, and those are just -- these
18 are from the beginning who our partners were and the
19 list is huge now of everybody who has participated.

20 These are some statistics about the
21 workshops. Again we started in 2003, and we had one
22 workshop with 36 students. In 2008, we'll have 6

1 workshops, 3 workshops are train the trainer sessions,
2 320 students and 90 people will be trained in train
3 the trainer. So over the years I have this depicted
4 in a graph. So you'll see that we've reached a great
5 number of people. To date we have reached 1387
6 people, and by the end of 2008, we'll have reached
7 nearly 1600 people with this training.

8 The 2008 workshops, we had one in Washington
9 in February. The one in Columbia, Missouri was just
10 last week and that was sort of monumental for us
11 because it was the first workshop that we used remote
12 locations for learning. So we had 50 people at the
13 site in Columbia, Missouri, and then we had 3
14 satellite locations where we have 25 people at each
15 site and there was an Epi-Ready graduate at each of
16 those other sites. So it's webcast, and there were
17 some glitches but I think the feedback from the
18 students is that where there is limited travel dollars
19 and training budgets, to be able to have this type of
20 learning is very beneficial. We have others scheduled
21 in 2008.

22 Just as a point of clarification, the

1 funding for this is typically not on a calendar year.
2 So you see a lot of workshops scheduled but this
3 overlaps different calendar years.

4 In 2009 already, and this is all pending the
5 funding for 2009, we've had these four requests and
6 these would be funded by the CDC and our other federal
7 partners and we've also had three locations throughout
8 the country who said they would be willing to pay for
9 the Epi-Ready program to come to their state.

10 These are the products that we offer. There
11 is Epi-Ready team training which is a two-day program.
12 We have Epi-Ready team training with a food defense
13 module which is a two and a half day program. We have
14 an Epi-Ready team training for train the trainer which
15 is a three-day program, and then we have the Epi-Ready
16 workbook and supplies that are given to each of the
17 students, and then we're working on a distance
18 learning. The workbook and supplies that we provide
19 are the course manual which have all the modules, all
20 the PowerPoint slides. We also give the Control of
21 Communicable Disease Manual, the Procedures to
22 Investigate Foodborne Illness book, and the Diagnosis

1 and Management of Foodborne Illness, a primer for
2 physicians and other healthcare professionals. So the
3 participants are armed with good resource material and
4 current resource material when they leave the program.

5 The next several slides are some feedback
6 that we've received from the students of the Epi-Ready
7 program, and we want to bring these success stories to
8 your attention because we've affected change in every
9 single workshop that we have done.

10 In the first, the question is, do you have
11 examples of how you've applied the team work training?
12 And this says that they have restructured the Epi
13 response team. I mean that's really a great thing, an
14 outcome of the workshops that we do.

15 And the second question, have you been able
16 to provide information received from the training to
17 others in your workplace, collaboration between the
18 epidemiologists and the environmental health
19 professionals? It's obviously by some of these
20 comments that these things were not taking place
21 before they attended the workshop.

22 Do you have examples of putting new

1 procedures in place? This group of people have
2 created a database for passive surveillance.

3 The workshop was excellent, sanitarians are
4 better working relationship with nurses, public health
5 nurses. How wonderful is this?

6 And this feedback, we've identified that the
7 food inspector and the epidemiologist and the
8 environmental health have approached the situation
9 jointly.

10 Now for this feedback, for a number of
11 workshops, for the first few years, we were just
12 collecting the information right after they took the
13 class, before they left the room, they had to fill out
14 an evaluation sheet but Elizabeth Ostertag who
15 joined the NEHA team and coordinates the Epi-Ready
16 sessions, she has actually implemented a three stage
17 evaluation process where the students actually give
18 feedback the day they're leaving, and then she e-mails
19 them and asks them for feedback after two months and
20 then she asked them for feedback after nine months as
21 well. So trying to stay with the students to
22 encourage them to use the techniques that they've

1 learned in these classes.

2 Some additional projects as we move forward
3 is the distance learning. I explained to you what
4 happened in Missouri last week, and we'd like to
5 participate. There were 50 students in the primary
6 site, and then we were able to have 3 sites with 25
7 more. So instead of servicing only 50 students, we
8 were able to serve 125.

9 We need to recruit additional Epi-Ready
10 instructors. So I'd like to open that challenge to
11 each of you if you think you would like to participate
12 in this program. On the last slide, I'll show you
13 Elizabeth Ostertag's phone number that you'd be able
14 to jot down if you'd like to be in touch with her
15 because she'd be the coordinator to take that
16 information. We also want to continue to integrate
17 the CDC EIS officers into the workshops. This is
18 where they lead the case study, practical application,
19 a practice session.

20 We want to offer support for train the
21 trainer graduates and also share success stories for
22 Epi-Ready graduates.

1 So there's Elizabeth Ostertag's phone
2 number, (303) 756-9090, Extension 346, and I'm here
3 today and tomorrow. I'd be happy to take any
4 information if you want to host an Epi-Ready session
5 in your locale or you'd like to think about being an
6 Epi-Ready instructor, we'd welcome that. And thank
7 you for your attention.

8 (Applause.)

9 DR. HAGEN: Thank you, Elizabeth.

10 Next we're going to move into a section in
11 which our federal partners are each going to discuss
12 current thinking and approach to outbreak and illness
13 investigations at their agencies.

14 We'll start with Dr. Ian Williams from the
15 CDC. Dr. Williams is the Chief of the OutbreakNet
16 team of the Enteric Diseases, Epidemiology Branch at
17 the Centers for Disease Control and Prevention in
18 Atlanta, Georgia. OutbreakNet is a national network
19 of epidemiologists and other public health
20 professional who investigate outbreaks of foodborne,
21 waterborne and other enteric illnesses in the United
22 States.

1 Dr. Williams is a graduate of CDC's Epidemic
2 Intelligence Service Program. He received a Ph.D. in
3 Infection Disease Epidemiology from the Johns Hopkins
4 School of Hygiene and Public Health, and has a
5 Master's of Science Degree in Preventive Medicine from
6 the Ohio State University.

7 He has worked at the CDC since 1994 and has
8 been involved in a number of foodborne outbreak
9 investigations that have resulted in public health
10 interventions, public health notifications, product
11 recall and regulatory actions. Dr. Ian Williams.

12 (Applause.)

13 DR. WILLIAMS: Thank you very much, and good
14 afternoon. Thank you very much for inviting me to
15 speak.

16 A lot of my talk today you've already heard
17 in bits and pieces in the other presentations this
18 morning but my goal is to really give you the CDC
19 perspective on what our current thinking is about
20 foodborne outbreak investigations.

21 And what I'm going to talk about, and some
22 of the stuff you've heard about, is how do we find out

1 about outbreaks of foodborne illness? How do we go
2 about linking products to illness? What's the
3 epidemiologic process? A little bit about
4 intervention and preventing future ones. But I also
5 want to try to sort of say this is where I see or CDC
6 sees current gaps in the system and then maybe a
7 vision for the future.

8 So you've heard this again very clearly in
9 the first presentation this morning about this tiered
10 public health system in the United States and where
11 the rubber meets the road is the city or county health
12 department. They are the front lines of public
13 health. This is where the work really happens, and
14 they are oftentimes backed up by state health
15 departments and not in all situation, but in many
16 state health departments that's where the expertise
17 for epidemiology, laboratorian, and sanitarian help
18 reside. So the state agencies in many places support
19 the local and city health departments.

20 The federal agencies come in really in two
21 roles. CDC's role again is risk identification, where
22 the regulatory agencies or risk management agencies

1 fill a separate role, and I'll talk a little bit more
2 about those in a second. But I want to make it clear
3 that there is a tiered response, especially in
4 emergency or outbreak situations, but CDC actually
5 provides backup to the states by providing
6 epidemiologists, laboratory support and coordination.
7 So our role is not to go in and take over the
8 situation, but our role there is really support our
9 state and local health department partners.

10 So to try to draw a little distinction
11 between what the different federal roles are, I tried
12 to put together a slide. So CDC's role really is
13 disease surveillance, outbreak detection,
14 investigation and education and training of public
15 health staff where the regulatory agencies, FSIS and
16 FDA, really focus on food safety policies, inspection
17 and enforcement, product recall trace back,
18 investigation of farm or production facilities.

19 So the bottom line is CDC really is the
20 problem identification, scope implication, where the
21 regulatory agency is more focused on risk assessment
22 and management and source assessment, once a source

1 has been implicated.

2 I don't think I have to convince anybody
3 today about the importance, public health importance
4 of foodborne disease. But just in case you need to
5 see the numbers again, they're on the top of this
6 slide here. But the point I want you to get from
7 looking at this slide, is sort of the magnitude of the
8 outbreaks we see at CDC. So last year or in 2006, we
9 had more than 1200 outbreaks of foodborne disease
10 reported to us resulting in more than 27,000
11 illnesses. So this is not an insubstantial public
12 health problem.

13 Another point that you heard this morning,
14 and I think it's good to reemphasize is that the
15 outbreak epidemiology is changing, has changed
16 dramatically in the last 15 years or so. The reasons
17 for this are many fold, but has to do with
18 centralization, industrialization, globalization of
19 our food supply. The number of outbreaks detected has
20 grown phenomenally in the last 15 years or so, and
21 I'll show you some data in a couple of slides on that.

22 So things aren't the same today as they were

1 5 years ago or 10 years ago, 15 years ago.

2 And effective foodborne outbreak
3 investigations are really important for a number of
4 reasons. One is to identify the food vehicles which
5 lead to outbreaks but also thinking about it from a
6 prevention perspective, to keep it from happening
7 again. And that's how I'm actually going to structure
8 the bulk of the rest of my talk for this morning
9 (sic).

10 A way that we think about, the way CDC
11 thinks about foodborne outbreak disease control and
12 prevention is sort of in a cycle that all feeds
13 together and feeds back on itself and it really starts
14 with the basis of surveillance. Surveillance leads to
15 an epidemiologic investigation. That epidemiologic
16 investigation leads to putting out the fire, direct
17 prevention measures to stop the outbreak but it also
18 leads to applied research, to figure out how to
19 prevent the next fire, and all of this feeds back to
20 improve our surveillance system. So it's the cycle
21 that feeds itself.

22 And what I thought I would spend just about

1 5 minutes or so, 10 minutes, walking through, is a
2 little bit about how this cycle of foodborne disease,
3 control and prevention, fits into sort of how we
4 investigate an outbreak from the CDC perspective, and
5 it all begins with surveillance.

6 Surveillance, we call stage 1. How do you
7 figure about the cluster in the first place? And
8 again you've heard a lot of this from this morning.
9 Really surveillance is this ongoing systematic
10 collection and analysis of data and the provision of
11 this information which leads to an action being taken
12 to prevent and control the disease. That's a basic
13 definition of surveillance.

14 And so this is really what we're doing.
15 We're trying to basically collect that data in a
16 systematic way and from a CDC perspective, and we
17 really do this through two ways. I know I just talked
18 briefly about both. One is reports of suspected
19 outbreaks by state and local health departments
20 provided to CDC. Bill Keene this morning told you
21 about that with spinach. We have an outbreak, we
22 think it's spinach, something's going on. Or

1 oftentimes where we hear most of outbreaks from are
2 PulseNet.

3 And just to illustrate a little bit of these
4 two different ways we hear about things, this is data
5 from Connecticut, courtesy of Jim Hadler (ph.) and I
6 just want to point out to you, this is between 2004
7 and 6, where did Connecticut hear about most of its
8 foodborne disease outbreaks. It wasn't through
9 PulseNet. It wasn't through PFGE. It wasn't through
10 a fancy surveillance system. It was from citizen
11 reports. People call up and say I think I'm ill.

12 So from a CDC perspective, we have to keep
13 in mind that most of what's going on at the state and
14 local level is not what's going on in our office.
15 We're hearing the very tip of the iceberg. We're
16 seeing the tail end of a system that's already well
17 underway.

18 So PFGE and surveillance are just a very,
19 very small part of what happens at the state and local
20 level. However, PulseNet is where we hear about the
21 bulk of our outbreaks, and again you heard about
22 PulseNet this morning. So I'm not going to actually

1 run through it in much detail other than to say that I
2 mean this is a large network, more than 75 public
3 health regulatory laboratories who participate in this
4 which is good because it feeds lots of data but as
5 you'll see, it's also a little bit of a double edge
6 sword because there is a lot of data. We are
7 identifying lots and lots and lots of clusters.

8 So what do we use PulseNet for from a CDC
9 perspective, and even from a state or local
10 perspective? As the patterns get submitted, we at CDC
11 look for similar patterns in the last two to four
12 months. We compare the patterns visually. When a
13 cluster is identified, PulseNet calls us and basically
14 says we've got something interesting going on. And
15 again a cluster does not mean an outbreak. You've
16 heard that several times today. Just because you have
17 a group of patterns that are the same, doesn't
18 necessarily mean that these are related, and that
19 becomes the stuff for the epidemiologists to work with
20 PulseNet to try to sort out.

21 And here's a little data talking about sort
22 of the changes in PulseNet in the last 10 years or so.

1 These are the number of PFGE patterns submitted to
2 PulseNet. So you can see that it's grown and grown
3 and grown, and in 2007, we're up around 60,000
4 patterns submitted. So that's one of the reasons
5 we're finding a lot more outbreaks because PulseNet is
6 being used and the data is going in which is a good
7 thing but again it makes a lot of work, a lot more
8 clusters are being found to determine what's going on.

9 So now that we've found the cluster or
10 there's been a report of a cluster to CDC, what are
11 the next steps? And I broke up, the next step is the
12 epidemiologic investigation, into three sort of chunks
13 to try to explain them quickly, and sometimes what I'm
14 calling Stage 2 and 3 generating a hypothesis and
15 testing hypothesis, sometimes happens simultaneously,
16 will happen iteratively. Some states actually do them
17 together but for purposes of illustration, I'm going
18 to talk just quickly about how hypotheses are
19 generated, how we go about testing them and then how
20 you reconstruct, how and when and where contamination
21 occurred.

22 So generating hypotheses. So if we know the

1 pathogen, we already know a lot of information at a
2 point. We know the reservoir, the biology, the
3 previous history of outbreaks. So this is already
4 starting to give us clues about where this might come
5 from.

6 We go back and actually look at all the
7 reported series of outbreaks in our electronic
8 foodborne outbreak reporting system or eFORC. It goes
9 back to 1973. So we have a history of all the
10 outbreaks that have occurred in the United States. Go
11 back and say, where have we seen this outbreak? Where
12 have we seen this cluster occurring before? What
13 outbreaks have been associated with these patterns
14 before?

15 We also look at a number of other sources of
16 data. Case control studies done among sporadic cases.
17 We work very carefully with our colleagues at USDA and
18 FDA to look at testing data of food and animals.
19 Where's it been found recently? In what foods is this
20 common? We also look at food recall history from the
21 USDA and FDA. We also do, some of which is the
22 classic epidemiologic tool of orienting the cases with

1 respect to person, place or time, figuring out how
2 they all sort of fit together.

3 In terms of figuring out what hypotheses to
4 go after, one of the common strategies you heard about
5 this morning is the hypothesis generating interview,
6 and there are a number of different ways to do this,
7 and a number of the states have quite a bit of
8 expertise in doing this, and there are sort of several
9 different approaches. One common way we heard this
10 morning is to use the trawling or shotgun type of
11 questionnaire where you ask about a structured list of
12 foods. But also intensive open ended interviewing
13 about everything that went in the patient's mouth for
14 the last five days is very helpful. This can mean in
15 depth interviews in the people's homes including the
16 refrigerator and the pantry, and oftentimes you use
17 both of these together, one or the other or sometimes
18 do both.

19 One of the critical things is when you have
20 a cluster, you need to do them all in the same way so
21 that you can pull the data across the cases you're
22 interviewing and also as you heard about this morning,

1 there's a need to do iteratively. If you find
2 something interesting on the first two cases, you need
3 to make sure you ask it of the third. If the third
4 and fourth, you go back and ask the first and second.
5 So there's an art to actually doing these hypothesis
6 generating.

7 And one of the important things I want to
8 drive home today is a food product is not the source
9 of all outbreaks. Just because you see a cluster in
10 PulseNet doesn't mean it's food. It could be animals
11 at a county fair. It could be something not related
12 at all to a food. So just as we're thinking
13 hypothesis, we don't think about food. We think about
14 lots of other things.

15 So how do we test these hypotheses? Once we
16 come up with a hypothesis, we systematically compare
17 exposures of those who were ill with those who
18 remained well, and there are really sort of two
19 structures for this investigation, these types of
20 investigations, not to go into a whole lot of depth,
21 but you do a cohort, a look at everybody who attended
22 an event, like a church supper, or you can actually do

1 a case control study. We look at a number of measures
2 of statistical association to sort of figure out if
3 our hypothesis is actually true or not, and it really
4 is not just is there a significant P value. It's a
5 whole variety of things. It's the direction
6 association. It's more than just a probability of
7 change alone. It's the strength, the dose response.
8 It's a lot of stuff that goes into not just a single
9 number but what does that number mean? We also look
10 very closely at is what we found plausible or not?
11 And one of the things that's often under appreciated,
12 as this process gets repeated as necessary, oftentimes
13 over and over and over again, four or five, six, seven
14 times, until you find the right hypothesis, to find if
15 your hypothesis holds water or not. So this is an
16 iterative process.

17 So once we have our hypothesis, we test it
18 and we think we have a good plausible hypothesis, then
19 we said about reconstruction how and where
20 contamination is likely to have occurred.

21 One of the important things with this is the
22 details of the implicated food, how and when it was

1 prepared, when it was purchased, the brand, the lot
2 number information. Oftentimes this is where we need
3 judgment. Was the contamination actually before or
4 after? Was it in the kitchen or by a food handler?
5 So there's some judgment that goes into this, and
6 hopefully you can appreciate that oftentimes you'd
7 have to go back to cases a number of times, two or
8 three or four times, to collect additional information
9 in order to figure out some of these things.

10 So if contamination is earlier in the
11 distribution chain, then it becomes the trace back.
12 We want to go back to figure out where foods
13 converged? And the precision of these trace backs
14 really depend on invoices, not only invoices, company
15 records and cooperations, but people actually have to
16 remember the information. They have to have the
17 information in order to generate these things.

18 If the dates converge, does the trace
19 forward from the party convergent go to other cases?
20 So again, the trace back is not just one way. There's
21 a trace back and often a trace forward.

22 So my team at CDC in some ways herds a lot

1 of cats. Our role is really to pull together and try
2 to provide coordination to this network of
3 epidemiologists and other public health officials who
4 do this. You've heard today that state, local and
5 county health departments have people who do this.
6 Our job is to work with this network of people who all
7 work independently to try to get this all going in a
8 common way, and again we work very closely with our
9 state and local health department partners but we also
10 provide the interface or try to work very closely with
11 USDA and FDA as well, sort of that interface as well.
12 We work very closely with PulseNet, and we try to help
13 insure rapid coordination detection and response to
14 multistate outbreaks, as well as promoting
15 comprehensive outbreaks surveillance.

16 So just one slide on. So you figured it.
17 You think it's this. Again, it's not just removing
18 the implicated food from the marketplace, a very, very
19 important part, but we're also very focused at CDC,
20 the Centers for Disease Control and Prevention, of
21 preventing the next outbreak. And it's actually
22 collecting the data and thinking about it in a way to

1 prevent it from happening again, such as how often do
2 these outbreaks happen. What are the critical
3 scientific questions that need to get answered? What
4 technological, behavioral or regulatory changes would
5 really be needed to keep this from happening again?
6 What education or training is needed? And oftentimes
7 this is not just us. This is again a very
8 collaborative effort. It involves public health
9 investigators, regulators, scientists, industry,
10 consumers. So it's everybody altogether.

11 So that is my spiel for how well it works in
12 terms of this process. However, there are some very
13 important limitations to the epidemiologic method. I
14 often say it's a blunt tool. Here are some of the
15 predominant limitations. If the person doesn't know
16 the information and are not aware of an exposure, they
17 can't report it. You need to have enough cases and
18 controls to achieve statistical power because if you
19 have two or three cases, it may not be enough. So
20 oftentimes you have to actually have a sufficient
21 number of cases to develop and test your hypotheses.

22 If the correct hypothesis is not considered,

1 you may not need to find it. So again this is this
2 iterative process.

3 One of the other challenges, too, as you
4 generate a hypothesis, oftentimes you may need a
5 partial trace back, that is I think I have an
6 interesting hypothesis. Wouldn't it be interesting to
7 know where they all got their blank from? And
8 oftentimes you can do that unless you know some of
9 this other information up front.

10 One other thing just to mention, --
11 associations are possible by chance alone. Just
12 because your statistic says it's significant, does it
13 actually mean it's biologically significant and you
14 pick the right thing, and just because the implicated
15 food can be connected to an unrecognized source that
16 you don't see.

17 One other last thing I wanted to mention is
18 that oftentimes people say, well, why don't you just
19 test the food and find out if it's positive. There's
20 lots of limitations to relying just on laboratory
21 testing of food in an outbreak investigation. This is
22 incredibly, incredibly helpful as a demonstration that

1 a particular food was contaminated. However, it can
2 be critical and is very critical if the number of
3 patients is small and the statistical power of the
4 epidemiologic study is low. And it can really provide
5 the critical break.

6 However, you may not identify the pathogen
7 and the implicated product because (a) the food that
8 caused the outbreak was already consumed, so you can't
9 collect it; the food that caused the outbreak was
10 overlooked when samples were collected. Examination
11 may be variable within a food. The pathogen may not
12 survive well in the food. The test may be insensitive
13 and unverified if the lab didn't do the right test.
14 There would be no assay at all for that food or the
15 lab tested it and did it wrong. So relying solely on
16 laboratory testing to solve outbreak investigations
17 can lead you astray but is a very, very important
18 tool.

19 So setting up that background, it's
20 important to consider what the gaps are in the current
21 outbreak investigation methods. One of the most
22 important things you heard from a number of people are

1 that there's very limited resources for health
2 departments to conduct interviews. Sporadic
3 illnesses, some of which may later be shown as part of
4 outbreaks, are not often interviewed. In many
5 jurisdictions, patients are not routinely interviewed
6 to collect information. So they're never interviewed
7 in order to determine if a sporadic case is part of an
8 outbreak. Some states do that. Not many states
9 actually do.

10 In terms of clusters and outbreaks,
11 interviews to probe possible sources may be delayed by
12 other priorities. It's a priority to you. It's not a
13 priority to the person doing it. Oftentimes you re-
14 interview to collect product information. This may be
15 delayed. Questionnaires are often not standardized
16 among states. Information from the questionnaires are
17 not put into a standard database in all states.
18 Information on exposures usually is not transmitted
19 electronically to CDC.

20 So in contrast to what we see in PulseNet,
21 in which lab information on every isolate is stored in
22 the standard database at the states, it's not rapidly

1 transmitted to a national database at CDC and summary
2 information is not available on all participants.

3 So the last slide is what would a vision for
4 a future look like? One of the visions to consider
5 potentially is a national multistate foodborne
6 investigation network. This is a network that
7 facilitate the collection of exposure from both ill
8 and well persons to help state, local and federal
9 epidemiologists more rapidly develop hypotheses and
10 implicate vehicles. This would facilitate the
11 collection of specific food information, things such
12 as lot number for trace back investigations. This
13 would more rapidly collate and analyze epidemiologic
14 and product information from multiple states. It
15 would routinely join that data we collect from an
16 epidemiologic investigation with PulseNet, so they
17 could share information more readily back and forth.

18 And the bottom line, this would improve the
19 quality and speed of product data provided to our
20 regulatory agencies for trace back. And really the
21 goal here is to shorten the time to pinpoint how and
22 where contamination occurred.

1 And so I would propose that as a potential
2 vision for the future, and with that, I think I will
3 stop. Here are a bunch of outbreaks we've worked on
4 over the last 18 months but due to time, I won't go
5 into those. So you can see that we've been very busy
6 over the last 18 months. With that, I'll stop. Thank
7 you very much.

8 (Applause.)

9 DR. HAGEN: Thank you very much, Ian.

10 We are next going to switch the speakers a
11 little bit. Scott Seys will be speaking first on the
12 FSIS current thinking and approach to investigations.

13 So Scott Seys has been with the USDA, Food
14 Safety and Inspection Service, since 2005, and is
15 currently the Chief of the Foodborne Disease
16 Investigations Branch. In his current position, Scott
17 oversees the investigation of foodborne illnesses,
18 possibly associated with FSIS regulated products and
19 participates in FoodNet, SNet, OutbreakNet and CIFOR.
20 His special interests include traceability of ground
21 beef, public health infrastructure and applied
22 epidemiology.

1 Prior to working at FSIS, he was the Deputy
2 State Epidemiologist for the Wyoming Department of
3 Health where he coordinated the investigation and
4 surveillance of infectious diseases.

5 Scott received his Master of Public Health
6 Degree in Epidemiology from the University of
7 Minnesota and worked for the Minnesota Department of
8 Health while completing his degree. Mr. Scott Seys.

9 (Applause.)

10 MR. SEYS: Thank you, Elisabeth. And today
11 I just wanted to go through quickly our current
12 thinking on foodborne illness investigations at FSIS.

13 So in general, our thoughts are that it is a
14 multifaceted, multidisciplinary undertaking when you
15 do have a foodborne illness investigation, and many of
16 you have seen this idea of a three-legged stool of
17 foodborne illness investigations, where you have the
18 three critical legs, environmental health,
19 epidemiology and laboratory. And if you don't have
20 the three legs, you're still falls over, your
21 investigation doesn't work well. And really our
22 thoughts on investigations kind of follow this three-

1 legged stool concept.

2 Before I get into kind of the epidemiology
3 of the laboratory and environmental health portions of
4 our investigation, I did want to talk about our
5 overall investigation objectives when we do hear about
6 illnesses that are possibly associated with FSIS
7 regulated products.

8 First, of course, we do want to determine
9 whether those illnesses are due to our product. We
10 want to identify the source of production and also
11 look at the distribution of that product. We want to
12 gather the information that we need to guide our
13 response as far as the distribution, maybe in-plant
14 data or trace back information. We want to take
15 appropriate action to prevent further exposure to
16 consumers. We initiate enforcement actions as
17 appropriate if it is our regulated products, identify
18 contributing factors to the outbreak, report on the
19 results of the investigation and finally to recommend
20 steps to prevent future occurrences of the problem.

21 And I do want to just talk a little bit
22 about in FSIS, that all investigations are unique and

1 for this investigation, I am outlining certain
2 components, but they're used just very generally. The
3 phases of an investigation may occur almost
4 simultaneously and the flow of information is really,
5 really dynamic. And the steps that I go over are not
6 necessarily the order that each investigation follows.

7 So I want to start with the epidemiology
8 component of an investigation at FSIS, and start with
9 our applied epidemiology division. If you look at the
10 definition of applied epidemiology, you're really
11 looking at the application and evaluation of
12 epidemiologic methods and epidemiologic practice in
13 protecting and improving the health of a population.
14 And it also looks at identifying and also
15 investigating any health problems.

16 Within our applied epidemiology division, we
17 have two branches, the foodborne disease
18 investigations branch and a zoonosis and food hazards
19 surveillance branch. And I wanted to talk a little
20 bit about the foodborne disease investigations branch.

21 Our branch coordinates the FSIS foodborne
22 illness investigations. We collaborate with public

1 health partners in local, state and territorial health
2 departments, to investigate illnesses that are
3 potentially associated with FSIS regulated product.
4 We also serve as liaisons between those public health
5 partners and FSIS specialty personnel, those that are
6 out in the field as an example.

7 We have a total of five public health and
8 epidemiology liaisons that are located in Omaha,
9 Nebraska, and Atlanta, Georgia. These sites work with
10 public health partners west of the Mississippi and
11 east of the Mississippi. And we, of course,
12 collaborate with our Headquarters staff in Washington,
13 D.C.

14 I wanted to start with how FSIS looks at
15 surveillance and information monitoring, how we
16 receive information about illnesses and potential
17 product links. We receive notifications from local,
18 state and territorial public health departments.
19 That's primarily how we do get notified of illnesses
20 that are potentially associated with our regulated
21 products.

22 We do also get notification from CDC via our

1 FSIS liaison to CDC. We receive notification from
2 other federal agencies such as FDA or the National
3 Park Service. Additionally, we have internal
4 foodborne illness and hazard surveillance. For
5 example, we look at consumer complaints that are
6 reported to the Agency, and we look at PFGE clusters
7 as has been mentioned multiple times today, and our
8 focus, of course, are especially those clusters that
9 contain isolates from FSIS regulated product testing.

10 Then finally, we do do information
11 monitoring of medical reports as well as lisesves.

12 Once we have this preliminary set of
13 information, we do a real preliminary assessment of
14 that information to get an initial assessment of the
15 strength of the data. We look at if the available
16 information suggests a link between FSIS regulated
17 product and illness, and we look at the surveillance,
18 investigative and laboratory methods and ask ourselves
19 if those are scientifically valid, are the preliminary
20 findings plausible, and do those preliminary findings
21 point to a consistent finding? Do they correlate with
22 each other. And finally, do the literature and past

1 experiences of the Agency and other agencies support
2 those preliminary findings?

3 So if the answers to those is yes, then we
4 feel that there is some possibility that human
5 illnesses are associated with FSIS regulated product,
6 we will initiate an FSIS investigation. We will
7 assign a lead investigator and within the Agency, we
8 will send out an initial alert to other FSIS program
9 areas for early notification. We also have weekly
10 FSIS investigations meetings, where we can brief other
11 program areas in the Agency. And this pertains to any
12 investigations that we feel necessitate Agency action
13 or resources.

14 I also want to mention just briefly that
15 when we do get notification of possible outbreaks, we
16 also assess the criteria for non-routine incidents
17 which I'll talk about just briefly here. When we're
18 looking at deliberate contamination, obviously we're
19 still doing investigations, but these investigations
20 are immediately reported and there are supplemental
21 protocols that are followed. They are handled as
22 criminal or a terrorist offense. So we still have the

1 same general feeling as to how our investigations work
2 but they are managed by an emergency management
3 committee with an incident commander from our Office
4 of Food Defense and Emergency Response.

5 So as was mentioned this morning, we can
6 take Agency action based on epidemiologic associations
7 alone. However, the laboratory component of our
8 investigations is still very critical, and we rely
9 very heavily on the expertise of our laboratories and
10 our microbiologists. Just to mention really quickly,
11 that FSIS does have three laboratories in Alameda,
12 California, St. Louis, Missouri, and Athens, Georgia.
13 And just to point out that our outbreak section lab is
14 in Athens, Georgia, and they do the majority of our
15 outbreak testing and also our PFGE analysis.

16 I want to talk about briefly our product
17 sampling assessment, when do we submit product samples
18 for laboratory analysis to support an investigation.
19 We first look at, do the available data and does the
20 available information from both the epi lab and the
21 environmental health, our investigations support a
22 link between product and illness. Is there a product

1 that meets the FSIS criteria for product identity,
2 meaning do we know what that product is, the chain of
3 custody and how that product was handled.

4 Has a non-FSIS, such as a state public
5 health laboratory already tested that product and had
6 reliable methodology? And finally, can tests be
7 performed by or in association with FSIS? Can the
8 FSIS laboratory do the testing or is there a private
9 university lab that may be able to assist us?

10 I wanted to briefly touch on non-intact
11 products and when we do sampling and testing in those
12 situations. A non-intact product is a product with
13 either open packaging or product that was removed from
14 its original packaging. An example might be bulk
15 ground beef that a consumer cut up and wrapped
16 individually before freezing it. It may either be in
17 commerce or in a consumer's home, and testing non-
18 intact product is useful when intact product is not
19 available or we really need some additional
20 information to determine whether there is a link or
21 not. And testing results from non-intact product can
22 be used to support Agency action.

1 With non-intact products, there are certain
2 questions that we definitely need to assess before we
3 do the testing. Specifically, how was that non-intact
4 product handled by the case patient? Was it used
5 previously? How was it used? How was it unwrapped?
6 How was it repackaged? Were the non-intact products
7 stored properly?

8 And finally looking at product identify, are
9 the packaging materials and product labels available?
10 And if not, is there some way for us to identify what
11 that product is?

12 We've talked a lot today about use of
13 PulseNet and PFGE, and I'll just touch on it here as
14 well. All PFGE patterns drive from FSIS foodborne
15 illness investigations and recall isolates are
16 uploaded to PulseNet, and the foodborne disease
17 investigation branch does monitor those isolates in
18 PulseNet to see if there are clinical isolates either
19 in PulseNet or that get subsequently uploaded to
20 PulseNet and we do that to insure that the scope of
21 the recall was adequate. So we do follow up with our
22 public health partners on isolates that may be

1 uploaded subsequently.

2 I'd also mention that PFGE from *E. coli*
3 O157, *Listeria* ready-to-eat and *Salmonella* ready-to-
4 eat, product isolates are uploaded to PulseNet, and
5 that PFGE from FSIS *Salmonella* raw product testing is
6 accessible through VetNet. So those are really
7 additional data points that we can grab during our
8 investigations.

9 Talking about the third component of FSIS
10 investigations, the environmental health components.
11 I want to just mention our extremely valuable
12 resources in the field, our district offices and
13 regional offices. The regional offices are in purple
14 and the yellow are the district offices located
15 throughout the country.

16 When we're talking about product in
17 commerce, we work very closely with our Office of
18 Program Evaluation, Enforcement and Review, and they
19 focus on the trace back or trace forward of product
20 that is in commerce. They locate or detain products.
21 They collect product samples for testing. They also
22 do environmental assessment of facilities such as a

1 grocery store. And, of course, there's a lot of
2 coordination when our investigators are out doing
3 these activities, coordination with our Office of
4 Field Operations, as well as public health partners
5 and those facilities such as grocery stores.

6 When the product is in the establishment, we
7 work very closely with our Office of Field Operations,
8 again for very similar reasons. We're looking at the
9 trace back, the trace forward of products in that
10 establishment chain, again locating or detaining
11 products, collecting product samples for testing. Our
12 field investigators gather information about
13 production practices and also perform assessments in
14 those establishments and again, I can't emphasize
15 enough the amount of coordination with our Office of
16 Program Evaluation, Enforcement and Review, as well as
17 the establishments themselves.

18 So I want to end with kind of putting all of
19 this together, the full investigation, the full three-
20 legged stool.

21 First I just wanted to talk about our
22 general data analysis and assessment and mention again

1 the data collection analysis, the assessment of
2 findings, are really ongoing throughout this entire
3 investigation and happen as data and information
4 become available.

5 The measure, and take a look at the strength
6 of association using established epidemiologic
7 principles, and we also have a framework that I'll
8 show you in a minute, for assessing whether the
9 collected evidence points towards an association
10 between FSIS regulated product and human illness. And
11 the framework that we use, many of you have probably
12 seen the procedures to investigate foodborne illness
13 by the International Association for Food Protection,
14 and our framework is based loosely on the framework
15 that they've presented in their procedures.

16 So kind of the first bullet point that we
17 look at for this assessment is the general descriptive
18 information, and just as one example, we look at the
19 geographic spread of the human illnesses as well as
20 the distribution of product.

21 We look at the time sequence. Does the
22 exposure precede the onset of human illness? And, is

1 it appropriate for the given incubation period?

2 We look at the plausibility. Could the
3 exposure have caused the disease?

4 We take a look at dose response when we can.
5 If people ate more food, was the illness more severe
6 or were there more people ill?

7 We look at consistency. As an example, do
8 similar exposures result in similar outcomes?

9 We look at the disease confirmation
10 laboratory analyses. Are we seeing the same results
11 in the food and the laboratory analyses?

12 Then finally, or additionally, we look at
13 the analytical studies. How strong are the measures?
14 And, were the measures scientifically valid?

15 And we go through this framework in essence
16 to answer the question, is there credible evidence to
17 support an association between human illness and a
18 FSIS regulated product?

19 And if we feel like that answer is yes, or
20 the framework points to a yes answer to that question,
21 we really look at Agency action and a recall committee
22 is convened to discuss the findings of the

1 investigations. And I wanted to mention here that
2 Agency action is not just voluntary recalls as well.
3 Other examples include increased, enhanced inspection,
4 such as a food safety assessment, increased frequency
5 of microbial sampling or issuance of a public health
6 alert like we mentioned earlier today.

7 Our Congressional Public Affairs Office
8 leads the public communication efforts such as news
9 releases. Our Foodborne Investigations Branch
10 continues communication to affected local, state and
11 territorial public health partners. And I just wanted
12 to mention that the investigation even as Agency
13 action is occurring, or after Agency action has
14 occurred, is really ongoing to insure that the actions
15 are sufficient in scope.

16 Our after action activities include
17 analyzing what occurred as well as the corrective and
18 preventive actions that were taken by the
19 establishment. We also look at possible changes that
20 the Agency could make to reduce the possibility of a
21 repetition of this circumstance. We make sure that we
22 address any data gaps that we have from the

1 investigation, and coordinate a FSIS close out call.

2 So to kind of just summarize everything
3 that we've talked about so far, and some of the
4 lessons learned, we believe that FSIS foodborne
5 illness investigations really are multidisciplinary
6 and involve the numerous program areas throughout
7 FSIS, the epidemiology, the laboratory and the
8 environmental health components. And finally that
9 there is substantial coordination and collaboration
10 and that's essential between the local, state and
11 federal public health partners. Thank you very much.

12 (Applause.)

13 DR. HAGEN: Okay. Out last speaker in this
14 section will be Jack Guzewich from FDA.

15 Jack is a Senior Environmental Health
16 Scientist in the Center for Food Safety and Applied
17 Nutrition of the Food and Drug Administration, where
18 he's worked since 1997. In this role, Jack works on a
19 number of special projects including enhancing
20 relations with federal, state and local partners,
21 including as a member of the workgroup developing
22 FDA's 50 State Meeting to be held in August 2008, here

1 in St. Louis, CFSAN's Produce Safety Initiatives and
2 coordination of several projects with the CDC.

3 Prior to this role, Jack was the Acting
4 Director of the Division of Public Health and
5 Biostatistics and before that, Center Emergency
6 Coordinator. Jack previously worked for the New York
7 State Health Department since 1970, where he was the
8 lead for foodborne disease surveillance, food service
9 establishment regulation and training officer for
10 environmental health staff in the state.

11 Jack has a Master of Public Health Degree
12 from the University of Minnesota. He's on the
13 editorial board of the Journal of Environmental Health
14 and The Journal of Emerging Infectious Diseases. He
15 is the past President of the International Association
16 for Food Protection and a member of the National
17 Environmental Health Association, the Association of
18 Food and Drug Officials and the Council of State and
19 Territorial Epidemiologists. Jack Guzewich.

20 (Applause.)

21 MR. GUZEWICH: Thank you, Elisabeth. I only
22 have a couple of hundred slides here. So with any

1 luck, we'll be done by 6:00. Does that sound okay to
2 everybody? (Laughter.) Would you like to see some
3 more PowerPoint slides? That's a capital idea.

4 Okay. The nice thing about being the last
5 speaker is everything's already been said. So I can
6 go through there pretty quickly and seriously, we've
7 referred to most of this stuff several times.

8 The FDA, one thing you haven't heard is that
9 we have our own system for investigating outbreaks and
10 responding to them. We have a FDA crisis management
11 plan. We have a FDA chemical and biological emergency
12 response plan. Those are Agency-wide plans for the
13 whole of FDA, and then within the Center for Food
14 Safety and Applied Nutrition, we have an emergency
15 response plan, and all these plans cover our
16 coordination internally, our roles and
17 responsibilities at various parts of the Agency, and
18 our communications internally and externally.

19 The office in the FDA that's responsible for
20 coordinating all of our responses is the Office of
21 Crisis Management. You heard from our Director of
22 that office, Ellen Morrison this morning, and within

1 that office, the Office of Emergency Operations, is
2 the actual people who are involved in coordinating the
3 many parts of FDA that respond to these kind of
4 emergencies and outbreaks.

5 Our field staff is called the Office of
6 Regulatory Affairs, and they're staffed through 20
7 district offices that Ellen mentioned this morning,
8 around the country. They're the investigators who
9 most of you in the field actually encounter when you
10 talk about you know somebody from the FDA, and they
11 also have field laboratories around the country that
12 do the analyses of the various samples that are
13 collected by FDA staff.

14 At the Center for Food Safety and Applied
15 Nutrition, we have our Emergency Coordination Response
16 Team who is responsible for coordinating the actual
17 response of our Center to these kinds of emergencies
18 and outbreaks, and we have the scientific and policy
19 experts that provide the input to the investigations
20 as they go forward.

21 I'll go quickly through an investigation
22 from our perspective. Hopefully, you've heard a lot

1 of this before. So it'll go pretty quickly.

2 In the surveillance area, as you all know by
3 now, if you didn't before you came here today, the
4 local and state health departments are the backbone of
5 disease surveillance in the U.S. and we depend on them
6 for their surveillance activities of infectious
7 diseases and their detection of the outbreaks as much
8 as anybody else in the country.

9 Laboratory surveillance is a very important
10 part of this. You've certainly heard a lot today
11 about how laboratory surveillance has become very
12 important through systems like PulseNet and EnviroNet
13 and the other ones that they have today.

14 Consumer complaints has also been mentioned.
15 I wasn't sure that was going to come up today, but I'm
16 glad to see it came up several times. Because we're
17 talking about outbreaks involving FDA and FSIS
18 regulated products mostly today, people forget, as we
19 have seen them earlier data, that a lot of the
20 outbreaks really are detected from consumer complaints
21 and are investigated locally and we don't get involved
22 at the federal level at all.

1 For us at FDA, CDC consultation is
2 essential. We are very fortunately to have a liaison
3 at CDC that works closely with them there. We talk
4 with Dr. Williams and his staff almost daily on
5 various situations, and we couldn't do our job without
6 our consultation with CDC. It's that simple.

7 I also want to mention since all we've
8 talked about today is this word surveillance, and
9 everybody today is now well primed to the fact that
10 surveillance is a disease function, but those of us at
11 the regulatory agencies also think of our inspections
12 and sampling as a surveillance activity as well. It's
13 a different kind but that's how we think of that term
14 as well.

15 Now we'll talk about the epi investigation.
16 As we all know today now, it's conducted by state and
17 local public health agencies. FDA, as I've already
18 said, relies on CDC -- lab investigation data and
19 CDC's recommendations. When there is an outbreak that
20 possibly involves an FDA regulated product, we wait
21 until we hear from CDC's epidemiologists on whether or
22 not they concur that there's an association between

1 the product, whatever it is, and an FDA regulated food
2 and the outbreak is well established. We actually
3 receive in writing many times a recommendation from
4 CDC that summarizes their investigation, their
5 collaboration with their state and local
6 epidemiologists and laboratories and the overall
7 recommendation as to what they feel they should do
8 next.

9 We in turn review that epi investigation
10 additionally with our own epidemiologists and lab
11 experts and look at that data one more time. So
12 there's a lot of vetting that goes on at these things
13 before we move forward on them.

14 Laboratory analysis, we've heard a lot about
15 that today. We depend on the clinical laboratory
16 system. The Food, Environmental and PulseNet systems,
17 I'm not going to dwell on those because we've heard a
18 lot about them. I'm going to try to move this along.

19 Environmental investigations are more along
20 the line of what you think of when you think of a food
21 regulatory agency. The point of service,
22 environmental investigation is very important in an

1 outbreak that has one setting. Many of the outbreaks
2 we're talking about today are widely diffuse outbreaks
3 and so you don't have one setting. You have sporadic
4 cases all over a county or a state or a whole nation,
5 but where there is one setting for the outbreak, we
6 have to have an environmental investigation that
7 establishes the fact that the contamination did not
8 occur there, and this has been a problem for us in
9 some investigations. State and local health
10 departments have implicated a product that FDA
11 regulates but the quality of the environmental
12 investigation locally wasn't sufficient to make us
13 comfortable that the contamination did not occur where
14 the food was prepared.

15 Along with chain of distribution, we conduct
16 environmental investigations at the distributor level,
17 the manufacturer and the repacker, all the way back to
18 a farm or a processor depending on the investigation
19 involved. We identify possible sources of
20 contamination, and it's not your normal inspection.
21 That's one of my biggest causes. Those of you who
22 know me is trying to get us away from doing regulatory

1 inspections at this time and doing a true
2 environmental assessment.

3 The environmental investigation is critical
4 to identifying where the contamination occurred and at
5 which point in the distribution chain it occurred.
6 FDA won't be involved if the contamination occurred at
7 a point of service, that is within the state's
8 jurisdiction. So if it's a restaurant outbreak, a
9 church supper outbreak, a wedding banquet outbreak,
10 we're not going to get involved in that unless it's
11 established that it was an FDA regulated product and
12 it was contamination where the food was prepared.

13 Most of our investigations these days
14 involve extensive sampling. We've learned in recent
15 years that if we collect enough environmental samples,
16 we've had pretty good success in identifying the
17 contaminant in the environment where the food was
18 likely contaminated, but it at a processing plant or
19 even on farms on some occasions.

20 Now we get to the response and recall phase
21 of things. It's important to realize the criteria
22 that we use at FDA to take actions, and this process

1 of acting on epidemiologic evidence, has really come
2 about in about the last 10 or 12 years at FDA.
3 Historically, we're more accustomed to taking
4 regulatory action based on inspectional findings and
5 laboratory sampling and testing of a contaminated
6 product. I know that a lot of industry people are
7 more accustomed to FDA regulatory actions based on
8 those kind of situations. But in the last 12 years,
9 we've become increasingly involved in taking
10 regulatory actions based on epidemiological evidence
11 and the findings of work done by local health
12 departments, state health departments and CDC. So we
13 have to have that epi association, it has to be well
14 vetted by the state and local people. We look at the
15 state epidemiologists for that. We look at the CDC
16 for that, and our own epidemiologists, to be
17 comfortable that the science was sound and the
18 conclusions are valid.

19 We look for laboratory associations. Most
20 often those are clinical laboratory findings. A
21 number of patients who have had the same organism in
22 many of outbreaks that are spread across multiple

1 states.

2 We want negative environmental findings at
3 the point of service meaning that if there is one
4 point of service involved, that the contamination did
5 not occur there. The environmental investigation done
6 by the state or local authority was convincing and
7 compelling that the contamination did not occur where
8 the food was prepared.

9 And we need to know whether there's a
10 population still at risk. In many of the outbreaks
11 that we get involved in of recent times, have been
12 produce. Produce is a very perishable product and by
13 the time this whole process has gone on, that
14 particular product is no longer available for
15 consumption. It's already spoiled or it's been
16 consumed but the consumers are no longer at risk for
17 that product and so our actions aren't as public about
18 them because the public isn't really at risk any
19 longer.

20 And then actions we can get involved with
21 are recalls. We've talked about the voluntary aspect
22 of recalls, about the recall actions taken by

1 companies. We're dependent very much on CDC for help
2 in that area because as has been brought up earlier
3 this morning by Dane Bernard and other speakers, the
4 industry needs to understand this epidemiologic
5 process. They're more accustomed hearing from a
6 regulatory agency talking about a pathogen having been
7 found in their product or some other contaminant in
8 their product, this idea that some people got sick and
9 some mysterious black box process called epidemiology
10 has suddenly pointed the finger at them, it's pretty
11 hard for them to accept and so we find it very
12 successful to have CDC involved in these conversations
13 with the companies to educate them as to the reasons
14 why this is a valid thing, this is valid as having a
15 positive sample in their product.

16 And, of course, then it gets to the issue of
17 issuing press and going through our own internal
18 review processes to get the press to alert the product
19 with hopefully a useful message.

20 Trace back and trace forward. This is an
21 example of a real trace back that's been sufficiently
22 de-identified that I don't think you can figure out

1 which one it was. You better not, or I'll be in
2 trouble with Ellen. I don't want to be in trouble
3 with Ellen ever. The important thing about this slide
4 is that every one of these steps, this point isn't
5 working, but I came prepared, no problem. Whoops, it
6 jumped on me. But everyone of these steps in this
7 process, an FDA investigator or sometimes it's been
8 the state or local investigator, has gone to a
9 facility and has collected documentation about the
10 source of the product, where it came from. Oftentimes
11 there are multiple suppliers for a given product at a
12 given point in time at this establishment, and our
13 investigator goes in there, does the best they can to
14 collect information. The information is forwarded
15 into the Headquarters in FDA because we have more
16 experience analyzing this stuff, and we find holes.
17 We find questions that haven't been answered by the
18 first trip, and there's a second trip and sometimes a
19 third trip back here trying to ferret out as best we
20 can the limited number of possible locations involved,
21 but you can see in this example, that there were three
22 possible suppliers of this product at this location

1 the same time. Then we have to go to every one of
2 these three locations and start all over again. Where
3 did you get this product at this point in time, what
4 is your documentation and it's very intricate trying
5 to eliminate the other possible kinds of explanations
6 for where the product came from. Did the
7 contamination happen at this source? Did it not
8 happen at this source? And this goes on every step of
9 the way. So everyone of these boxes that looks just
10 sort of uninteresting in itself on that diagram
11 represents hours and days worth of work of field staff
12 from FDA going to a place, accumulating records and
13 then people from FDA going through these records,
14 trying to sort them all out, making sense out of them,
15 finding holes, questions not answered, repeat visits
16 back in time. So somebody can say, well, we've
17 determined it's X product. Why didn't you just go out
18 and trace it back? We should have an answer in a
19 matter of hours or days. We'd love to be there, too,
20 but rarely are we that lucky to get back there.

21 Now if it's in a labeled product, if it's a
22 packaged food, and it's a labeled product, and the

1 labeled product is still available in the consumer's
2 home, and there's the product label, and it's got code
3 numbers on it and all kinds of things, that's a cake
4 walk. But when you have fresh produce, it doesn't
5 work like that. Fresh produce is a nightmare. Also
6 we've learned in fresh fish lately.

7 Okay. We're going to make an environmental
8 health person out of you yet, we really are.

9 Farm investigations. What we look for in
10 farm investigations is not your typical inspection.
11 We're trying to identify in a farm environment how
12 foods got contaminated. This is a very complex
13 science or art that we've kind of evolved over the
14 last 10 or 12 years. Trying to go into a setting like
15 that and identify how pathogens could have gotten onto
16 fresh produce, but the same kind of process goes on in
17 a processing plant, if that's the setting involved.

18 We found that a team approach is critical.
19 We do use FDA investigators, the lead of our team. We
20 have an environmental health person, like a sanitarian
21 who is a water expert. On one occasion at least, we
22 had a CDC water engineer involved. We use

1 microbiologists, wildlife biologists, epidemiologists,
2 I don't have them up there, but we use veterinarians.
3 We have all kinds of expertise that come to play on
4 these investigations in these settings. So it's a
5 team approach. We have different kinds of expertise
6 brought to there.

7 Lessons learned. Up until now you've heard
8 15 times today, and I'm sure you'll say, gosh, one
9 more time we've got to hear this one more time this
10 afternoon. Well, I'm going to talk about some lessons
11 learned which is a little bit like airing some laundry
12 things, but there's some things we've learned over the
13 years from these investigations.

14 First of all, there's variable capacity in
15 different state and local public health agencies.
16 You've sure heard that today. Some states and locals
17 do not notify FDA or CDC. They don't notify each
18 other either. We've had a number of investigations
19 involving FDA regulated products where we've had more
20 than one local health jurisdiction or state health
21 jurisdiction, diligently working on this investigation
22 that they assumed was something involved in their own

1 jurisdiction and doing a great job but not realizing
2 that really it had implications far beyond their
3 jurisdictional borders. And so sometimes there's
4 things lost in these investigations for communication
5 there.

6 In the epidemiologic investigations, how
7 good is the epi data and who decides? And there's two
8 kinds of criteria here, folks. I've only heard about
9 one criteria these days. I've heard a lot about the
10 epidemiologic criteria or how well the epidemiologists
11 are comfortable with the findings, but there's also
12 the legal aspects. We are regulatory agencies after
13 all, and we have this profession called lawyers, and
14 they're not epidemiologists. They're not really
15 always wild about this kind of stuff, and so they pin
16 our epidemiologists down on how good is this epi? Is
17 this study really meet the acid test? Is this data
18 collected properly? Were these interviews done
19 properly? So it's just not a matter of passing the
20 epi mirror test. We also have to pass the legal test
21 and the compliance test as to whether we can act on
22 these things.

1 And what if CDC is not involved? We've had
2 a number of outbreaks now where for one reason or
3 another the state or the locality did not involve CDC
4 in its investigation. We'd much rather have CDC
5 vetting of these investigations, but if that hasn't
6 happened, then we're in the position of dealing with a
7 state or local agency usually directly in trying to
8 get comfortable with their epi data. They take this
9 as a personal affront that we're not comfortable with
10 their data because we should have confidence in their
11 ability. We'd love to be able to, but there are
12 public health and legal reasons why we have to be very
13 careful and make sure that the information really does
14 pass the test.

15 We've had times when we haven't been able to
16 go forward on situations because the epidemiology done
17 by the state or local agency wasn't of sufficient
18 quality that we felt comfortable going forward with
19 it.

20 The other thing that happens here is that
21 locals and states need to keep their investigation
22 data. We've had a few cases now where we've tried to

1 move forward on situations but the gathering and
2 keeping of the information was not that good at the
3 state or local level which made it harder for us to
4 act upon the information and the investigations that
5 they had conducted.

6 Trace back. Some of these things you've
7 heard before but poor and incomplete recordkeeping is
8 a real problem in trace backs. When we get back to
9 these places I showed you all those little boxes in
10 the diagram, that means that they don't have records
11 at all or the records -- we had one case in the trace
12 back where the records were in a shoe box in the
13 trailer of the owner, and the owner had gone away
14 fishing for a week. That really happened. And no one
15 could get into his trailer to get the records, and so
16 we lost a week in the trace back.

17 And just because the records are on a
18 computer doesn't make it any better either because
19 they can go to a computer and they can dump out a
20 stack of printouts this high and say here's our
21 records, and then someone's got to figure out from
22 that, you know, where are the little threads that

1 we're looking for that take us back on the source of
2 this product.

3 We have a problem with slow response in
4 providing records. We have multiple sources of the
5 same product at the same time at various steps in the
6 system and trying to sort out which is the one that's
7 involved is very difficult when this product shows up
8 all over the place. Records from one point do not
9 line up with records from the next point in the
10 system. Processors cannot match finished product with
11 incoming raw ingredients and trace backs often require
12 huge amounts of resources. And Bonnie's about to give
13 me the hook. I see it over there. I can see it over
14 there. (Laughter.) You don't want Bonnie staring at
15 you either, I want you to know. I can feel her
16 bearing right through the side of my head here.

17 Response. Need to be fast. You saw this on
18 the slide this morning. We need to be fast. We need
19 to be right, and there's quite a balance here for us
20 in public health. We never do it fast enough but
21 there's something about having to do it right as well,
22 and that dilemma faces us every day in the week. We

1 need to review the legal requirements and make sure
2 that things stand up legally. We're now using a
3 system called Incident Command more and more. I know
4 that the epidemiologists' blood curdle when they hear
5 that term, National Incident Command or National
6 Incident Management System, but the regulatory
7 response agencies are going more and more in that
8 direction, and it doesn't fit very well to the
9 epidemiologic paradigm, I know, but in the response
10 paradigm we've saw recently in the case of North
11 Carolina, if you want to talk to people from that
12 state, where they made very effective use of Incident
13 Command in their response to Castleberry chili, and as
14 time goes on, I think more regulatory agencies will be
15 going to that system.

16 Information technology. Just when you don't
17 want it to happen, it happens. Servers crash.
18 BlackBerrys fail. That's been a common problem in
19 some of our situations, like spinach outbreak when the
20 servers crashed and the BlackBerrys failed.
21 Communicating with field investigating teams is
22 difficult when they're out in the field and people

1 want answers to questions and you can't reach them.

2 Information management. One of the problems
3 we have in these investigations is information
4 overload. We have so much information that we don't
5 know how to manage it meaningfully and get the
6 important things out of all of the information
7 received. We have a system that we have called --
8 that we're using in our center, and now at the Agency
9 level, Ellen Morrison's staff has this new system
10 called Emergency Operations Network, which is going to
11 be the Agency's information management system just to
12 keep track of all the stuff that's going on. I'm
13 moving.

14 Communication. We've heard a lot about
15 communication, but what I haven't heard anybody say
16 today is about information overload when these things
17 happen. We have so many e-mails that you can't keep
18 up with your inbox. The phones are ringing off the
19 hook. Everybody wants a report hours ago about what's
20 going on. The poor people in the field are trying to
21 do their job, but they can't get the job done because
22 they have so many questions coming in, give me a

1 status report of what you're doing. It's I'll give
2 you a status report when I get the job done kind of a
3 thing, you know. So we have those kind of problems.
4 We need early information for consumers if we know
5 what that information is. We need to keep everybody
6 informed inside and outside of Government, domestic
7 and international. We can't forget international
8 these days. Many of our products have an
9 international component to them. So we have all those
10 situations to deal with.

11 We have secondary -- distribution. The
12 rolling recalls. No one has explained why you have a
13 rolling recall. You have a rolling recall because
14 you're continually learning new information, and as
15 new information comes out, you identify additional
16 product that's involved that you didn't know about the
17 first day, but two days later you know about
18 additional product that's involved.

19 A need for clarity in roles and
20 responsibilities. You heard today about all the
21 confusion about roles and responsibilities. We need
22 to coordinate public statements within and among the

1 agencies. Then we have to overcome our restrictions
2 on information that can be shared. We have our
3 criteria in FDA for when they get involved, criteria
4 for initiating recalls, trace backs and et cetera, and
5 when a perishable product is out in distribution, do
6 we warn the public or not.

7 I'm about there, folks. I really am.

8 I'm going to go onto my last slide I think.
9 General comments. Other things we haven't heard about
10 today is staff burnout. We have staff burnout in
11 Government and I imagine they have it in industry,
12 too. If you're a company and suddenly your product is
13 being recalled, people who don't normally do this kind
14 of thing or do it once in a while in an exercise,
15 suddenly are working long hours day after day after
16 day. It's a real problem for industry. It's a real
17 problem for Government. We only have so many staff.
18 They work long hours. They work extra days of the
19 week, and pretty soon they can see double, and then
20 it's hard to think clearly. So we do have a problem
21 with staff burnout.

22 Staff does the best in emergencies those

1 things that they are familiar with. In an emergency,
2 you're not doing the things you do every day, and this
3 unfamiliarity with activities slows down your
4 efficiency and your effectiveness. We always need
5 more training and exercises to try to overcome some of
6 these activities. That's why there's going to be an
7 exercise tomorrow thanks to FSIS.

8 Last three comments. Trace backs take time,
9 folks. Sorry about that, they take time. Sometimes
10 they take a lot of time and a lot of resources.

11 Environmental investigations take time as
12 well and sometimes they're being done days and weeks
13 and months after the contamination occurred.

14 And laboratory analysis takes time although
15 the laboratorians are always coming up with better
16 rapid methods. Even in the best of times, there's
17 still a lot of time involved to get all your
18 laboratory analysis done and take another sample and
19 get it analyzed. And I think I'm done. I'm done. My
20 apologies, Bonnie.

21 (Applause.)

22 DR. HAGEN: Thank you, Jack, and thank you

1 to all the speakers. I have 3:32 on my BlackBerry.
2 So let's take a break until 3:45, and that will still
3 allow us to have almost an hour for questions if you
4 want that much time, and then we'll still be able to
5 wrap this up by 5:00. So there's coffee and tea, and
6 I think there may be some cold drinks in the back as
7 well.

8 (Off the record.)

9 (On the record.)

10 DR. HAGEN: If all the speakers from today
11 would please come toward the front of the room and sit
12 either in the first few rows over here. That will
13 make it easy if someone has a question that pertains
14 to the earlier discussions. We can pass the
15 microphone around like we did.

16 But for those of you who have questions and
17 comments, please feel free to go ahead and line up at
18 the microphones. We're going to begin our question
19 and comment period unless there are no questions or
20 comments. I would be shocked. (Laughter.)

21 Donna, I knew I could count on you to get
22 things started. Okay. So we have our panelists from

1 this afternoon and hopefully everyone's heard me. The
2 other speakers from this morning, if you could move
3 toward the front of the room, so that if we need to
4 pass the microphone around, we can do that.

5 So as a reminder, please state your name and
6 if you have an affiliation, let us know where you're
7 from so our transcriptionist can catch that.

8 MR. COTELL: Good afternoon. Daniel Cotell
9 (ph.), EHA Consulting Group. My question's related to
10 the FDA trace back system. Using the current import
11 alert related to cantaloupes, in this situation the
12 FDA is dealing with products that do not have any
13 particular brand identity and are frequently
14 commingled throughout the distribution system all the
15 way to the supermarket. That being said, what type of
16 controls does the FDA have in place within its own
17 decision making system to make certain that it has
18 identified the proper company, particularly in the
19 absence of any direct evidence of product
20 contamination?

21 And let me just give you the second part
22 before you answer please. And how transparent is this

1 process given the impact your decision has upon the
2 party involved.

3 MR. GUZEWICH: Well, I'll answer the second
4 part of your question first. Because of the legal
5 implications involved, it's not very transparent, and
6 it can't be because of legal implications because in
7 the course of one of these investigations, we're
8 seeing the names of many companies, and we're seeing
9 the distribution systems and all of the customers and
10 the clientele. That's all confidential information,
11 and any investigation that the FDA conducts has the
12 possibility of resulting in some kind of ultimate
13 enforcement action and we don't publicly discuss any
14 investigation that has the possibility of ultimate
15 enforcement actions. So the transparency, which would
16 mean talking about the details and all the steps
17 involved, really isn't there for a regulatory agency.

18 As far as the rigor of the trace back
19 involved, we spent hundreds if not thousands of hours
20 in that particular trace back investigation. That's
21 field staff going out and collecting records and often
22 times multiple visits to verify information. That's

1 just FDA staff. We also had the help of some state
2 and local health and agriculture agencies involved in
3 that investigation.

4 The field staff collects the information but
5 the actual analysis of the information is done in our
6 Headquarters partially by the Office of Crisis
7 Management and partially at the Center for Food Safety
8 and Applied Nutrition. We also had a Headquarters
9 person from the Office of Regulatory Affairs involved.

10 We go over that information frontwards,
11 backwards, sideways. We come up with questions. It
12 drives our field nuts because they'll think they've
13 got all the information that we asked for. They do it
14 very diligently. They're very proud people who do a
15 very good job of what they do, and they've gone out
16 and they've collected all these records and maybe
17 they've made a several hour trip in a car to get there
18 and all the rest of it. They get the records. They
19 FedEx them off to us. We pour over those records and
20 son of a gun, if there's not another question that
21 comes up or something doesn't fit. There's a piece
22 that isn't just right. There's a question we haven't

1 gotten answered, and we have to call up that district
2 office one more time and talk with that director of
3 investigations one more time and ask him or her to
4 send an investigator out one more time, and they love
5 to get those calls I want you to know but that's part
6 of the job. That's my job, and to do it right.
7 That's where we get into this problem with fast and
8 right, and we have to balance these two things because
9 we want to protect public health and it still can be
10 public at risk for this disease in the case of this
11 cantaloupe because the shelf life of a cantaloupe
12 being a little longer, we still had the potential for
13 having product in the marketplace.

14 But we still have this legal and ethical
15 obligation as a Government to do it right. And so we
16 go through this very carefully checking the records,
17 cross-checking the records. We have epidemiologists
18 involved. We have investigators involved. We have
19 people with different kinds of expertise involved,
20 reviewing these records to make sure we've got it
21 right, making extensive diagrams, blackboards are full
22 of things, pieces of papers are full of things,

1 documenting the whole aspect of the trace back.

2 So when we get done, we have to have a real
3 level of comfort that we've come up with the right
4 thing, but in the process of doing that, we consider
5 many companies, many possibilities, and then in any
6 commodity you want to talk about at any point in time
7 and in the distribution, there can be multiple sources
8 for it, domestic sources and foreign sources, and we
9 have to treat all those the same.

10 In the case of this investigation, we were
11 very comfortable with our conclusion when we finally
12 got there.

13 DR. WILLIAMS: I have one additional thing.
14 I think another important thing to consider is how
15 good the quality of the exposure information is, given
16 how much work these are to do. It's very critical to
17 make sure that you collect the right information from
18 the cases and make sure it's of high quality so when
19 you start on one of these, and start to invest
20 hundreds of hours, you're basing it on the best
21 possible information.

22 MR. COTELL: Thank you.

1 DR. HAGEN: Next question.

2 MS. ROSENBAUM: Good afternoon. I'm Donna
3 Rosenbaum, Executive Director for STOP, Safe Table Our
4 Priority, and I have a three part question here.
5 First I'm going to start with a comment and then I
6 have a request and then actually I'll end with a
7 question.

8 My first comment is one that I've shared
9 with Dr. Raymond at FSIS, and that is about the public
10 health alerts. With 15 years of experience in dealing
11 with consumers and media extensively with foodborne
12 illness response and outbreaks and concerns, I can
13 share with you, as I've shared with Dr. Raymond, that
14 public health alerts are not usually very helpful to
15 consumers or the media and they lead to a lot of
16 confusion. So that's just a comment that I wanted to
17 make.

18 The second thing I wanted to do is put in a
19 request. We've heard all throughout today from all
20 the various public health entities on the state, local
21 level as well as federal agencies, that they do deal
22 with consumer, consumer complaints and there's a lot

1 of information that's generated from the consumer
2 sector that comes to them. What I want to make a
3 request is that you all, no matter where you are, on
4 the local, state or federal level, try to close that
5 loop by getting back to those consumers because we
6 hear about it when you don't, and it does create a lot
7 of problems for people, whether it's just, you know,
8 complaints about something that's gone wrong with the
9 food product that they're reporting to an agency or
10 there's a consumer complaint with an illness. It is
11 really dropping the ball to not get back to that
12 consumer and let them know what has become of their
13 complaint, and whether it's just something mundane or
14 in the case of a fairly drastic illness, we have just
15 scores and scores of people who haven't been gotten
16 back to after the state or the federal agencies have
17 identified that they're part of an outbreak or even
18 part of something or that they've had something that's
19 matched in PulseNet. There's no feedback back to that
20 person. Of course, that entity, federal or state
21 entity, takes that information and does something with
22 it. It might even get entered into the statistics but

1 the people who are actually involved in it sometimes
2 aren't getting that feedback, and I think that's very,
3 very important as part of your work with the public.
4 For public trust and for personal information, it's
5 very important to close that loop. So that would be a
6 request that I'd make.

7 And then my question is, this is for
8 interagency work between USDA and FDA. What happens
9 when you're investigating something with a mixed
10 product where there's not really any definitive link
11 to, it might be a meat or it might be a vegetable
12 product within a larger product that encompasses both
13 those, such as like a sandwich that's out on the
14 market that's mass distributed and it might have a
15 tomato or lettuce component as well as a deli product
16 on it, a meat product. And you know those sandwiches
17 are implicated and you know they're making people sick
18 but yet you really can't find what subcomponent of
19 that is causing the illness. What then happens
20 between the agencies and who would take the lead and
21 who would initiate a recall?

22 MR. GUZEWICH: FDA has a policy on that.

1 Those are USDA regulated products. I'm just teasing
2 you. That's not true. (Laughter.)

3 Actually we do have those problems. The
4 problems don't start though for USDA and FDA actually.
5 The problems start with the epidemiologists because
6 it's really the science and art of epidemiology to try
7 to tease those apart, and it's not uncommon that when
8 certain foods are served together, tacos being a great
9 example of that, where you have ground beef which is a
10 USDA regulated product, oftentimes maybe even coming
11 from a regulated plant where it was prepared and
12 precooked and everything. You have the cheese in
13 there which is an FDA regulated product. You have
14 guacamole which is FDA and sour cream which is FDA and
15 lettuce which is FDA and tomatoes which is FDA and
16 onions which is FDA. Only one for USDA so far, right?

17 MS. ROSENBAUM: FDA wins.

18 MR. GUZEWICH: The tortilla -- it's always
19 going to be the ground beef in those, you see. But,
20 but seriously, we hope that the epidemiologists are
21 able to tease that apart. Sometimes they aren't, and
22 it's not because not of want of trying. They have a

1 lot of techniques they use to try to tease that apart.
2 When they're not able to tease it apart, that's what
3 Dr. Williams was talking about earlier today, they
4 want to do one of these epidemiology trace backs.
5 They're hoping that by doing some kind of a trace back
6 on more than one product, that will help them figure
7 out a commonality. If there's only one setting
8 involved, we can't do that, but if there's multiple
9 settings involved, you can see if there's some
10 commonality about one of the ingredients that helps
11 narrow it down. It's a real challenge. I'll let you
12 talk with the epidemiologist.

13 DR. WILLIAMS: Yeah, and I think the reality
14 is this is part of hypothesis, generating testing sort
15 of phase, and oftentimes we have both FDA and FSIS
16 liaison. We're informing them what's going on and
17 sharing information that the states are working on
18 with everyone, very much is a team process in order to
19 try to sort out this issue.

20 MS. ROSENBAUM: My concern is, from a
21 consumer perspective, and I've heard this actually
22 from consumer complaints, is that precious time is

1 lost when the actual identification of the larger
2 product that's on the market is known when there's
3 interagency squabbling over whose regulated product it
4 is, but you know what it is consumers shouldn't be
5 eating, you know. So there's a problem there.

6 MR. GUZEWICH: I have to say in my
7 experience, I've been with FDA for 11 years, and we
8 have this good natured kidding back and forth about
9 whether it's FDA or USDA. We do play that game. I
10 have to confess. But there's never been really a
11 squabble kind of thing. We're trying to get to the
12 bottom of the story seriously. I guess you have this
13 impression that there's some kind of a cat and dog
14 fight going on there, and it is not like that at all.
15 We --

16 MS. ROSENBAUM: No, no. I'm just concerned
17 over the time that may be lost --

18 MR. GUZEWICH: So are we.

19 MS. ROSENBAUM: -- in which we could have
20 identified and recalled the product earlier.

21 MR. GUZEWICH: Believe me, fast and right.
22 Fast and right. That's our dilemma every day of the

1 week. Fast and right. We want to get it right and we
2 want to get the right product and we want to do it as
3 fast as we can to prevent exposure, and that's our
4 dilemma.

5 MS. ROSENBAUM: Let me put it out there
6 then in a more general term. What happens if you do
7 all of those epidemiological studies and you really
8 can't come up with one sub-item in that that is the
9 problem. Then what?

10 MR. GUZEWICH: We do have inconclusive
11 investigations.

12 MS. ROSENBAUM: But is there no recall then?

13 MR. GUZEWICH: Recall of what?

14 MS. ROSENBAUM: Recall of the product. So
15 if it's a mixed product that's out on the market, and
16 you know that that product is out there on the market,
17 it is making people sick would there not be a recall
18 because one agency can't find one product to call
19 their own?

20 DR. HAGEN: I guess I would -- I can jump in
21 here, too. I mean it think it depends on the product
22 and I think that products that are packaged and, you

1 know, it might be a mixed product and a mixed
2 jurisdiction establishment that have both components
3 in them, do fall under the regulation of one agency or
4 another most of the time. So with the Banquet
5 potpies, even though those had vegetables and chicken
6 and pastry dough in them, that is a FSIS regulated
7 commodity. So it depends on the product.

8 If you have, you know, loose tacos being
9 made at a restaurant, that gets a little more
10 confusing although I've been impressed by the number
11 of taco outbreaks where we've been able to figure out,
12 collectively between the states and CDC and the
13 regulators, that it was the produce usually.

14 So I think if the product, if it's sort of a
15 whole product that comes out of an establishment, even
16 if that's a cross-jurisdictional establishment, soups
17 are another good example. A lot of soups end up being
18 FSIS regulated because of the components that are in
19 there even though they have potatoes and other things
20 in them. And if the evidence can point to that one
21 product, we can still do a recall as we did with the
22 potpies. But it's when the products are assembled

1 like in a restaurant or something like that, where it
2 gets a lot more difficult if you can't ferret out that
3 piece of it by doing the epidemiologic analysis, by
4 getting enough exposure histories, you're kind of
5 stuck, recalling individual products, components that
6 went into that.

7 MR. GUZEWICH: Between the techniques that
8 the epidemiologists use, which they're very artfully
9 at applying to tease these things apart, and
10 occasionally some of these epi trace backs combined.
11 It's surprising how often they're able to tease apart
12 all these things that come together in one of these
13 investigations. There have been times when we end up
14 having to investigate multiple products and we do a
15 sampling. We didn't say that either. If we think
16 it's one of three products, we try to get samples from
17 that same lot number and test those with a chance that
18 we might find the contaminant that way.

19 So there's a number of different things we
20 try to do to try to get to the bottom. These kind of
21 investigations are not uncommon these days.

22 DR. HAGEN: David, did you want to make a

1 comment?

2 DR. WARNOCK: Are we not getting away from
3 the key point here which is prevention and control?
4 Very often the product will be taken off the market
5 and then we carry on trying to figure out what
6 component caused the problem so we can prevent it
7 happening again. I do think --

8 DR. HAGEN: Very good point.

9 DR. WARNOCK: -- things get taken off the
10 market as quickly as possible. We may not know which
11 precise component was involved, but we keep on working
12 to make sure it doesn't happen again.

13 DR. HAGEN: That's a good point. And,
14 Scott, did you have anything to add to that?

15 MR. SEYS: I was just going to add that, you
16 know, we definitely have had investigations in dual
17 jurisdiction establishments, and there are often FDA
18 and FSIS investigators working on that investigation
19 at the same time.

20 UNIDENTIFIED SPEAKER: I was going to ask a
21 question, I should but I can't resist commenting a
22 little bit. There are a lot of investigations that

1 start out very ambiguously or at least not start out
2 that way. You end up with two or three products, and
3 if they do come from different suppliers in a sense
4 and have no connection other than being assembled at
5 some point, I think there would be reluctance to tell
6 people to stop eating lettuce and tomatoes and cheddar
7 cheese. We don't know which, but if you avoid all of
8 them, you'll avoid the problem. And those outbreaks
9 would continue if they weren't already over. There
10 would be reluctance. Fortunately that rarely happens,
11 and when it does, it usually results more in delay as
12 we get these additional kinds of information rather
13 than the whole thing collapsing. But investigations
14 do collapse sometimes.

15 The question I wanted to ask was whether or
16 not any progress was being made in terms of improving
17 the ability to track produce. I read things in the
18 newspaper about labeling fruits and vegetables with
19 things, with kind of brand kind of markings, and is
20 any of that likely to show up and do you get
21 resistance from companies doing it because it's
22 expensive and deep down they really don't want to be

1 identified as the source of an outbreak or it more
2 just the technical problem of doing something that
3 will stick with a product like that?

4 MR. SEYS: I don't see David Gombus (ph.) in
5 the room right now. Too bad he's not in the room.
6 David's here from the United Fresh Produce
7 Association.

8 The United Fresh Produce Association, the
9 Produce Marketing Association, the Canadian Produce
10 Marketing Association and a lot of the other trade
11 associations from the farm to the table are working on
12 an initiative right now in this whole area of produce
13 trace back, and they're getting buy in from the whole
14 distribution chain, again from the farm to the table,
15 to work together to try to come up with a system.
16 It's very complicated because what happens now, a lot
17 of the produce growers and packers have some pretty
18 good systems at their point in the system, but because
19 you go through multiple steps along the way, it
20 doesn't carry forward through all the various
21 distributors and wholesalers to the retailers, be it
22 the restaurants or supermarkets. And so it's a matter

1 of getting everybody to play by the same nomenclature
2 if you will under the same system all the way along so
3 that you can carry through in the trace back, and it's
4 very much in their interest to have that happen
5 because it's to the point now where if you read the
6 foodborne disease popular press, every time there's an
7 outbreak, people say what was the produce served at
8 that place kind of a thing, and they're getting kind
9 of a black eye as being the cause of all outbreaks.
10 And so they're very aware of the need to combat that
11 and to limit, even if it is produce, to limit the
12 impact. I mean the spinach outbreak had tremendous
13 impact on not just one company but multiple companies
14 because they couldn't initially sort out where the
15 spinach came from. So they're very much attuned to
16 the fact that they've got to do everything they can to
17 limit the impact even when it does happen.

18 So we have great cooperation. In fact,
19 those associations are all coming into FDA next week,
20 a week from today actually, to meet with us and report
21 to us on all their activities around that produce
22 trace back system. So we're hopeful but, you've got

1 to realize, Bill, that, you know, to tease you a
2 little bit, but you've worked on the epidemiological
3 investigation for days or weeks and sometimes even
4 months and now you come to, at 3:00 in the afternoon,
5 and say, gee, guys, it's the whatever, and what are
6 you going to do about it this afternoon. Well, it
7 does take a little bit of time. It takes time to do
8 that trace back even in the perfect system, and to
9 trace things back to the source.

10 But I think over time it will get better,
11 but it's always going to be a problem in that kind of
12 a commodity, and then Caroline and I had this
13 conversation recently about the stickers. You can put
14 stickers on the cantaloupes. You can put stickers on
15 the apples and the tomatoes and so on but by the time
16 it's sold and you go through the whole process that
17 leads up to the identification of an outbreak, that
18 sticker is long gone. So is the carton. So is
19 everything else. All of the identifiers are gone, and
20 on a rare occasion, we have a spinach outbreak where
21 the package still has the label on it, but when it's
22 loose bulk produce, all the connectors you can come up

1 with are not going to be around by the time we do our
2 trace back. That's been our problem.

3 MS. SMITH DeWAAL: I was going to ask that
4 question but I have another one. The title of this
5 meeting started with something about effective
6 communication and so this is kind of a comment and
7 kind of a question.

8 I've heard a whole lot about outbreak
9 investigations, and the epidemiology and I mean how it
10 really is progressing, dramatically from what we
11 started with back in 1992-93, when a number of us
12 really started in this area. But what I haven't heard
13 and we'd need a whole other day for it is how the
14 agencies really work to insure how they're
15 communicating these recalls to the public and to the
16 industry really delivers the messages, that they need
17 to.

18 Now Terri said everything they've got is,
19 you know, everything USDA is doing is science based
20 but then when someone asks for a study, I came up with
21 one from like 1994, and she came up with one that was
22 somewhat unrelated.

1 So what level of science is going into how
2 you effectively communicate to the public and how to
3 deal with these issues of ineffective communication
4 which we've seen a number of examples of lately, and
5 maybe we need to have another meeting to discuss that
6 because I don't think we ever really got to that.

7 MR. GUZEWICH: I can give you a partial
8 answer to that, Caroline. Ellen just reminded me that
9 after the spinach outbreak, Rutger's University did
10 conduct a very good study of the communication
11 messages, they tracked the print media, the electronic
12 media and so on, and how it impacted -- you're nodding
13 your head so obviously you've seen it. That was a
14 very good study on that one particular case.

15 I can tell you that under the Food
16 Protection Plan, one of our goals is to improve the
17 communications and the consumer studies folks at FDA,
18 CFSAN, will be involved in some more studies trying to
19 work on this whole messaging issue. Part of the Food
20 Protection Plan that has come out last November now,
21 FDA is to improve this issue of communication. That's
22 one of the many steps that are in there. So we

1 recognize at least that our agency will improve that
2 and your question about science is well taken, and I
3 think we're going to try to do some of those kinds of
4 studies to understand this messaging and how do
5 consumers understand messages and all that kind of
6 stuff because we realize that we need to do a better
7 job.

8 MS. NICHOLSON: Hi. I'm Stephanie Nicholson
9 (ph.) from USDA, Food and Nutrition Service, and we
10 administer USDA's nutritional assistance programs, and
11 I have a quick comment and then a question.

12 My comment is included in our program is the
13 National School Lunch Program, and so I just wanted to
14 encourage everybody, when you have a product that
15 might be related to an outbreak and distributed
16 through schools, to think of us and call, even if it's
17 not a USDA purchased commodity. We'd love to hear
18 about it and we also have ways to get messages out to
19 school and state food directors. And so please think
20 of us.

21 And then my question is actually we've heard
22 this question from a food bank director who in

1 addition to the commodities that they receive from us,
2 they also purchase commodities, and he wanted to know
3 what information should he be collecting from his
4 suppliers in case those commercially purchased
5 commodities are recalled so that he can trace them
6 back and trace them forward.

7 DR. HAGEN: That's a good question. Scott,
8 do you want to speak to the kind of information that
9 would be helpful if a trace back needed to occur on
10 those kind of commodities?

11 MR. SEYS: Sure, sure. And we commonly do
12 look at recordkeeping when we are doing trace backs
13 and trying to follow up with recalls, but some of the
14 basic information I'm thinking about are establishment
15 names and numbers, any kind of dating that would help
16 narrow down the window such as production dates or
17 sell by dates. So pretty much any kind of
18 descriptions of that product as well. I think those
19 are some of the common data fields that they would
20 want to be capturing.

21 MS. NICHOLSON: He said that he didn't get
22 that information routinely on the invoices, that it

1 usually just said the product name and maybe some sort
2 of internal code. Is that sort of information usually
3 included in invoices or --

4 MR. SEYS: I would say typically not. You
5 know, it kind of varies depending on the investigation
6 of how much information is available on invoices and
7 in purchase orders but generally a lot of that
8 information has been missing when we've looked for it
9 unfortunately.

10 DR. BUGDEN: Second Harvest which is the
11 network that controls the food banks throughout the
12 country has a guide that has information in it on what
13 they're supposed to look for. When I was at Ocean
14 Spray, we actually participated in the inspection
15 program of food banks around the country, and we did
16 training. So every food bank has a partner industry
17 person who can guide them as well, and if the
18 information is not on the invoice, then the receiver
19 at the food bank should actually write certain
20 information on the invoice so it's kept with the
21 records throughout the record keeping process.

22 MS. NICHOLSON: Oh, great. Thank you.

1 MS. HARRISON: Also, Stephanie, I would
2 suggest that anyone who's purchasing should make what
3 they need part of their purchasing requirements that's
4 known, so the vendor knows up front what they're going
5 to be asked for.

6 I just have a comment. It doesn't require a
7 response. Again I'm Jean Harrison from Peer Foods,
8 and I'm speaking from the narrow perspective of school
9 lunch, both commercial and commodity, although it's
10 not necessarily a small program, serving about 30
11 million lunches a day and 10 million breakfasts a day.

12 As you make your list of things going
13 forward, the Westland/Hallmark, of course, was the
14 last to-do that we had, we learned a lot from that.
15 But I kept warning people, identifying, locating,
16 destroying the product was going to be easier
17 psychologically than what was going to be the second
18 surge which was going to be from schools, particularly
19 small schools, who have out-of-pocket costs for
20 identifying, locating, arranging to have the product
21 destroyed and having to serve something else on their
22 menu.

1 The whole reimbursement mechanism of who
2 pays for what particularly when it's a combination
3 product and the mechanism for funding. I won't go
4 into the details about what the regulations say, that
5 we've got trying to change that now. But for school
6 food service, and I think I can fairly speak for the
7 School Nutrition Association which has about 55,
8 60,000 members, and the American Commodity
9 Distribution Association, you need to address whose is
10 responsible for paying what within what timeframe and
11 also be very clear up front about who's asking for
12 what information and on what form and who gets the
13 information. It's been an incredible source of
14 frustration for schools, states and distributors.

15 So I just ask that, I know it's a dirty
16 word, money, but it impacts everyone involved in a
17 recall process. So I ask that you address that.

18 MS. KOWALCYK: Hi. My name is Barbara
19 Kowalcyk with CFI, and it's probably more of a comment
20 than a question but I think the recurring theme that
21 we've heard today is that there's not enough sharing
22 of information and/or data. And it's been

1 demonstrated not just within the federal agencies but
2 also coming back to the state and local health
3 departments and also to reiterate a comment that Donna
4 made earlier, to the consumers. Lots of times
5 consumers don't find out, don't get feedback.

6 So my question is, and I'm a
7 biostatistician, so I'm very interested in data, is I
8 think we need to better identify what the barriers are
9 to data sharing, and find out how we can improve that
10 among federal and state and local health departments.
11 That probably is a conference all in itself but if any
12 of you would care to comment, that would be great.
13 Thank you.

14 DR. JONES: Yeah, this obviously is a
15 question that comes up at every meeting where more
16 than one agency are represented, and usually we're
17 looking at each other and saying, why don't you give
18 us yours and why don't you give us yours first.

19 I guess the one comment I will make is that
20 Mike Taylor, University of Maryland --

21 MR. GUZEWICH: No, George Washington.

22 DR. JONES: -- George Washington, I believe

1 actually at the end of next week going to be making a
2 release of a white paper or a report, that he's been
3 working with multiple agencies and probably a lot of
4 the folks in this room, in large part focusing on
5 exactly that issue.

6 One of the first challenges which he
7 addressed quite nicely at least in a draft that I saw
8 was just cataloging what data are out there. You
9 know, there are lots of websites and databases which
10 theoretically we all have access to but we'd never
11 even know where to start looking. So to me, just
12 seeing what was out there was useful but I think that
13 that's been a formal process specifically looking at
14 ways to help with sharing, and I'm not sure what the
15 answers are but I know he's been working on it very
16 seriously with a lot of people.

17 DR. WILLIAMS: And I guess maybe from my
18 perspective, it's not just sharing, but it's being
19 able to look at the data and sharing good quality data
20 because really in this age of information overload,
21 you probably don't want all the data that I see
22 because there's a lot of it. Somebody has to filter

1 through the data and share the data, and that's really
2 the challenge, to wade through those mounds and mounds
3 and mounds of signals in order to find whats important
4 and not missing things.

5 So it's a very important point, but it's the
6 quality of the data and figuring out what is important
7 within those mounds and mounds of stuff. It's
8 something to keep in the back of your mind, too.

9 MR. TAYLOR: Hi. My name is Allen Taylor
10 (ph.). I'm from Maryland State Health, and first,
11 thank you for the invitation to come today. I've
12 enjoyed it, and I'd like to make a comment.

13 During the recall and subsequent destruction
14 of the ground beef, one of our local jurisdictions was
15 involved in documenting it and cataloging it,
16 inventorying it, but they were told that because of
17 the quantity that they had found, they couldn't
18 witness it, that the state health department had to do
19 it. And that was very counterproductive to whole
20 process we were trying to get through. So I would
21 just like to offer that the local health departments
22 have registered sanitarians who are perfectly capable

1 of counting boxes and packages, and I would suggest
2 that you reconsider that requirement in the future,
3 hopefully never again, but in the future.

4 The other thing, you know, we're talking
5 about labeling and identifying, and I don't know if
6 any of you have worked with or seen the micro labels
7 now that are available, that are completely food
8 grade. They're on the grass list. You can put an
9 incredible amount of information on it, that you can
10 read through I think 20 loop eyepiece, and it can be
11 rinsed on and washing and everything else, and I don't
12 know if you're aware of them, but there was a
13 presentation done at one of the AFDO (ph.) affiliates
14 that was very helpful in talking about doing this, and
15 I would ask you to at least take a look at those
16 because they have a tremendous possibility.

17 And my final comment which has nothing to do
18 with communication or anything but will ultimately
19 have a tremendous amount of influence on what we're
20 doing now is, and this is open to any of the speakers.
21 Have any of you thought about your succession plan for
22 what happens when this brain crust here leaves? And I

1 don't mean that sarcastically. I mean I heard Ellen
2 say, well, I won't be here in 10 years for the next
3 one. But, you know, if you look around there's a lot
4 of us that aren't going to be here in 10 years, and
5 when I look at my office, 43 percent can retire today
6 and 55 percent within the next 5 years, and that's
7 where all our senior skills are. So have any of the
8 agencies started a succession plan where they're
9 passing on, you know, Jack's knowledge or Scott's or
10 Ellen's or anybody's and not just at the last minute.
11 Well, I'm out the door tomorrow. Here, it's your job,
12 read the manual, I mean a concerted effort, and if you
13 are, how are you doing it. We're going through
14 something right now that seems to be helping, but I'd
15 love to hear some other ideas, and I'll be quiet.
16 Thank you.

17 MR. GUZEWICH: I can maybe address the last
18 of Allen's questions. A succession plan is very much
19 in the minds of the leadership at FDA. Now I can't
20 speak for FSIS or CDC, but we recognize these
21 demographics very much, and at the Center for Food
22 Safety and Applied Nutrition where I work, we have a

1 group called the Leadership Development Board which I
2 happen to be on right now, and the purpose of that
3 board is to identify potential, future leaders in
4 CFSAN and put them through a designated training
5 program to make them a pool of potential candidates
6 for future jobs as people like myself leave. So we're
7 very aware of the demographics. We're very aware of
8 the fact that the brain crust is leaving or whatever
9 kind of phrase you want to use. But we recognize the
10 responsibility of preparing for that and preparing
11 CFSAN.

12 Also recently the Commissioner has obtained
13 approval to expedited hiring process or whatever the
14 devil they call this thing, direct hiring process for
15 the FDA which has enabled us to have an expedited
16 process for hiring new people, and as other people
17 come on board, we're getting some very talented
18 people. It is gratifying to see the caliber of people
19 who are applying for jobs at FDA, and I hope that says
20 good things for the future for our organization.

21 MS. HAINSTOCK: Part of the problem is that
22 they don't pay two people to hold the same job -- pay

1 someone -- but I think that's a real challenge -- to
2 the next generation that comes -- particularly the
3 first year -- what a terrible job we're doing, and
4 then work with the CDC -- how to do a better job --
5 but I think that's a real problem for the federal
6 agencies and the other agencies --

7 UNIDENTIFIED SPEAKER: I just wanted to make
8 quick comment on this. A couple of years ago, our
9 state sponsored a leadership academy and I was very
10 grateful to be able to attend that, and we were
11 actually tasked with a project, and that was looking
12 at what was available out there for knowledge capture
13 and succession planning. And so I was part of a team
14 that actually went out and looked at various programs
15 that was identified across the country and obviously
16 we need something that was cheap, you know, we're
17 state government people. We don't have a huge budget
18 for, you know, hiring some third party consultant and
19 we actually looked at the Tennessee Valley Authority's
20 program which they have developed themselves in
21 knowledge capture and succession planning, and we've
22 actually begun implementing it within the Michigan

1 Department of Agriculture. We started in our own food
2 and dairy division, and then just recently I was
3 tasked with doing that for the department, and we're
4 actually seeing some success, even what we're trying
5 to do is at this point, just identify where are we
6 vulnerable, and that's not just, you know, food
7 people. That is, you know, all of the different
8 people who are like myself, are job specialists, we're
9 the only ones doing it and just because I'm not coming
10 up on retirement, doesn't mean I can't take a job with
11 FDA or anything else. So we're trying to build in
12 some redundancy and so, you know, if you're interested
13 in looking at that, I found the people at Tennessee
14 Valley Authority to be very helpful and give us a lot
15 of good advice. We've tweaked the system. It didn't
16 cost us anything. They're very gratified that we're
17 interested and they're sharing it.

18 UNIDENTIFIED SPEAKER: Is it a software
19 system?

20 UNIDENTIFIED SPEAKER: Well, it is kind of a
21 software system but not really. It just sets out, it
22 gives you some very, very basic tools on how to

1 identify your vulnerability, you know, how to go about
2 trying to gather one of those real nuggets that we
3 have within this person or this position, that we
4 absolutely do not want to let go of, and it's very
5 simple. It's certainly not elaborate like a lot of
6 these third party consultants, but it gives you a good
7 starting point, and they actually have no problems if
8 you want to take their program and make changes. They
9 just said let us know what you're doing to improve it.
10 We're grateful that you're even interested. So if you
11 are, I would suggest maybe getting on the Internet and
12 taking a look at that.

13 DR. HAGEN: Next question.

14 MS. BUCK: Hello. My name is Pat Buck, and
15 I'm with the Center for Foodborne Illness, Research
16 and Prevention. And first of all, I want to thank
17 everybody for including me at the meeting. I have
18 found it likewise very informative.

19 I think it's obvious from this meeting that
20 everyone agrees that there are improvements in
21 outbreak investigations but there's also a lot of
22 challenges out there. So my question is more to

1 Dr. Williams and to the rest.

2 In your presentation, you mentioned that all
3 of us need to consider making technological,
4 behavioral and regulatory changes to improve foodborne
5 investigations. Now I read FSIS' publications a lot
6 and they have a plan and I've recently read FDA's
7 plan. Does the CDC have any plan that would help us
8 to coordinate and bring the sciences together so that
9 we can really, you know, move forward.

10 DR. WILLIAMS: Dr. Warnock, do you want to
11 or do you want me to? He's the boss.

12 DR. WARNOCK: Thank you.

13 DR. WILLIAMS: You're welcome.

14 DR. WARNOCK: Let me start by saying we are
15 way forward of where we were a decade ago. We've
16 built systems that some people said would never work,
17 but today do work that are state of the art, and yet
18 there are areas in which there are deficiencies and
19 clearly the subject of this meeting outbreak
20 investigations today. That has pointed out a lot of
21 areas where we still need to make improvements, and
22 we're not going to be able to make improvements

1 without close coordination and cooperation through
2 many, many different groups, local, state and federal
3 level, and we've heard this afternoon about CIFOR
4 which is a tremendous effort to systematize a lot of
5 information, bring together, really involve the key
6 workers at the local and state level.

7 And our hope, our vision is that we can move
8 forward and with cooperation with these many and
9 varied groups, that we can turn outbreak investigation
10 into something in a decade's time that is very much
11 more state of the art than it is today. But in order
12 to do that, we have to have consensus. We have to
13 have leadership and we have to have investment. I
14 think there are many people, federal, state and local
15 level, with a common vision of what needs to be done,
16 and we've heard much of that alluded to today. I
17 think, you know, with good will and a lot of hard
18 work, we can make it happen.

19 MS. BUCK: Thank you. I just want to make
20 sure that as we're doing this, we're looking at all
21 three areas, technology, we're looking at the behavior
22 of the consumer and what's important there, and that,

1 of course, we are looking at the regulatory and what
2 needs to happen at the regulatory level to make
3 improvement come about. Thank you.

4 MR. BERGMIRE-SWEAT: This is David Bergmire-
5 Sweat. I'm going to take off my ASTHO hat and put on
6 my State of North Carolina Division of Public Health
7 hat, and this isn't a question. It's just to get it
8 on the public record since they are transcribing it.

9 One of the most frustrating things as an
10 epidemiologist trying to make a handoff to the
11 regulatory agencies is we can go in after the fact we
12 recognize an outbreak. We investigate the outbreak.
13 We do the case control study. We do great
14 epidemiology on it, and we implicate a product, but,
15 of course, this is a real example. Last year I had an
16 *E. coli* O157:H7 outbreak. It was London broil which
17 is a regulated product in commerce. It was served by
18 a catering company and so it wasn't like you could go
19 to the cooler and pull it out because they just order
20 what they need for the event, it's consumed, it's gone
21 and, you know, an *E. coli* pathogen with a 2 to 10 day
22 incubation period. They probably had 40 catered

1 events in between when the meal occurred, where the
2 outbreak was and when I went to try to talk to them
3 about the menu for that particular event and, yeah, we
4 were able to implicate the product. We had -- 96
5 percent of the cases were explained. We knew exactly
6 most likely how these people got sick, and the
7 environmental investigation showed that it probably
8 was undercooked, you know, because London broil is
9 typically served a little bit pink, a little bit rare,
10 and we realized that they probably didn't cook it hot
11 enough to kill the pathogens.

12 But we also knew, even though it was
13 probably undercooked, there shouldn't have been
14 O157:H7 in that London broil. And so when we wanted
15 to try to figure out where did it come from, the trash
16 is gone, the boxes are gone, the labels are gone, and
17 all we could come up with were the invoices, but
18 there's nothing on the invoice that gives you a clue
19 as to who the producer was. We could tell who the
20 distributor was but when I tried to hand that over to
21 my state level regulatory agency, they looked at the
22 invoice and said, David, there is nothing here that

1 anybody can take action on. So that meant that some
2 producer had London broil in commerce in the United
3 States to some number of people but I couldn't even
4 tell Scott about it because I didn't have anything to
5 tell him. And so my request -- everything in the
6 world these days is RIFD tagged. There is no reason
7 why the producer codes that are on that carton can't
8 be on the invoice because seven weeks from now, the
9 invoice is all that's going to exist.

10 DR. HAGEN: I would say to you that FSIS has
11 a very similar concern and has developed over the last
12 six months to a year quite a focus on the need for
13 improved recordkeeping. It started with the issue of
14 grinding logs and became evident that it was things
15 like this, too, you know, things that are in commerce
16 at all levels. So we're working very hard on this
17 right now in partnering with the affected industry,
18 particularly at the retail level, to try to come up
19 with some best practices and to clarify what our
20 expectations are because we share that same
21 frustration. Scott has led numerous investigations in
22 which we felt we were stopped in our tracks as well

1 because we simply couldn't identify the product
2 definitively.

3 DR. WILLIAMS: To make one other comment
4 though, but this is some of the beauty in the power of
5 PulseNet is we may not figure out this one, but if
6 there's another matching pattern, we can link stuff
7 together quickly, try to get there quickly, find the
8 information to get the product off the market, and
9 again this is part of this epidemiologic process you
10 may not get the first time but we can work harder on
11 the next one. It's important information for doing
12 future prevention activities.

13 MR. GUZEWICH: Yeah, trace back has come up
14 several times today. It's a real problem for FDA.
15 We've talked about that several times. We've got to
16 go back to our Food Protection Plan. Trace back is
17 one of the things we're trying to address in our Food
18 Protection Plan. Yes, Bonnie, it is. And Dr. David
19 Acheson, who is our Assistant Commissioner for Food
20 Protection, has taken a personal interest in this
21 issue of trace back, and he's been meeting with a
22 number of industry organizations and manufacturers of

1 new technologies and innovative things. We're
2 reaching out to consumer groups, to industry groups,
3 to regulatory groups, and he hopes for us to have some
4 kind of a plan or a guidance document out of this
5 process to help address this issue, trace back at
6 least the products that we regulate because it drives
7 us crazy within the Agency and I know it drives
8 everybody else crazy outside the Agency, too.

9 So we recognize the problem and he, at that
10 level, has taken a personal involvement in all of
11 these meetings because he wants to get this thing
12 addressed.

13 DR. HAGEN: My comment is if the beef
14 industry, the poultry industry, the seafood industry
15 and the juice industry are regulated by HACCP, then
16 why don't those documents exist because a good HACCP
17 plan would have recordkeeping. That would solve that
18 problem.

19 MR. BERGMIRE-SWEAT: Well, in the instance
20 that I was just describing, I mean we could name the
21 distributor. It would be bought from the distributor.
22 The distributor has a whole bunch of suppliers and in

1 order to do the trace back, it wasn't important to
2 implicate CISCO. It was important to figure out who
3 produced the London broil.

4 DR. HAGEN: But that should be part of the
5 HACCP program.

6 UNIDENTIFIED SPEAKER: We found that when
7 the Westland/Hallmark was expanded to commercial. We
8 went to our distributors and we went to also all of
9 our commercial beef suppliers and asked them for a
10 statement of the negative that they never received
11 anything from Hallmark/Westland because we require on
12 our purchase documents from whomever we buy from, that
13 they have traceability. So we wanted to know. I know
14 we bought from you, but did you buy a scrap from
15 Hallmark/Westland. And so we literally got from every
16 single solitary -- because our system requires us to
17 do that. And so we could trace back every single,
18 solitary thing, and I would think their production
19 records, and we went to the distributors as well.

20 So I'm speaking just about in terms of -- I
21 knew that we were able to do it with our suppliers.

22 DR. HAGEN: I'm going to go ahead and move

1 on. We have two more questions. I believe we have
2 time for two more.

3 MS. GRUTTERS: Hi. I'm Susan Grutters (ph.)
4 and I'm here today on behalf of STOP, Safe Tables Our
5 Priority. And my question I guess stems from where we
6 were a few years ago, and kind of where we are now. A
7 few years ago, there was a lot of talk about a single
8 food safety agency, and as we talk about improving
9 collaboration and improving communication, is it time
10 again to maybe think about another single food safety
11 agency and not only at the federal level but also
12 among state health departments? Is it time to maybe
13 reconsider our whole sort of construct and maybe
14 revisit the idea of a single food safety agency?

15 DR. HAGEN: Does anybody want to answer that
16 from FSIS or FDA?

17 MR. GUZEWICH: The single food agency, I
18 won't address but I do want to make a comment about
19 the relationship with the states. I think we'd have
20 to change our Constitution. We have the Constitution
21 of the United States that it's called a federalist
22 form of government and the power resides in the

1 states, and I would literally have to change the
2 Constitution before we could federalize or nationalize
3 the food safety system as it applies to the states and
4 locals.

5 As far as what's going to happen at the
6 federal level, I won't go anywhere near that one but
7 nationalizing the food safety system, that would
8 involve changing the Constitution.

9 DR. HAGEN: Thank you for the question and
10 the comment.

11 MR. BERNARD: Dane Bernard from Keystone,
12 and this is not a question, just a comment, a
13 clarification if you will on the extent of HACCP. And
14 it's not a defense in the current food distribution
15 chain at all but just a statement as to the reality of
16 the situation.

17 We as a manufacturer know where everything
18 we produce went. We can tell you that. But once it
19 gets into the distribution system, that's kind of the
20 extent of it. The distributor problem that was
21 discussed, unless a distributor actually repackages,
22 opens, repackages, they're not covered under mandatory

1 HACCP. They don't have to do that. So there's a gap
2 there.

3 Also people over order, under order, there
4 are all kinds of secondary shipments, product just
5 goes in a lot of different directions. So it
6 complicates that trace back. So this is not a defense
7 to that system. It's just a statement to say that
8 it's not as easy as it may sound because the
9 distributor that may have provided the London broil
10 may get from two or three processors for a single
11 shipment, and it may be two or three processors the
12 next week that he ships to the same client. That's
13 just the reality of the marketplace.

14 DR. HAGEN: Thanks, Dane.

15 DR. HOUSTON: Two quick comments. Outbreaks
16 are highly visible. They get a lot of media attention
17 and they service as a vicarious rehearsal for all of
18 the companies and industries that are not involved.
19 The importance is that that vicarious rehearsal
20 provides a window of opportunity. We often call it
21 teachable moment.

22 And I want to reiterate a point that was

1 made earlier. I think the lessons learned, I believe
2 one of the operational lingo at the moment is after
3 action reports, are extremely useful and the
4 opportunity to turn those into a just in time training
5 opportunity, going out to the regulated industries,
6 going out to the partners and collaborators and the
7 other agencies. We've got the technology to do
8 webcasts across the nation, and one of my colleagues
9 here does programs. They develop a program. They
10 offer at 9:00 in the morning at 6:00 in the afternoon
11 to their employees around the world in one day, using
12 a webcast and a conference call. I think that there's
13 some simple technologies where we can capture some of
14 these lessons, and really work towards our ultimate
15 goal which is prevention. Most of my career has been
16 prevention, and the sad part about prevention is if
17 we're successful, we're criticized for wasting the
18 Government's and public's money on something that
19 never happened. If we're unsuccessful, we're
20 criticized for not being more aggressive.

21 The second point then is because of the
22 visibility and attention and energy that you see in

1 the room about outbreaks, these are also one of the,
2 if you will, sexiest parts of teaching about the food
3 system. So we have a large number of students in
4 Schools of Public Health and in food science
5 departments and colleges of veterinary medicine, that
6 are really energized, intrigued and interested in
7 working on and learning about being involved in
8 outbreak investigation.

9 You talk about capacity building and
10 succession planning, and I think the examples, David
11 talked about, Dave talked about in terms of this Team
12 Diarrhea, you know, catchy title, the students are
13 standing in line to get involved in that, and those
14 individuals through their involvement in outbreak
15 investigation and through their one-on-one
16 interactions with individuals that have been involved
17 in the outbreaks, they learn compassion, they learn
18 epidemiologic techniques, they learn outbreak response
19 capacity, and they become, if you will, the foundation
20 of our next generation.

21 So I really think there's some wonderful
22 opportunities for FDA and for USDA and for CDC working

1 through cooperative agreements to develop programs
2 with the universities, with the Schools of Public
3 Health, colleges of veterinary medicine, to utilize
4 the surge capacity there. Through these students,
5 graduate students, MPH students, that would be very
6 interested and willing to generate time that have the
7 energy to stay up 24 hours for 3 days in a row and
8 still be remarkably sane, and to incorporate that and
9 I just throw that out as an opportunity for the group.

10 DR. HAGEN: Thanks, Will.

11 DR. HOUSTON: For the record, my name is
12 Will Houston, University of Minnesota.

13 MR. GUZEWICH: Thank you, Dr. Houston.

14 One comment on that that gets back to the
15 comment the lady from Vermont had earlier about
16 feedback to the epidemiologists after an outbreak
17 investigation. We've historically done a bad job at
18 that. We don't give you good feedback. Guilty as
19 charged. And we say with the best of intentions that
20 we're going to do better and somehow we haven't
21 delivered on it very much in the past, but it has come
22 again in our conversations with the CIFOR process,

1 this idea that there's got to be some kind of an after
2 action, one month, three months, six months down the
3 road. And by the way, sometimes the regulatory thing,
4 it goes on many months down the road. So we couldn't
5 tell you much in one month anyway because the
6 investigation is still ongoing. But the idea of
7 giving feedback is legitimate and I hope that our
8 CIFOR group can come up with a mechanism to make it
9 more effective because we intend to do it. The
10 problem is we're onto the next emergency and the next
11 emergency and the next emergency and the next
12 emergency, and we never seem to find the time to close
13 the loop on the one that was some months ago but
14 recognize we need to that. I hope we'll do better in
15 the future.

16 DR. HAGEN: Thanks, Jack. Okay. I think
17 that brings us to the end of our question and answer
18 period. We have a second for David or for I to kind
19 of wrap things up. In the interest of time, I'm going
20 to just make a couple of observations or try to pull
21 this together and talk about where we think we might
22 go from here but I want to leave time for our Deputy

1 Under Secretary, Scott Hurd, to provide us some
2 reflections on what he heard today.

3 So I've been sitting and taking notes all
4 day long in addition to trying to keep us on schedule,
5 just all the things that I've been hearing, and I have
6 to say that I'm actually very encouraged by everything
7 I heard today, warts and all, all of it, because I
8 think for me, just the simple fact that we're all
9 sitting in this room and we're having an honest
10 discourse and meeting people and hearing viewpoints
11 that we might not have heard before, is very
12 encouraging.

13 I think when David and I have been talking
14 about the planning of this meeting with the Steering
15 Committee and with our Under Secretary, about, you
16 know, what do we really think we want to have happen
17 this day, we've said repeatedly that we hope people
18 have these moments of discovery where kind of a light
19 goes on or someone says, oh, I didn't know that that
20 was why that took so long to get that done or I didn't
21 know what that really meant for industry to undergo
22 that process and recall, and I think based on the

1 comments I'm hearing in the hallway, I think we've
2 been successful at that, at producing some of these
3 kind of light bulb moments today.

4 There's no question that we have a lot of
5 work to do, but there's obviously an abundance of
6 enthusiasm and commitment to helping us move forward
7 in this room.

8 So I think where we go from here is really
9 not up to FSIS, CDC, and FDA who cosponsored this
10 meeting. It's really up to all of you but I can share
11 with you briefly just I think what FSIS' vision about
12 our next steps might be.

13 The very next step, because we're extremely
14 resource oriented, is tomorrow, we are going to engage
15 in an interactive exercise with a subgroup of the
16 people in this room today, and this is really just a
17 different approach to getting at the same issues and
18 really continuing the dialogue, doing it in a more
19 interactive way, a mock exercise, a mock outbreak in
20 which we'll get to see how other stakeholders deal
21 with these things as we move through events. What are
22 the obstacles that people face and perhaps watching

1 and hearing about how they deal with things as they
2 come up, with the focus on the communication and the
3 coordination aspect. So we'll be doing that tomorrow,
4 and we will be having an after action event at the end
5 of it, and then we will have a report that we will
6 certainly share back with all of the people who have
7 participated.

8 But I guess the question we're all having is
9 then what happens after we leave? And I think I would
10 challenge each and every one of you in this room to
11 just think about what you've heard today and just take
12 the simple step to think about one thing that you
13 could do, one thing that you or your association, your
14 professional organization could do. Did you hear
15 something today from another stakeholder that impacts
16 you? Did you hear something repeatedly where people
17 said I wish that at the federal level this would
18 happen, or I wish at the state level this would
19 happen? Is that what they were talking about? Is
20 there something that you can do, and think about how
21 you're going to share what you heard here with your
22 colleagues back in your states and your localities and

1 in federal organizations and think about what
2 mechanisms you might already have in place to move
3 forward with perhaps that one solution, or if you have
4 something that's already working, can you share that?
5 Can you share these programs that are working at state
6 and local levels or in consumer advocacy groups? Can
7 you somehow get that out and get other people to be
8 able to utilize it?

9 So, of course, we don't want to go back to
10 our silos and just work in these, you know, work on
11 solutions on our own. So we have to think about how
12 we can continue moving forward with this together. I
13 think one thing is just building simple relationships.
14 We heard a lot of people say today, I don't even know
15 who to call in my own state, in my own locality. I
16 don't know who to call at the federal level. I think
17 building those relationships and finding out who is in
18 the food safety public health community, that you
19 should know, that you don't want to exchange business
20 cards with in the middle of a crisis. I think that's
21 really important.

22 I think that we should also be taking

1 advantage of some of the terrific efforts that are
2 already going on out there. FSIS has said since the
3 beginning of planning this meeting, we didn't want to
4 start from scratch. We wanted to acknowledge and take
5 advantage of wonderful efforts like CIFOR, like
6 OutbreakNet, FoodNet, Epi-Ready, these programs and
7 projects and efforts that are going on to already
8 address, you know, communication challenges and
9 coordination challenges. And so we certainly hope
10 that people who are involved in those programs and
11 have heard all the things that were said today and may
12 be present tomorrow, will take those things into
13 account as we move forward with the projects and
14 future proposals with these organizations.

15 So finally I guess we would all agree that
16 we need to check back with each other and see how
17 we're doing. So we're all going to go home and we're
18 all going to think about that one thing that we might
19 be able to do or those 10 things that we might be able
20 to do, but we need to be able to evaluate whether this
21 is getting any better.

22 I know one thing that David and I also said,

1 every time we talked about this meeting, was we really
2 didn't want to get together and have all this
3 enthusiasm bubble up and then we all go back and keep
4 doing things that we've always done things. So I
5 think we need to think about how we can check in on
6 each other and see how we're doing. There are a lot
7 of possibilities and we're open to all kinds of
8 suggestions. Some of the things I wrote down were
9 increased use of after action activities and reports
10 and perhaps making them more inclusive. Perhaps
11 bringing in other stakeholders in an investigation
12 that you might not normally into an after action
13 activity and sharing the report. You know, perhaps we
14 want to have dedicated workgroups going forward, you
15 know, you're meeting some colleagues here, you're
16 making associations you haven't made before, and
17 perhaps we want to have some ongoing workgroups that
18 will tackle some of these issues. Maybe we want to
19 have a follow up meeting or a follow up exercise in
20 the year. There's a lot of possibilities and I know
21 FSIS, CDC, FDA and really all the participants in the
22 Steering Group are committed to whatever we need to do

1 to start making a dent in this.

2 So I'm going to leave it at that, and
3 introduce our Deputy Under Secretary who is going to
4 close the day. If Dr. Hurd wants to start making his
5 way up here.

6 Dr. Scott Hurd is our Deputy Under Secretary
7 for Food Safety at the U.S. Department of Agriculture.
8 He comes to FSIS from Iowa State University where he
9 has served as an epidemiologist in the College of
10 Veterinary Medicine for the past three years. At Iowa
11 State University, Dr. Hurd has lead important research
12 of epidemiology and food risks affecting human health.
13 Dr. Hurd specializes in *Salmonella*, *Campylobacter* and
14 antibiotic resistance risk assessments, and he was
15 selected in 2007 as the U.S. Delegate to the Codex
16 Alimentarius Intergovernmental Task Force on
17 antimicrobial resistance.

18 Prior to becoming an Associate Professor at
19 Iowa State University, Dr. Hurd served in the USDA's
20 Agriculture Research Service and the Animal and Plant
21 Health Inspection Service from 1989 to 2004. At ARS,
22 Dr. Hurd managed research programs and laboratory

1 initiatives focusing on *Salmonella* in turkeys and
2 swine. At APHIS, Dr. Hurd provided expert assistance
3 to the USDA Chief Veterinary Officer and other
4 officials to develop animal health programs to protect
5 against *Salmonella*, tuberculosis and avian influenza
6 infections. He led the design and analysis of the
7 APHIS National Health Monitoring System which today
8 still conducts national studies on the health and
9 health management of domestic livestock and poultry
10 populations.

11 Dr. Hurd is a native of Pensacola, Florida,
12 and received his Bachelor of Science and Biology from
13 the Virginia Polytechnic Institute, where he also
14 played football as a defensive tackle (laughter). We
15 didn't hear that about anybody else today.

16 DR. HURD: It was good preparation for this
17 job.

18 DR. HAGEN: He received his Doctor of
19 Veterinary Medicine Degree from Iowa State University
20 and completed his Ph.D. in Epidemiology from Michigan
21 State University. Dr. Scott Hurd.

22 (Applause.)

1 DR. HURD: Thank you. I whispered to them
2 that the football training was actually very good
3 experience for this job and actually earlier I was
4 thinking about an analogy that in a way, or not an
5 analog but an experience from football that relates to
6 what we're doing here. The fact that this group has
7 come together in a very cooperative sense, people who
8 are in other situations may be somewhat adversarial,
9 the industry groups and the consumer groups, but it's
10 similar maybe to when I was playing football and we
11 were practicing. We were practicing against our
12 friends, and I'll never forget a day when the coach
13 was on me big time and I just was angry, and I was
14 really rough on a good friend of mine, Charlie Wilson,
15 on the field. And afterwards, you know, I kind of
16 apologized and it was no big deal. It was no big deal
17 to him because it was for the team. He was willing to
18 be, you know, roughed up, and I think we're really
19 exhibiting that here in this meeting, and it's very
20 remarkable. I know Dr. Raymond would be thrilled and
21 he does apologize that he couldn't be here at this
22 meeting. He would be thrilled about the collection of

1 groups that are here, industry and consumer groups,
2 and states and CDC and FDA, working together on this
3 issue, and that's really one of the things that I
4 think we were really hoping for.

5 There's three principles that Dr. Raymond,
6 which one of these is the go button, would have shared
7 with you, and I'll use them as just to kind of
8 summarize what I observed today, and that's the
9 principles of communication, cooperation and
10 collaboration.

11 Clearly this is happening today and an
12 example of communication, the issue of voluntary meat
13 recall versus mandatory recall. USDA says we don't
14 need mandatory recall. When we think about it, we
15 think about it from a legal standpoint. I never
16 thought it about the Caroline Smith DeWaal pointed it
17 out. Voluntary from the risk communications
18 standpoint, from the consumer, it's voluntary, we
19 don't have to worry about it. It's one word,
20 radically different perspective on how to view that
21 one word just because we communicated about it. So
22 that was interesting. Now we're going to have to

1 think real hard about it.

2 Communicating better is the key, not
3 necessary communicating more. I've heard a number of
4 people talk about information overload here. Now with
5 my wife, it's different. When she says we need to
6 communicate, she means more. Okay. More information.
7 More words. But for those of us who are overwhelmed,
8 that may not be true.

9 For example, the Epi-X system, I guess you
10 can get daily e-mails on all these different things
11 and there might be a notice on there, squirrel found
12 dead on road on Monday. On Tuesday, the e-mail comes
13 out, squirrel sent to laboratory. On Wednesday the e-
14 mail comes back tire tracks found on squirrel. So
15 that's a lot of information for something that, you
16 know, it shouldn't rise to the top of your radar
17 screen. So we actually need a way to communicate
18 better. What are the key pieces of information that
19 you need at different places in the process, whether
20 it's an outbreak, you know. So maybe when we think
21 about these outbreaks, think about, okay, if we're
22 here, then we need to communicate this information

1 with that group. If we move to level B, then we need
2 to communicate this information to a different group.
3 So maybe some way to prioritize the communication,
4 because we can get overwhelmed. So it would be
5 focused in purposeful communication is what I would
6 encourage.

7 Cooperation, that's clearly happening here.
8 Cooperation is a spirit that says when somebody calls,
9 if you're in the state office and Uncle Sam from the
10 fed calls, your first response is what can I do to
11 help, not your first response is, oh, gee, what are
12 those guys doing messing in my area? Okay. Or vice
13 versa. I believe in state's rights, and state's
14 rights makes a big difference when we're trying to
15 implement these things.

16 On the issue of a single food safety agency,
17 I have to comment on that one. That's part of my job.
18 USDA is not in favor of that, and I think this meeting
19 is a very good example. You could combine all the
20 heads in Washington, put a new name on it, call it the
21 Single Food Safety Agency, and we'd still be here.
22 Okay. It would just be now this branch has to

1 communicate better with that branch. Okay. You can
2 combine the heads but the feet and legs out in the
3 field across this enormous country are still there and
4 still have the same challenges.

5 So then on the issue of collaboration, I
6 think what the CIFOR group is doing is really great
7 and is a good example of the sort of things that we
8 need to do, putting the system together. One of the
9 things I noticed today that, to me could be addressed
10 under this collaboration heading, is the issue of
11 consistency. How do you define an outbreak? Is that
12 consistent across the country? How do you decide when
13 to respond? When you go out and pull stuff off
14 shelves or not. Maybe that should be consistent and
15 then maybe the CIFOR group is a way to bring that
16 together.

17 How do you communicate with, who and when?
18 Maybe we can develop some consistent guidelines. And
19 then maybe there could be a cookbook. We talked about
20 the institutional memory. If there's a cookbook, the
21 National Outbreak Investigation Guideline. So when
22 the new people come in, they can go to the cookbook

1 and find that wisdom on who's the person to contact
2 for different issues.

3 Backing up to the collaboration, I think I
4 missed this one, the communication, the issue of
5 feedback and closing the loop. That is a real need
6 and the Office of Public Health and Safety within FSIS
7 has committed to improving that area, for the
8 outbreaks, the recalls that we're involved in. We're
9 going to write those up and we're going to kick them
10 back to the industry these are our learnings from
11 those events. So that's something we're working on
12 and there's a real need there.

13 Lastly, let me talk briefly about the
14 future. Let's say we do everything right here on
15 these outbreaks and we get this system working really
16 well. There's a couple of thoughts to keep in mind
17 beyond that.

18 Number one with outbreaks. Now we're
19 backing up to the question of prevention. Somebody
20 raised that point, and I appreciate that. We need to
21 get beyond this outbreak. We need to stop it as fast
22 as we can and then talk about how to prevent the

1 problem. So in doing that, a couple of thoughts to
2 keep in mind, in my opinion. One is that the more
3 analysis the better. Just like with your GPS, you
4 have to have at least three satellites in order to
5 figure out where you are in the world. Okay. One
6 outbreak is not enough to set public policy. The more
7 the better and if those outbreaks continue to tell you
8 there's a problem, then maybe we can address how to
9 prevent it.

10 As you, outbreaks are like icebergs. We
11 talked all about that, and all the epidemiologists
12 know this but I just love the picture. So I had to
13 share that one, but the data we shared here today, CDC
14 sees 27,000 cases out of an estimated 76 million.
15 That's .035 percent. So we're seeing a tiny-weeny,
16 weeny, weeny top of the iceberg when we're seeing
17 outbreaks.

18 So when we start to think about how to make
19 policy, we need to remember that. You know the reason
20 a deer has a white tail, don't you? It's for the
21 predators. The predator focuses on the white tail and
22 misses the target, and we have to be careful that we

1 don't let outbreaks do that to us. Outbreaks are the
2 tip of the iceberg and may not be where the real
3 problem lies. So that's something to keep in mind.
4 And statistically speaking, another way to think about
5 icebergs and outbreaks is outbreaks are often bimodal.
6 This is the time to illness, number of cases, a lot of
7 epidemiologic phenomenon are like this. They're
8 bimodal. So which one of these modes of the outbreak
9 might you be looking at or modes of the epidemic?
10 Notice the similarity between icebergs and bimodal
11 disease outbreaks. So that's something to keep in
12 mind.

13 And there's a good story from that. I won't
14 name the mention of the country, but there was an
15 outbreak of *Salmonella*. There was a strike, all the
16 meat packers in this particular country went on
17 strike. So the little state mom and pop operations
18 were essentially feeding the country and doing the
19 inspection. And during the course of this strike,
20 there was a significant outbreak of *Salmonella* in the
21 capital city. So based on that outbreak, which was an
22 outlier which was the result of a strike and so forth,

1 an entire national *Salmonella* control program was
2 developed about 12, 15 years ago now. So the whole
3 country and the whole industry jumped on board, we're
4 going to stamp *Salmonella* out of the swine industry.
5 So after 10 years and many millions of dollars, that
6 country is saying, maybe we shouldn't have done that.
7 If you look at the publications coming out now and
8 looking at the resources they spent versus the impact
9 that they've gotten, it's possible that that outbreak
10 led to a national policy that wasn't as effective as
11 some other analysis might have led to.

12 So it does happen, and I think those are
13 just a couple little things to keep in mind.

14 Going forward, remind each other of what we
15 see, you know. I see this. Oh, yeah, you're right,
16 but that's just the tip of the iceberg. Okay.
17 Communicate. As we do that, look deeper. I think
18 you're doing that today. You'll do that tomorrow
19 during the tabletop exercise, and move nimbly. It's
20 tempting to say move cautiously but that's going to
21 make you go slowly. Move nimbly, but move quickly.

22 Lastly, I want to just say that I'm

1 encouraged as Dr. Hagen said, by what we see here,
2 what can be done, what I've seen over the years and
3 how the community has changed in response to these
4 things. So I'm encouraged and positive about what you
5 can do.

6 I do also want to thank the organizers,
7 Dr. Goldman, Dr. Hagen, and Bonnie Kissler. I was
8 going to say Kissling, and whoever else helped to
9 organize it, I want to thank them and have a good
10 night.

11 (Applause.)

12 DR. HAGEN: Thanks, Scott. All right. I
13 think we're done. Thank you all for sticking it out.
14 We're only five minutes past schedule.

15 For those of you participating tomorrow,
16 we're starting early, don't forget. We will be
17 starting by 7:30, or you will miss your planes home.
18 So we need to get there by 7:00 for registration, and
19 7:30 we will be starting. Okay. Thank you.

20 (Whereupon, at 5:10 p.m., the meeting was
21 concluded.)

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C E R T I F I C A T E

This is to certify that the attached
proceedings in the matter of:

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

BETTER COMMUNICATIONS,
BETTER PUBLIC HEALTH OUTCOMES -
STRATEGIES FOR IMPROVED COORDINATION
DURING FOODBORNE OUTBREAKS

St. Louis, Missouri

May 15, 2008

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.

Deborah Carter, Reporter

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