

**EXAMINATION OF FEDERAL FOOD SAFETY
OVERSIGHT IN THE WAKE OF
PEANUT PRODUCTS RECALL**

HEARING
BEFORE THE
**COMMITTEE ON AGRICULTURE,
NUTRITION, AND FORESTRY**
UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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CONTENTS

	Page
HEARING(S):	
Examination of Federal Food Safety Oversight in the Wake of Peanut Products Recall	1

Thursday, February 5, 2009

STATEMENTS PRESENTED BY SENATORS

Harkin, Hon. Tom, U.S. Senator from the State of Iowa, Chairman, Committee on Agriculture, Nutrition and Forestry	1
Chambliss, Hon. Saxby, U.S. Senator from the State of Georgia	2
Klobuchar, Hon. Amy, U.S. Senator from the State of Minnesota	15

Panel I

Khan, Ali S., Rear Admiral, M.D., Assistant Surgeon General and Deputy Director of the National Center for Zoonotic, Vector-Borne, and Enteric Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia	7
Sundlof, Stephen, M.D., Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, Rockville, Maryland; accompanied by Michael Chappell, Acting Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration	4

Panel II

Dewaal, Caroline Smith, Director, Program on Food Safety, Center for Science in the Public Interest, Washington, DC	28
Hubbard, William, Former Senior Associate Commissioner for Policy, Planning, and Legislation, U.S. Food and Drug Administration, Chapel Hill, North Carolina	30
Meunier, Gabrielle, Mother of Affected Child, South Burlington, Vermont	26

APPENDIX

PREPARED STATEMENTS:	
Dewaal, Caroline Smith	48
Hubbard, William	59
Khan, Ali S.	74
Meunier, Gabrielle	85
Sundlof, Stephen	88
DOCUMENT(S) SUBMITTED FOR THE RECORD:	
American Frozen Food Institute, prepared statement	100
Grocery Manufacturers Association, National Association of Manufacturers, National Confectioners Association, National Fisheries Institute, National Restaurant Association, Produce Marketing Association, Snack Food Association, prepared statement	104
QUESTION AND ANSWER:	
Harkin, Tom:	
Written questions for FDA	108
Casey, Robert P., Jr.:	
Written questions for Stephen Sundlof, Ali S. Khan, William Hubbard and Caroline Smith DeWaal	109

IV

	Page
Grassley, Charles E.:	
Written questions for Stephen Sundlof and William Hubbard	110
Stabenow, Debbie A.:	
Written questions for William Hubbard, Stephen Sundlof and Caroline Smith DeWaal	111
Dewaal, Caroline Smith:	
Written response to questions from Hon. Debbie Stabenow	113
Written response to questions from Hon. Robert P. Casey, Jr.	115
Hubbard, William:	
Written response to questions from Hon. Charles E. Grassley	117
Written response to questions from Hon. Debbie Stabenow	117
Written response to questions from Hon. Robert P. Casey, Jr.	120
Khan, Ali S.:	
Written response to questions from Hon. Robert P. Casey, Jr.	123
Food and Drug Administration:	
Written response to questions from Hon. Tom Harkin	126
Written response to questions from Hon. Charles E. Grassley	128
Written response to questions from Hon. Debbie Stabenow	129
Written response to questions from Hon. Robert P. Casey, Jr.	130

**EXAMINATION OF FEDERAL FOOD SAFETY
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Thursday, February 5, 2009

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC

The committee met, pursuant to notice, at 10:04 a.m., in room 216, Hart Senate Office Building, Hon. Tom Harkin, Chairman of the committee, presiding.

Present or submitting a statement: Senators Harkin, Leahy, Casey, Klobuchar, Chambliss, and Johanns.

**STATEMENT OF HON. TOM HARKIN, U.S. SENATOR FROM THE
STATE OF IOWA, CHAIRMAN, COMMITTEE ON AGRICULTURE,
NUTRITION AND FORESTRY**

Chairman HARKIN. The Senate Committee on Agriculture, Nutrition, and Forestry will come to order.

Good morning, and I welcome everyone to this hearing. I hope you will forgive me, but I will skip the niceties and get right to the point. I am nothing short of outraged at the increasing number of outbreaks of foodborne illnesses in our country. Everything from spinach and lettuce and peppers to beef products and now peanut products has been implicated. Within the last year, we had the biggest recall ever under USDA jurisdiction. In the last month, with the recall of peanut products from the Peanut Corporation of America, we have had one of the largest recalls ever under FDA jurisdiction.

To say that food safety in this country is a patchwork system is just giving it too much credit. Food safety in America has too often become a hit or miss gamble. That is truly frightening. When Americans can't count on the safety of basic items, like peanut butter that goes into our kids' sandwiches that they take to school—look at a jar of peanut butter. I mean, what could be more ubiquitous? I mean, everyone has this on their shelf. I do at home. I still have peanut butter and jelly sandwiches, and it is good for you. Peanuts are good for you. It is a healthy food. And when we can't even depend on that, that peanut butter that we put in our kids' sandwiches that they take to school, that that is not safe, then we have to ask, what is?

It has almost come back to the point where before we had truth in packaging, it was always buyer beware. We are almost to that

point now in food where it is eaten beware. Beware of what you eat. You are on your own.

The Centers for Disease Control and Prevention tells us there are 76 million cases of foodborne illness annually in the U.S., resulting in 325,000 hospitalizations and 5,000 deaths. That is not my figure, that is the Centers for Disease Control and Prevention. This is intolerable in the United States of America.

Now, reducing the instances of foodborne illness in this country means examining every step in the food safety process. Our systems for tracing tainted products and removing them from commerce must be stronger, better coordinated, faster, and more efficient. Regardless of the level of contamination, we need to be able to identify the source accurately and promptly and act quickly.

However, as in all of health care, prevention of the illness is the key. Prevention is much less costly than the treatment. So we must focus on getting the food safety done right in the first place, before the pathogens get into the food and they need to be recalled.

Bear in mind this is not only a health issue, it is also an economic issue. It is inevitable that demand for the food crop that is involved in the outbreak will fall sharply. During a recall, retailers lose business. Processors lose customers. And, as we all know and as I am sure our Ranking Member, Senator Chambliss, knows all too well, farmers suffer, as well. Entire communities can face economic devastation, as I think we will hear about this small community in Georgia.

We have got to come up with a better, smarter approach to food safety. We have got to make the investments both in better systems and in putting more inspectors on the ground. It is about the integrity of our food supply. It is about the health and wellness of our people and the protection and safety now of our children who eat peanut butter. Who would have thought, peanut butter?

So our goal this morning is to explore what went wrong. What do we need to do to get things right? This is under the jurisdiction of our committee and we intend to pursue it.

Now, we have a distinguished panel of witnesses. I look forward to your best counsel on how we can do a better job of preventing outbreaks. I am not an expert in this. I am not a veterinarian. I am not a doctor. I am not an epidemiologist. But something has got to be done and we need the best information possible on what to do, first on prevention, and second, when outbreaks happen, how can we do a better job of stopping them early before they spread.

So with that, I will now turn to my friend, my Ranking Member, Senator Chambliss.

STATEMENT OF HON. SAXBY CHAMBLISS, U.S. SENATOR FROM THE STATE OF GEORGIA

Senator CHAMBLISS. Thank you very much, Mr. Chairman. Last year, it was tomatoes. Today, it is peanuts. Next week, it may be some seafood. But you are exactly right. We have a system that is flawed and a system that in this particular instance has once again failed consumers across America.

I am pleased to see you with this jar of peanut butter here, because coming from a State that grows almost 50 percent of the peanuts that are grown in America, we want to make sure that every

consumer that walks into the store and buys a peanut product can have the comfort of knowing that product is safe, and frankly, it is not just with peanuts, but it is with every product on the shelf. We are seeing now that has been called into question.

It just so happens this jar of peanut butter is totally safe. Under the testimony that you will hear today, the issue of salmonella that has caused serious problems around the country came from one isolated facility and went into a number of products around the country. But a jar of peanut butter like this or Peter Pan or whatever it may be is totally safe.

Not only do we have a failure in the mechanisms of detecting foodborne illnesses, but we have a flawed system of educating the public about products, as well. So I am very pleased that in today's hearing, it is an important step to help members of this committee examine the various roles of Federal and State officials and the responsibilities of private food manufacturers in ensuring that our food supply is safe.

Clearly, there are lessons to be learned from this latest salmonella outbreak from a peanut processing plant in my State of Georgia. While I understand that today's government witnesses may be limited in some responses due to the ongoing criminal investigation, I do hope that we can identify how to better coordinate the Federal, State, local, and private sector response to a food safety situation. Our goal is to put in place the most effective tools to protect the American consumer and to put confidence in the marketplace where it is lacking today.

An effective public-private sector partnership is critical to ensuring a safe food supply. The private sector has the responsibility to follow Federal guidelines and ensure the safety of their products. The Federal and State governments have the responsibility to oversee these efforts and take corrective actions when necessary. We need to quickly identify gaps in the system and act swiftly to correct them.

The current salmonella outbreak could prove to be one of the largest in our history. The fact that a contaminated product was ultimately used as an ingredient in hundreds of other products has challenged our food safety system to a new degree.

I appreciate the FDA and CDC witnesses for sharing their knowledge and initial reactions to this situation with us today and I look forward to continued collaboration with their agencies as we move forward to develop and implement improvements to protect our food supply.

I want to extend a special thank you to Ms. Meunier for appearing before the committee today to share her family's personal experience. I read her testimony and I applaud her efforts to bring tangible recommendations to Congress. They are practical and they are common-sensical, things that simply make almost too much sense that the bureaucracy has a difficult time comprehending.

I look forward to working with the pertinent Federal and State agencies, private industry, the scientific community, and citizens as we strive to achieve the common goal of maintaining a safe, affordable, and nutritious food supply that all Americans can enjoy, and I thank you, Mr. Chairman, and look forward to the testimony today.

Chairman HARKIN. Thank you very much, Senator Chambliss.

I just want to, again, before we introduce our panel here, I just want again to reassure parents across the country that the peanut butter that they buy in these jars, whether it is Skippy, Jiffy, or what was that other one you said?

Senator CHAMBLISS. Peter Pan.

Chairman HARKIN. Peter Pan, of course, all those are safe. These are safe, and if anyone disagrees with me, say so, but I believe that is factual. You don't have to worry about it. I will even eat my own peanut butter sandwich while I listen to the witnesses just to show you that I don't have any fear of eating peanut butter.

[Laughter.]

Chairman HARKIN. Let me now turn to our first panel. We have Dr. Stephen Sundlof from the FDA Center for Food Safety and Applied Nutrition. He was appointed Director of this Center January 7 of 2008. He provides the executive leadership to the Center's development and implementation of programs and policies relative to the composition, quality, safety, and labeling of foods, food color and additives, dietary supplements, and cosmetics. In the 14 years preceding this, Dr. Sundlof served as Director of FDA's Center for Veterinary Medicine. Before that, he was a professor at the University of Florida College of Veterinary Medicine.

We have Rear Admiral Ali S. Khan, M.D., currently Assistant Surgeon General and Deputy Director of the National Center for Zoonotic, Vector-borne, and Enteric Diseases from the Centers for Disease Control and Prevention. He joined the CDC and the U.S. Public Health Service Commissioned Corps in 1991 and has been with them ever since.

And we have—I am sorry, you will have to introduce Mr. Chappell. I don't have a bio on Mr. Chappell.

First, I have all your testimonies. They will be made a part of the record in their entirety. I would ask if you would sum it up in about 5 minutes or so, maybe seven, but around that timeframe so we can get into a discussion with all of you, and I will start with Dr. Sundlof and then we will go to Rear Admiral Khan.

Dr. Sundlof, welcome and please proceed.

STATEMENT OF STEPHEN SUNDLOF, M.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MARYLAND; ACCOMPANIED BY MICHAEL CHAPPELL, ACTING ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMINISTRATION

Mr. SUNDLOF. Thank you, Mr. Chairman and Senator Chambliss. As you indicated, I am Dr. Stephen Sundlof, the Director of the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration, which is part of the Department of Health and Human Services, and I am accompanied today by Michael Chappell. Michael is FDA's Acting Associate Commissioner for Regulatory Affairs. FDA appreciates the opportunity to discuss the ongoing investigation of the foodborne outbreak associated with *Salmonella Typhimurium*, which has been found in peanut products produced by the Peanut Corporation of America, and I will refer to that as PCA from here on out.

In a typical traceback process employed by the FDA and our partners at the Centers for Disease Control and Prevention or CDC, they notify FDA when it identifies the possible foods associated with a foodborne illness outbreak through its epidemiological investigation, and it is at that point that the FDA starts its investigation to identify the source of contamination. In the current case, FDA started its tracing process before the CDC notified us of the strong epidemiological link, both to help inform the epidemiological study and to shorten the time period required to get the potentially contaminated food off of the market.

Since December of 2008, FDA has collaborated with CDC and the Food Safety Inspection Service of USDA and public health officials in various States to investigate a multi-State outbreak of human infections due to *Salmonella Typhimurium*. Peanut butter was first identified as one of several possible sources in mid-December.

On January 7 and 8, based on conversations with the CDC, Food Safety Inspection Service, and the Minnesota Department of Health about preliminary epidemiological data, FDA decided to begin to investigate institutional food service sources of peanut butter rather than to wait for more conclusive data. And on January 8, based on the preliminary information from CDC's multi-State case control study, FDA made its initial contact with the King Nut Company in Ohio. King Nut distributes peanut butter manufactured by PCA to institutional facilities, not supermarkets or retail, but to institutional facilities, food service industries, and private-label food companies in several States.

On January 9, FDA initiated an inspection of the PCA manufacturing plant in Blakely, Georgia. As part of its epidemiological investigation, the Minnesota Department of Health tested an open five-pound container of King Nut peanut butter obtained at a nursing home where three patients were sickened by the outbreak strain of *Salmonella Typhimurium*. And by January 10, Minnesota officials had found that the peanut butter contained the same strain of *Salmonella Typhimurium* associated with the illness linked to the outbreak. However, because it was an open container which could have been contaminated by someone or something else in the environment, these results did not conclusively confirm that the Blakely plant was the source.

So FDA expanded the testing of unopened containers of the same brand of peanut butter, and on January 19, testing by the State of Connecticut Health Department of an unopened container of King Nut peanut butter showed that it contained the same strain of *Salmonella Typhimurium* associated with the illnesses linked to the outbreak. The fact that *Salmonella Typhimurium* was confirmed in an unopened container of peanut butter indicated that the peanut butter was contaminated when it left the plant in Blakely, Georgia.

As I noted earlier, FDA had already initiated the inspection of PCA's Blakely plant on January 9. FDA completed its inspection on January 27 and FDA's environmental sampling of the plant found two salmonella strains, but neither of these were the outbreak strain. We are confident, however, that based on the investigations by the States, CDC, and the FDA, that the Blakely plant is the source of contamination related to the *Salmonella Typhimurium* outbreak. Further, FDA's review of the firm's testing records re-

vealed that there were instances in 2007 and 2008 where the firm distributed product in commerce which had tested positive for salmonella.

The first recalls began on January 10 by the King Nut Company and on January 13 by PCA. PCA's most recent recall began on January 28, 2009, when the firm issued an expanded voluntary recall of all peanut products processed in its Blakely facilities since January 1 of 2007, including the following products: Dry and oil-roasted peanuts, granulated peanuts, peanut meal, peanut butter, and peanut paste. Many companies that received peanuts and peanut products manufactured by the PCA's Blakely facility have, in turn, conducted voluntary recalls.

FDA is continuing to work with the purchasers of PCA's peanut and peanut products to identify affected products and facilitate their removal from the market. FDA initiated inspections of the direct consignees of PCA and King Nut and continues to follow the distribution points for products. FDA and State officials have contacted hundreds of firms throughout the entire distribution chain that may have purchased or further distributed PCA products.

We would like to emphasize that the major national brands of peanut butter in jars found in grocery stores are not affected by the recall, as Senator Chambliss has already pointed out. Further, FDA has no evidence suggesting that the contamination originated in any manufacturing facility other than the PCA Blakely plant. That facility is no longer operating at this time.

FDA has established a webpage to provide constantly updated information on the contamination and recall. It includes a searchable data base to assist consumers in quickly identifying recalled products. FDA encourages consumers to check this website to determine which products have been recalled and continue to check that as new recalls appear.

In closing, let me assure you that the FDA is working hard to ensure the safety of the food supply in collaboration with its Federal, State, local, and international food safety partners and with industry, consumers, and academia. In the current outbreak, FDA acted expeditiously to determine the source of the contamination and to identify affected products to facilitate the removal from the marketplace.

Although the *Salmonella Typhimurium* foodborne illness outbreak underscores the challenges that we face, the American food supply continues to be among the safest in the world. Food safety is a priority for the new administration.

Please be aware that FDA is actively conducting both criminal and regulatory investigations related to this matter. To protect the integrity of these ongoing investigations and any related actions that might be pursued in the future, FDA must necessarily keep certain information confidential. Further, it is premature for FDA to draw conclusions about its preliminary observations or how FDA's legal authorities might apply to those observations. But that said, we will do our best to respond to any questions that you may have.

Thank you again for the opportunity to discuss these important public health matters.

[The prepared statement of Dr. Sundlof can be found on page 88 in the appendix.]

Chairman HARKIN. Thank you very much, Dr. Sundlof.

Now we will turn to Admiral Khan. Admiral Khan, welcome to the committee and please proceed.

STATEMENT OF REAR ADMIRAL ALI S. KHAN, M.D., ASSISTANT SURGEON GENERAL AND DEPUTY DIRECTOR OF THE NATIONAL CENTER FOR ZOO NOTIC, VECTOR-BORNE, AND ENTERIC DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GEORGIA

Admiral KHAN. Good morning, Chairman Harkin, and thank you for the invitation to address the committee today. I am Ali Khan, an Assistant Surgeon General and Deputy Director of the National Center for Zoonotic, Vector-borne, and Enteric Diseases at CDC.

As the nation's prevention agency, CDC leads the Federal efforts to gather data on and investigate foodborne illnesses and outbreaks and to monitor the effectiveness of prevention and control efforts. CDC depends on our critical partnership with State and local public health departments and our very close collaborative relationship with FDA and USDA to get this work done.

Salmonella is a group of bacteria that is widespread in the intestines of reptiles, birds, and mammals, and it is the most common cause of bacterial foodborne disease in the United States. The current outbreak is caused by the most common type of salmonella, *Salmonella Typhimurium*, which causes about 15 to 20 outbreaks each year.

On November 10 of 2008, CDC began to monitor a small, highly dispersed, multi-State cluster of 13 cases of *Salmonella Typhimurium* with an unusual laboratory pulse fingerprint, something that we call the PFGE fingerprint, and those 13 isolates were reported by 12 States to PulseNet, and PulseNet is our national network of public health and food regulatory agencies that is used to detect foodborne disease outbreaks.

On November 25, the cluster had increased to 35 isolates reported from 16 States and was subject to increasing investigation. Beginning in early December, this cluster was combined with another laboratory cluster of 27 cases in 17 States that was shown also to be the same salmonella using better laboratory tools. These combined clusters were then joined for an intense investigation and communication during December into early January that usually starts with numerous interviews to suggest the likely food item or common exposures followed by these detailed epidemiological studies of these food items.

The early epidemiologic evidence suggested an association with peanut butter served in institutions as a possible explanation for at least a part of the outbreak. Salmonella was isolated from an open container of King Nut peanut butter in Minnesota, and the outbreak strain of *Salmonella Typhimurium* was isolated from a previously, as you heard, unopened five-pound container of King Nut creamy peanut butter in Connecticut.

However, ongoing interviews indicated that many cases actually did not eat peanut butter in an institution but had eaten various other peanut-containing products. To better determine the associa-

tion of illness with other peanut butter-containing products, a second large study was conducted by CDC in collaboration again with its partners between January 17 and 19 to assess these exposures in these non-institutional settings, and preliminary analysis suggested looking at people who were ill compared to people who weren't ill showed that they had actually eaten specific brands of prepackaged peanut butter crackers, and these both brands of peanut butter crackers were made at one plant which is known to receive peanuts from PCA.

As of yesterday, we have had 575 persons from 43 States and one person from Canada who have been infected with this outbreak strain. We have had reported onset of illness starting from September 1 of last year until January 22 of this year. A total of 127 people have required hospitalization, and the infection may have tragically contributed to the death of eight persons.

The epidemiologic, laboratory, and traceback findings from this continuing investigation indicate that peanut butter and peanut paste produced at PCA are the source of this outbreak. More specifically, the outbreak was caused by contaminated peanut butter used in institutions and by peanut butter and peanut paste used as ingredients in food products. So we call this an ingredient-driven outbreak in which a contaminated ingredient can affect many different products that are distributed through various channels and consumed in various settings.

The outbreak appears to be slowing, but we will not be able to know that for sure at this point. Because of the natural time lapse in reporting, it will be two to 3 weeks after it ends before we can actually tell you the end of the outbreak.

In conclusion, this event illustrates how a large and widespread outbreak can occur from distribution of a single item into hundreds of foods. It also highlights the continued need for robust disease and detection response systems at all levels, local, State, and Federal to really enjoy that prompt recognition, response, and investigation into outbreaks.

CDC will also continue its efforts to focus on research, education, and training that will assist with strategies to prevent foodborne illness before they happen, incorporate the food industry into our prevention, response, and information sharing activities, and really help bolster the State public health infrastructure to effectively and promptly identify and respond to these outbreaks. We are prepared to continue to work with regulatory authorities, State and local partners, food and environmental microbiologist scientists, and the food industry to find long-term solutions to prevent foodborne disease and limit those that do occur.

Thank you again for the invitation to testify before you today. I will be happy to answer any questions you may have.

[The prepared statement of Ali S. Khan can be found on page 74 in the appendix.]

Chairman HARKIN. Well, thank you very much, Dr. Khan and Dr. Sundlof. We will open our first round of questions here.

Dr. Sundlof, news reports indicate that FDA is increasingly relying on contracts with State agencies to carry out the responsibilities of FDA, such as inspection of facilities like those of the Peanut Corporation of America. If I have it correct, according to the Wash-

ington Post, FDA last inspected that Blakely, Georgia plant in 2001, that is, last inspected it before January of this year. Is that correct?

Mr. SUNDLOF. The plant was inspected by FDA inspectors in 2001, but FDA does have contracts with the State of Georgia to conduct investigations on our behalf and those investigations did occur in 2007 and 2008.

Chairman HARKIN. OK. As I understand it, the FDA contracted inspections to the Georgia Department of Agriculture in 2006, correct?

Mr. SUNDLOF. I believe that is correct, yes.

Chairman HARKIN. So what happened between 2001 and 2006, can I assume it just wasn't inspected by anyone?

Mr. SUNDLOF. I don't think that is the case. The State of Georgia was in that plant frequently, at least twice a year every year. They were inspecting under their own authority and not under contract from the FDA. We formalized those contracts, I believe, with them in 2006.

Chairman HARKIN. But the reports show that the Georgia Department of Agriculture found problems at the plant in 2006, 2007, and 2008. Did the FDA know at that time about this? Did they learn about this from the Georgia Department of Agriculture? Three times, 2006, 2007, and 2008, the Georgia Department of Agriculture found problems there. Was this reported to the FDA?

Mr. SUNDLOF. The problems were reported to the FDA in 2007 and 2008 under the inspections that were conducted under FDA contract.

Chairman HARKIN. So again, if, in fact, the Department of Agriculture of Georgia found these problems, reported them to the FDA, did the FDA take any action at that point in time?

Mr. SUNDLOF. The State of Georgia investigating or inspecting under our authority found infractions where they discussed these with the firm and the firm took corrective actions. So when the report goes back to the FDA from the State of Georgia, we make a determination of whether or not those violations were corrected, and if they were, then we would schedule them for a regular reinspection.

Chairman HARKIN. Let me get this clear. When the Department of Agriculture of the State of Georgia found these problems, they reported them to the FDA. Did the FDA—is that a requirement under that contract?

Mr. SUNDLOF. Under the contract, they are required to report.

Chairman HARKIN. To report that. But then what communications took place between FDA and the Department of Agriculture of Georgia regarding those problems?

Mr. SUNDLOF. Well, the Department of Agriculture—in fact, if I can ask Mike—

Chairman HARKIN. Did they actually—because I understand they found things like mold and they found roaches and they found different things like that. That is from what I read. I can't say that.

Mr. SUNDLOF. Those were things that we found, that the FDA found in its inspection last month.

Chairman HARKIN. Oh.

Mr. SUNDLOF. There were some sanitary and maintenance issues that the State of Georgia uncovered, and maybe Mike Chappell can talk to that since he is in charge of that part of the FDA.

Chairman HARKIN. Can you enlighten us, Mr. Chappell? After the Department of Agriculture of the State of Georgia reported this to the FDA, what happened?

Mr. CHAPPELL. Thank you, Mr. Chairman. These reports based on State contract inspections are evaluated by a supervisor in the district that is responsible for that State. In reviewing that report, the supervisor felt that the State's inspectional findings and then the firm's corrections based on the State inspections were consistent with observations and corrections that FDA would have made.

If there had been an issue there where the supervisor felt that these were significant unresolved issues, they would have entered a dialog with the State inspection group to talk about those. The inspection reports that they got under State contract, those issues during the review of that were considered to be somewhat resolved and the State was working with this company over several inspections to resolve ongoing issues.

Chairman HARKIN. So if this committee requested to see those reports that came from the Department of Agriculture of Georgia to the FDA and FDA's response to that, that would be on file, right?

Mr. CHAPPELL. Yes, sir.

Chairman HARKIN. We could take a look at those, right?

Mr. CHAPPELL. They are on file with FDA, yes, sir.

Chairman HARKIN. And I would like to request that you make those available to this committee.

Mr. CHAPPELL. Yes, sir.

Chairman HARKIN. I ask this because just yesterday, media reports showed that a Texas plant that also contracted with the Peanut Corporation of America may have gone uninspected for as many as 4 years by the Texas Department of Agriculture. Have you read that? Do you have any knowledge of that?

Mr. SUNDLOF. Yes. Those food firms are required to be licensed by the State of Texas, OK. This does not involve FDA, but they are required to be licensed and apparently this firm was unlicensed in that State. It was known to the FDA. I think we had it in our registry. The FDA has a registry of all food firms, whether it is foreign or domestic, that came out of the 2002 Bioterrorism Act. They were in our data base and we knew of that company.

Chairman HARKIN. Are you telling me that FDA knew that there was this plant in Texas that was not being inspected by the Texas Department of Agriculture? Is that a fact, that they were not inspected by the Department of Agriculture?

Mr. SUNDLOF. My understanding is that they were not inspected by the Texas Department of Agriculture because they were unaware, based on their data base, that the firm was manufacturing.

Chairman HARKIN. And shipping interstate?

Mr. SUNDLOF. And shipping interstate.

Chairman HARKIN. Should I be alarmed about that? I mean, how many more of these instances are there in the United States where you may have a plant that is manufacturing, shipping interstate,

and you don't know about them and the State doesn't know about them? Or you know about them, but you didn't inspect them, and the State doesn't even know they exist, should I be concerned that there are dozens of these in the United States?

Mr. SUNDLOF. Each State deals with these issues a little bit differently. We maintain, again, an inventory of all the food firms and we try and get to those food firms based on a lot of different criteria—whether or not they are producing a high-risk product, whether or not they have a past inspection history that indicates that they are likely to be out of compliance—a number of different factors as to how we choose specific food firms to inspect. But it is based largely on our identification of them as being a high, medium, or low risk.

Chairman HARKIN. I know I have gone over. I just have one more thing I want to tie down here. Regarding the salmonella testing at the Blakely plant, is it correct that there were on five occasions positive tests for salmonella at the Blakely plant in 2007? The months, I believe, were June and July.

Mr. SUNDLOF. Over the history from 2007, we know that on 12 different occasions, they had tested positive for salmonella.

Chairman HARKIN. Twelve occasions? Five in 2007?

Mr. SUNDLOF. I believe that is correct, yes, sir.

Chairman HARKIN. Well, what happened then?

Mr. SUNDLOF. Well, as far as we know, and again, this is still part of the ongoing investigation, they shipped product. They retested the product at some point and received a negative finding. So they originally had a positive finding for salmonella. They sent another sample to a laboratory, an independent laboratory for analysis, and they came back negative and they shipped the product.

Chairman HARKIN. Right there, now they did not have to report to the FDA the findings of salmonella.

Mr. SUNDLOF. That is correct.

Chairman HARKIN. But you could go under the Bioterrorism Act and request later on, as you did, those reports, and that is how you found that out just recently, right?

Mr. SUNDLOF. Right. We started to uncover some of that information before we actually invoked the bioterrorism provisions for records, but certainly that helped.

And let me just say in regard to that, under the Bioterrorism Act, FDA cannot require records unless there is a reasonable belief that the product is adulterated and could result in serious adverse health effects. That is the criteria by which the FDA can require, demand records. So for the most part, in a routine inspection, those records may not be revealed to us because the company is not required to give us that information.

Chairman HARKIN. Well, it seems to me that is one gaping loophole, that a company that does its own testing finds salmonella, does not even have to report that to the FDA.

Mr. SUNDLOF. Yes, and let me just say—

Chairman HARKIN. To me, that is a big loophole. That one, at least, ought to be closed.

Mr. SUNDLOF. There is some partial relief on that, and that is the Food and Drug Administration Amendments Act, I believe, of 2007, in which there is now the requirement that FDA develop a

reportable food registry in which companies would be required to notify us in the event that they thought they had a problem. But in that particular case, the food would have had to have already been distributed. So the finding—if a company found salmonella in its product and did not ship product, it would not have to report to us. So there are still some additional loopholes, as you indicated.

Chairman HARKIN. Thank you very much, Dr. Sundlof.

Senator Chambliss?

Senator CHAMBLISS. Thank you, Mr. Chairman.

Dr. Sundlof, let me see if I can get a time line based upon your testimony and previous discussion with you. The first time that FDA became aware that PCA was manufacturing peanut butter at the Blakely facility was in 2001, is that correct?

Mr. SUNDLOF. In 2001, PCA was not manufacturing peanut butter. They were listed as a peanut roaster and blancher. That was their operation at that time.

Senator CHAMBLISS. All right. And the only reason FDA knew that there was any peanut processing going on at that Blakely facility was when some peanuts were attempted to be shipped into Canada and there were metal fragments found in those peanuts, is that correct?

Mr. SUNDLOF. No. We knew that the plant was producing peanut butter in 2007 because the State of Georgia—

Senator CHAMBLISS. No, I am talking about 2001.

Mr. SUNDLOF. Oh.

Senator CHAMBLISS. In 2001 is when you discovered that there was any processing of peanut products going on at the Blakely facility, and the reason you discovered it then is because product was attempted to be shipped into Canada and there were metal fragments found in that processed product, isn't that correct?

Mr. SUNDLOF. I don't believe that is correct. I think the metal fragments were found much later, in 2006, was it?

Mr. CHAPPELL. Two-thousand-and-eight.

Mr. SUNDLOF. It was 2008 that they shipped the peanuts to Canada and Canada rejected those because of metal fragments.

Senator CHAMBLISS. All right. Well, let us go back then. Tell me when you found out that there were peanut products being processed at that Blakely facility.

Mr. SUNDLOF. We knew in 2001 that they were roasting and blanching peanuts. That is what they reported to us. It was not until 2007, when the plant was inspected under FDA contract by the Department of Agriculture in Georgia, that we recognized that they were now—in addition to producing just the peanuts, they were producing peanut butter and peanut paste and peanut meal.

Senator CHAMBLISS. And how did you become aware in 2001 that they were processing a peanut product there?

Mr. SUNDLOF. They are registered in our data base of all food firms and they registered themselves as a roaster/blancher.

Senator CHAMBLISS. OK. Do you know whether or not that is the point in time that they started producing products?

Mr. SUNDLOF. We do not know that.

Senator CHAMBLISS. OK. Then you had your first inspection, I believe you said 2006, 2007? What was that date?

Mr. SUNDLOF. Mike, maybe you can help me out on the dates.

Mr. CHAPPELL. Yes. The first inspection of the Blakely facility was in 2001, and as Dr. Sundlof said, that was the time that they were blanching and roasting peanuts. They were not manufacturing peanut butter at that time.

Senator CHAMBLISS. All right. And the Georgia Department of Agriculture conducted inspections from that point until what additional point in time before FDA went back into the plant?

Mr. CHAPPELL. Actually, the State of Georgia conducted several inspections, as Dr. Sundlof mentioned, between 2001 and as late as 2008. They do not keep their records, my understanding is, more than 3 years, so we know we have some instances where they inspected it four times in 2006.

Senator CHAMBLISS. All right, but from an FDA perspective, when was the next time that FDA went into that plant, either under contract or on your own?

Mr. CHAPPELL. The two inspections prior to the one in January were conducted by the State of Georgia under contract with FDA.

Senator CHAMBLISS. And what is the date of that?

Mr. CHAPPELL. Well, 2007 and 2008, as I recall.

Senator CHAMBLISS. OK.

Mr. CHAPPELL. I can get you the exact dates on that later if you—

Senator CHAMBLISS. All right. And when you ultimately discovered that the Blakely facility was the source of this outbreak, you immediately went to the plant to do what? What was your intention of going to the plant?

Mr. SUNDLOF. Before we had absolute conclusive evidence but we were fairly certain that those products were involved, we went to the plant—I believe that was on the 9th of January—and we discussed the findings with the company. I would ask Mike to talk about that interaction with the company.

Mr. CHAPPELL. The inspection was initiated because of information that we obtained—and I would like to back up a little bit and talk about how we got there. When it was obvious that King Nut was possibly implicated in this outbreak, we knew that King Nut corporate headquarters was in Ohio, and when we visited the Ohio facility, we learned that the King Nut brand peanut butter was actually manufactured exclusively in the Georgia plant, and it was based on that and the emerging data that suggested we need to be looking at peanut butter as a possible vector for this outbreak. That is when we initiated the inspection in the Blakely facility.

Senator CHAMBLISS. And at the time you inspected the facility in January, did you have any authority to ask for all of the inspection records that the plant had done on its own?

Mr. CHAPPELL. We routinely ask for records when we are following up these types of suspect links to foodborne illnesses. The firm was not required to provide us records based on our notice of inspection and initiating the inspection.

Senator CHAMBLISS. Did they voluntarily give you those records?

Mr. CHAPPELL. There were requests made for records, and during the course of the inspection, we did receive records on multiple occasions.

Senator CHAMBLISS. And is that when you discovered that there had been 12 tests done in that plant that showed positive for salmonella in 2007 and 2008?

Mr. CHAPPELL. Actually, this is a series of events that occurred. When we originally started the inspection, we were focused on King Nut brand peanut butter, asked specifically for records relating to King Nut. As the investigation continued, and that included the epidemiological investigation and then reports coming in of samples of other products—an example would be crackers—that implicated other products, we asked for additional and other records. We did that on multiple occasions during the course of the inspection as this began to expand to other products other than King Nut peanut butter.

Senator CHAMBLISS. Well, I am still not clear about your answer to the question, though. When did you discover that there had been 12 previous positive findings of salmonella?

Mr. CHAPPELL. We discovered that as we got these records over time. So by the end of the inspection, we had all 12 incidences.

Senator CHAMBLISS. All right. What period of time did that cover then?

Mr. CHAPPELL. The inspection started on January the 9th and ended on January the 27th.

Senator CHAMBLISS. OK. So within that period of time, and you can't tell us exactly when you found out that there were positive findings for salmonella, but somewhere during that period of time?

Mr. CHAPPELL. It was on multiple days during that inspection.

Senator CHAMBLISS. All right. Did anybody ever ask the company, have you ever found salmonella and can you give us the dates of when you found it and the test results showing positive results on salmonella?

Mr. CHAPPELL. Early on in the inspection, we asked, had there ever been a positive salmonella finding for King Nut peanut butter and the firm provided us that information. As we moved forward and implicated other products and made other requests for other types of products they produced, the firm did provide some records.

Senator CHAMBLISS. So when you asked that question to start with, they didn't give you all their test results showing positive for salmonella?

Mr. CHAPPELL. No, sir.

Senator CHAMBLISS. Did the State of Georgia have this information relative to those tests?

Mr. CHAPPELL. I couldn't answer that, Senator.

Senator CHAMBLISS. Well, I mean, you are under contract with them. Do you not know whether or not they had that, as your contractee?

Mr. CHAPPELL. They did not provide that to us as part of the contracting inspections.

Senator CHAMBLISS. But you don't know whether or not they had that information?

Mr. CHAPPELL. No, sir, I do not know that.

Senator CHAMBLISS. Mr. Chairman, I am going to stop to let other folks ask questions and I will come back in the next round.

Chairman HARKIN. We will do another round.

I will ask Senator Klobuchar both for an opening statement and for questions since a lot of this did focus in Minnesota.

**STATEMENT OF HON. AMY KLOBUCHAR, U.S. SENATOR FROM
THE STATE OF MINNESOTA**

Senator KLOBUCHAR. OK. Well, thank you very much, Chairman Harkin, and thank you to our witnesses.

This did focus on Minnesota in one tragic way and then in one positive way. The outbreak most affected my State in that three people have died, the most of any single State. One victim was Shirley Mae Almer of Perham, a small town on Northern Minnesota. At age 72, she was still a strong lady, but on December 21, she died and she died because every morning she liked to have toast with peanut butter.

I believe it is shameful that a death like this could happen in America. All of this has obviously renewed public concerns about the safety of America's food supply, as well as the Federal Government's capacity to ensure the safety of the food that we consume. I am glad that the Department of Justice has opened a criminal investigation.

On Monday, I sent a letter to President Obama urging him to nominate a new permanent FDA Commissioner as soon as possible to begin the process of reforming the Federal Government's food safety system. A number of positive reforms have been discussed, including greater coordination and streamlining of responsibilities among Federal agencies, more resources, added authority for mandatory recalls, which I believe touches on some of the things we have talked about this morning, more effective prevention of foodborne illnesses, and better coordination between State, local, and Federal, which also has come up already this morning.

The other way that this crisis has touched our State is in a positive way in that it was the Minnesota Department of Health, not a Federal agency, that discovered the source of the current salmonella outbreak, and I want to commend our Minnesota food safety team for their work. They are on the front line in the fight against unsafe food. I believe their work should be looked at as a model.

This is not the first time that the Minnesota Department of Health has found the needle in the haystack. Last summer, there was another serious salmonella outbreak that caused hundreds of Americans to get sick. Initially, the FDA thought it was tomatoes, but after six Minnesotans got sick from eating in a local restaurant, the Minnesota Department of Health was able to pinpoint jalapeno relish as the source. They contacted the CDC and helped track down the culprit. It was the jalapeno peppers imported from Mexico.

I admire the hard work of our Health Department, but all of this happened because of a failure, the failure of our government to prevent unsafe food from entering the food chain.

The question that I have of you, Dr. Sundlof, I listened with some interest and sort of shock that we now—it seems to me just based on the questions with Senator Harkin, that a company can repeatedly have a salmonella problem in their plant and the FDA never knows about it, is that correct?

Mr. SUNDLOF. Thank you, Senator. Yes, that is correct. Again, the law that has recently passed, the Food and Drug Administration Amendments Act, does give us some additional authority to require that information if they have already shipped the product from their facility.

Senator KLOBUCHAR. So you have to have this shipping, which obviously creates a much more hazardous possibility, before you can even find out. Do you think this is something the FDA should know about, when you have repeated outbreaks of salmonella at a plant?

Mr. SUNDLOF. We would like to have as much information as we possibly can get, yes.

Senator KLOBUCHAR. But right now, you don't have that information. And if the States have it, if the States find out about it—he was talking about Texas and these things—then you automatically get it?

Mr. SUNDLOF. If they report it to us. The States do a lot of inspections on their own. We don't necessarily have access to that—

Senator KLOBUCHAR. So they are not automatically required to give you the information?

Mr. SUNDLOF. They are not.

Senator KLOBUCHAR. So we have a situation where plants can have repeated salmonella outbreaks, or salmonella discoveries. They are not required to tell you. And then you can have State departments of food and drug inspection that find this out and they are not required to tell you, is that correct?

Mr. SUNDLOF. I think that is correct.

Senator KLOBUCHAR. Yet we have seen from these deaths across the country that this isn't a single State issue. To me, it seems like it is a national issue.

Mr. SUNDLOF. That is correct.

Senator KLOBUCHAR. All right. In April 2008, a Canadian distributor refused a shipment of peanuts from the Peanut Corporation because the peanuts had metal fragments in them. Are you aware of that?

Mr. SUNDLOF. Yes.

Senator KLOBUCHAR. And the products were then returned to the U.S. and destroyed after the FDA found the peanuts to be unacceptable. Now, I don't know about you. If I found out my 13-year-old daughter, who, by the way, loves peanuts, loves peanut butter, if she was eating metal in her peanuts, I would expect the government to do something about this. So what happened? Was there any further action taken?

Mr. SUNDLOF. We required the company to destroy that lot of product.

Senator KLOBUCHAR. But you didn't have the company—is there some allowance in the tools that you have now to then have the company on some special watch list where you are looking at repeat offenses and are concerned that there may be a problem here?

Mr. SUNDLOF. Again, the plant was inspected on numerous occasions, several times by the State of Georgia, and again, some of those were under our contract. So Georgia was very vigilant in

making sure that they were going to that plant on a very frequent basis.

Senator KLOBUCHAR. So Georgia went, but you guys didn't really know they were going?

Mr. CHAPPELL. Senator, when this lot was attempted to be reentered into the United States and several attempts to recondition it failed, we did ask the State of Georgia, under contract with us, to cover that during their next inspection, and they did that and they evaluated the firm's ability to monitor and control metal fragments.

Senator KLOBUCHAR. OK.

Mr. CHAPPELL. And they reported back to us that their assessment was that the firm had in place processes to ensure that they didn't get metal fragments in their product. That is not a real common occurrence. It typically is the result of some kind of machinery malfunctioning. It is not typically something that goes on over a long term.

Senator KLOBUCHAR. And back to the salmonella issue, how much do you think this is going on in food processing plants and in different plants across the country where salmonella is found? If we find out there were, what, 12—is that what it was, Dr. Sundlof, 12 instances of this—

Mr. SUNDLOF. Yes.

Senator KLOBUCHAR [continuing]. At this plant, is this unique or is this happening all over America?

Mr. SUNDLOF. Well, this practice has been universally condemned and the industry certainly understands that this is not an appropriate way of ensuring quality of your product. Since the incident back in 2007 with Peter Pan peanut butter in the ConAgra plant, there has been a great amount of effort both on the part of the peanut industry and the FDA to inspect these plants and make sure that they are not engaging in practices that would lead to the salmonella contamination.

There have been seminars and symposiums. There have been articles written that specifically talk about the fallacy of trying to test products into what we call compliance. In other words, once you find a positive sample of salmonella, it is well known within the industry that that product needs to be destroyed at that point in time because continued sampling to obtain a different result is fraught with problems. We know this.

So I don't believe this is a problem that is rampant throughout the industry. I believe this is one individual company.

Senator KLOBUCHAR. But do you acknowledge that there are problems with the information flow here to the Federal agencies?

Mr. SUNDLOF. We would like to have more information, there is no question. I think you can say that about all the products we regulate. The more information that we have, the quicker we can take the proper actions to prevent illness.

Senator KLOBUCHAR. Do you think there are problems in that we have these voluntary recalls? Do you think that is working for the people of this country? That will be my last question. I see you going like this, Senator Harkin.

[Laughter.]

Mr. SUNDLOF. Regarding voluntary recall, FDA has a number of tools. Right now, as you indicated, we do not have the authority to

demand recalls. We do have the bully pulpit and we use that all the time. I don't think there has ever been a case to my knowledge where a company has refused to recall product when we have told them in very specific terms that we would be taking additional actions, and those additional actions can be things like seizure. We can seize the product. We can enjoin the company from doing further business—

Senator KLOBUCHAR. But if you don't have the information, you are not going to do that, and that was the problem, I think, for Ms. Almer and her family, so all right.

Mr. SUNDLOF. Thank you.

Senator KLOBUCHAR. Thank you.

Chairman HARKIN. Thank you very much, Senator Klobuchar.

Senator Leahy?

Senator LEAHY. You know, I listened to the question of cooperation and it sounds good. Obviously, there wasn't a heck of a lot of cooperation here. One of the witnesses we are going to hear from later is Gabrielle Meunier of South Burlington. She lives there in Vermont. Her 7-year-old son, Christopher, became severely ill. He was actually hospitalized for nearly a week with salmonella. He got that from peanut crackers.

Now, all this voluntary cooperation didn't tell her anything to say, take that out of her pantry. She is a mother, like all mothers. If she had gotten any kind of a warning that this is a danger, none of that stuff would have been fed to her children. We don't have young children in our household, but our home in Vermont and our home down here, we constantly have grandchildren coming in and my wife and I scour the lists of any kind of recalls from your Department or anywhere else all the time.

We are going to have Caroline Smith DeWaal testify here today. She is a native Vermonter, a graduate of the University of Vermont. Her mother still lives there. Her father, the late Dr. Durwood Smith, was Chairman of the Pharmacology Department at the Medical School at the University of Vermont, a highly respected person.

I mention all this because as I sit here and listen, we hear, well, we want cooperation. Maybe we will get cooperation. For one thing, in this particular case, at least based on the news reports I have heard, this was a company that should have shut everything down immediately—immediately. I think, Admiral Khan, you would agree with that. At the first sign of salmonella, you go back and clean everything out.

Wearing another hat, as Chairman of the Senate Judiciary Committee, I have written asking for criminal prosecutions in this case. If a company thinks, well, I will wait for an inspection, maybe there will be an inspection, maybe there won't—I know, Doctor, that your Department is shorthanded. There is no conceivable way you could inspect everywhere. But if they think, well, if we get caught, maybe something, maybe a recall, maybe we will get a fine, it is a cost of doing business. Well, in this case, the cost has been people who have lost their lives. It has certainly been an enormous cost to companies who may have totally safe products, but they have had to recall them and now their products are tainted, at least in the public's view.

I would like to see some people go to jail. I don't really care what kind of a fine is put on a company that ignored this because I don't think that really bothers people. It is like the horrible things that have happened in the financial markets. You give them a fine. It is the cost of doing business. When somebody thinks they are going to go to jail if they don't report something, report it adequately and clean it up, that is an entirely different thing. It is not corporate headquarters that is going to pay a fine. It is the person who discovered it who is thinking, I might spend the next few years as a guest of the State in a small cell with bars on the window eating food that I am not too sure of. Then you are going to get them.

What kind of steps are going to be taken in the next few months to make sure these kind of things don't happen again, or do we have to assume they will happen again in some other area?

Mr. SUNDLOF. Well—

Senator LEAHY. And you understand, Doctor, this is not directed at you. I am just so frustrated. I am looking at these people in Vermont. They do everything they are supposed to do and still their child ends up 6 days in the hospital with the anguish of the parents wondering, is the child going to live?

Mr. SUNDLOF. Thank you, Senator, and there is a criminal investigation currently ongoing in this case. We don't know how that will turn out, but certainly it is a concern that we had.

We had our first wake-up call in 2007 with peanut butter causing salmonellosis on a nationwide basis, and at that time, we took what we thought were prudent measures in, first of all, inspecting peanut plants, peanut butter plants around the country to make sure that they were practicing good, safe production processes. We held seminars. We discussed a lot of this with the peanut industry. We thought, and we still do think that they have made changes to their process and they have educated their members to make sure that this doesn't happen.

It was just as disappointing to us to find out that after all of this additional work that had gone on, that a single company could let this happen. After the recall is completed, we will be looking back and see about what went wrong, what could we do in the future to prevent this from ever happening again, I can assure you.

Senator LEAHY. My time is up, Mr. Chairman. No, that is OK. I am hoping to get to the next panel before I have to leave.

Chairman HARKIN. All right, good.

Well, we do want to get to the next panel, but I do want to ask Admiral Khan from CDC a question. It seems to me that, well, as I said earlier, we want to get to the prevention. We want to stop this before it happens. But if something happens and there is an outbreak, the question has to do with coordination and discovering things more quickly. Now, this has been going on for 3 months—three months. It seems that PulseNet has helped to coordinate all this, but they need to be discovered more quickly.

Besides the solution to add more money to the budget, what other authorities does CDC need to more quickly diagnose these outbreaks? As I understand it, PulseNet is triggered at a certain level of illnesses. I don't know what that is. What threshold causes an activation of this system? Should it be lower than what it is right now? How can we get to these more quickly than 3 months?

Admiral KHAN. Thank you, Senator, for that question. I do want to make a comment. I am a pediatrician and Christopher's story really resonates with me. With these diseases, unfortunately, it is the very young, the very elderly, and the immunocompromised who get infected, and again, there were eight tragic deaths associated with this illness. So prevention really is key, and that is a shared public health mission between CDC and FDA and industry. We all have the same mission. We want to really limit these illnesses, and if we can't limit them, find them as early as possible.

Now, the outbreak originally started in September, so it took two months of cases before PulseNet was triggered, a blinking light that we have some lab cases that are associated. And December was when sort of the alarm bells go off. There is too much of this, so an extensive, intensive investigation conducted in collaboration with FDA and our State and local partners. And 1 month of investigation that got us eventually to what we thought the agent was likely to be, and then the timely investigation by FDA that went into the plant to figure out what was going on.

Now, this is actually quite typical for what happens with foodborne outbreaks. This time line that I have just laid out to you over a couple of months is very typical of what is going on with our outbreak responses currently. And as you just mentioned, there are a number of opportunities to really shorten this time line to where we have cases identified a lot quicker and we have a response a lot faster.

And to make that happen, we need a couple of things. So the first thing is we need new tools at the local, State, and national level to investigate these outbreaks. So I mentioned originally how PulseNet had two separate patterns, that with new technology, we recognized it was one, the same outbreak. So we need new laboratory tools to make that happen.

We need new information tools to do the investigation. We need tools such as computer-assisted telephone interviews to do these investigations. We need new ways to standardize, analyze, bring information together in real time, so right away, to understand what is going on.

So there are a number of tools we need. We need new tools to look at new diseases, such as *C. difficile* and other diseases that we want to look at. So we need new tools.

The second thing we need is better investment at the State and local level to actually make these diagnoses quickly, do the PulseNet testing very quickly, do the interviews very quickly, and then come to a determination that we think this is an implicated exposure and then hand that off to FDA as fast as possible so they can do their timely response.

So more tools, new tools at multiple levels, and the investment in public health at the State and local level. I am a big fan of CDC. I work at CDC. CDC is vital. But the bottom line is public health occurs at the State and local, Tribal and Territorial levels. That is where thousands of public health professionals every day are making these diagnoses, investigating these outbreaks, and we need to support them.

Chairman HARKIN. Now, you just told me something I didn't know. Obviously, this has been over a 5-month period of time now. You say it was started in September?

Admiral KHAN. Yes, sir, September 1st, I believe, was the first onset case, sir.

Chairman HARKIN. So a lot of people are getting sick and perhaps even dying as this thing goes on and on and on. So you are telling me in order to make this more efficient and quicker, we need new lab tools, more tools, more personnel?

Admiral KHAN. Definitely. I met last week with the State and Territorial epidemiologists. These are your leaders at the State level, the public health leaders, and basically they want boots on the ground. They need people who can help look at—so we are just describing for you one PulseNet cluster. There are over 150 PulseNet clusters.

Any given large State health department, such as yours, would be investigating during the winter maybe 20 or 25 clusters at any given time. So they need the boots on the ground to analyze those specimens, not have to wait weeks potentially to test them. They need boots on the ground to say, this is a cluster. They need tools to look at those clusters.

And they need boots on the ground to make all the calls and follow up with these people and say, what did you eat, in a timely manner instead of four or 5 weeks, months after the fact, say, what did you eat back in September? You would like to be as close to the illness as possible to ask those questions while the memory is fresh.

Chairman HARKIN. Admiral, you are saying what I have been saying for a long time. We have been saying the same thing, and that is we have for far too long ignored our public health sector in this country. I think we have just assumed that, well, things are OK. We just don't have to do anything.

But the fact that our—and we really haven't done anything about good manufacturing practices under FDA since 1986. Think about the changes that have taken place in our food manufacturing and distribution system in the last 20—some years. You have something manufactured at a plant someplace and within 24 hours, it could be in 40 different States. That wasn't true 20—some years ago. It is true now.

So we haven't changed and updated our public health system to cope with this new distribution system that we have in the United States, both with the manufactured food but also with produce that comes into this country that is just distributed all over, which we found with the peppers last year and tomatoes that Senator Chambliss mentioned.

So it just seems to me that we have an obligation, I think, to the American people to really look at the public health structure in this country, the new challenges that we face, and come up with the resources that we need to get the boots on the ground, as you say, the people that are out there to help protect the health and well-being of the public out there.

That is one thing. I asked you if the threshold should be lower on what triggers a PulseNet. Do you have any response to that? When I talk about that, people say, well, if you do that, then that

might lead to too many false starts, false things, and that takes a lot of time and consumes a lot of energy and money, so I am not certain where that threshold should be.

Admiral KHAN. Sir, there is not a specific threshold. There are a number of factors that drive these investigations. So there are over 60,000 patterns in PulseNet generated any given year, 60,000 patterns, and so as you look at those patterns, what happens is they look at the pattern itself, how distributed the pattern is into multiple States, how severe the disease may be associated with that pattern, how unique the pattern is. If it has never been seen before, like this one, that says, OK, this is probably more likely to be interesting, and whether or not that pattern has previously been associated with some other product.

So there are a number of factors that go into deciding that this is a cluster that we need to follow, and then as that cluster is followed, there are triggers based on the disease that say, OK, we now need an additional level of investigation that requires us to call into place OutbreakNet and work with all our—more closely with all our State and local epidemiologists to really start making the calls.

Throughout that process, we work very closely with FDA, and this was actually a really good example, as a side topic, of that closeness occurring back at the end of November-beginning of December to make sure that we had a collaborative relationship.

Chairman HARKIN. Well, I will stop with this and yield to Senator Chambliss here, but it just seems to me here you have got an FDA that doesn't require reports to be made to it if there is an outbreak of salmonella, as this plant did not have to report these things. They don't have really the authority to go in and do much, as I understand it, right now. Then you have the CDC that basically is understaffed, undermanned, and really tracking these outbreaks down in a timely manner. It seems the two of them together really does cry out for some kind of better coordination, stiffening our laws.

I think one of the things, we have got to close that loophole on requirement of reporting of internal findings of pathogens. And then a better coordination between FDA and CDC with more support for the Centers for Disease Control and Prevention in terms of being able to track things down in a more timely manner. Five months, I just think that is way too long to bring a closure on this and find out what is causing all these illnesses. Surely we can do better than that.

Admiral KHAN. Yes, sir. Surely we can do better than that. We actually have excellent coordination and collaboration with FDA, and in this specific investigation, FDA was involved in the investigation way early in the investigation. We shared people between the agencies extremely early in the investigation, and we really worked very well on communications, which was something that came up after the tomato outbreak, to improve our communication strategies. We have gone to novel communication strategies together, Twitter, our blogs, podcasts, coordinated communications strategy with FDA, and FDA set up an excellent searchable website where people could quickly go in and figure out what products had been recalled.

Actually, I should best turn it over to FDA to talk about some of their coordinated activities, also.

Chairman HARKIN. Well, I have to yield to my Ranking Member here. We have to move along right now. I will close it with that. Senator Chambliss?

Senator CHAMBLISS. Dr. Sundlof, does FDA have any jurisdiction or control over the private labs, such as the one or ones that would have done the testing at this PCA plant?

Chairman HARKIN. Good question.

Mr. SUNDLOF. I don't believe that we have any direct authority to require them to provide the results that they have based on a private firm, for instance. We don't have the authority to require information that they would consider to be proprietary to that firm that they were testing for.

Senator CHAMBLISS. You don't have the authority to ask them for the information, nor is there any requirement that a private lab that tests a facility that processes food to be shipped in interstate commerce that finds a positive test, there is no requirement that they report that to you?

Mr. SUNDLOF. Let me correct one thing. We do have the authority to ask, and we do ask on almost every occasion. They are not required to provide us with that information.

Senator CHAMBLISS. But that is what I am saying. They don't have to give it to you, nor is there any requirement that if they find a bacterial infestation in a food product that is going into interstate commerce, they don't have to tell you about that, do they?

Mr. SUNDLOF. I believe that is correct.

Senator CHAMBLISS. Which is, again, one of those very serious loopholes that we need to try to plug.

Last to you, Dr. Sundlof, the recall of products such as found to be contaminated with salmonella in this instance, does that have to be voluntary or can you demand that those products be recalled?

Mr. SUNDLOF. We cannot demand that they be recalled. We work with the companies and the company—the recall is the responsibility of the company. The FDA does the audit checks to make sure that products are actually coming off of the shelves.

Senator CHAMBLISS. And in this particular instance, it seems like every day for about the last two or 3 weeks, we have been getting in the media reports that additional products are being added to the list. So again, there is no way FDA has any control over what products are recalled other than the company itself advising the people to whom it sold the product to make their own recall of their products, is that correct?

Mr. SUNDLOF. That is correct, and it has to go all the way down the supply chain, too, so that Kellogg's is recalling their peanut butter crackers. It is not just the PCA company.

Senator CHAMBLISS. Admiral Khan, I, too, am bothered by the fact that the first indication of this came on your PulseNet the first of September and here it was actually January the 19th before anything positive was done. November 10, you said in the monitoring of the Pulse system there were 16 States that showed up on the PulseNet. Now, that is a third of America that has all of a sudden developed some sort of illness. I don't know whether you knew

it was salmonella or not then, but obviously you knew there was something going on in a third of the States. I don't understand why that didn't trigger more of an alarm on the part of the CDC to try to figure out what the heck is going on.

Admiral KHAN. Thank you very much, Senator, for that question. So the original illnesses occurred in September and October and the first PulseNet indication that something was going on was in November. The initial PulseNet patterns didn't come in until early November. So we recognized them very quickly.

But I talk about this as akin to driving while looking through your rear-view mirror. It takes 3 weeks for us to understand what is going on; and then to understand the impact of any decision it takes another 3 weeks in the future to understand the impact of those decisions. So based on the way our systems work, there is that delay.

Now, there were actually, as I said, 13 patterns in 12 States on November 10. We have 60,000 patterns, over 300 to 400 clusters that are being investigated every year. In the winter, 25 to 30 clusters at any given time. So based on a number of criteria, such as how rare the pattern is, what the agent is, the severity of the agent, how widespread that pattern is, whether or not it has previously been associated with a food item is how we begin that investigation.

And so the early steps of the investigation were as you heard, sir. Then the moment we sort of say, this looks like a unique pattern, we then reach out for increased monitoring of laboratory patterns to say, please, if you have any *Salmonella Typhimurium*, please type them very quickly. *Salmonella Typhimurium* is not at the top of the list in a State for typing. It is more likely diseases that are more severe, such as *E. coli* and *listeria* that would be likely to be typed. So we try to enhance the States to start doing the laboratory testing, and many of these clusters just disappear.

When the cluster doesn't disappear and has started to gain momentum, and in this case we were actually able to add it to a second cluster, and when those two clusters came together, it became very clear that this was a nationwide multi-State outbreak, and that triggered the full press with all the State epidemiologists saying, what is going on? Let us start interviews. Let us do some hypothesis generating. And then it takes about a month to sort of figure out what is going on.

Senator CHAMBLISS. Well, you all have got to figure out some way to speed up that process. I don't understand, with technology being what it is today. It appears that there is that public health network out there. We knew that 16 States were involved. I see nothing to indicate that CDC was aggressive in notifying public health systems in all 50 States that, hey, be on the lookout for this. I see nothing to indicate that, as I think has been evidenced by what Dr. Sundlof says, that because we have no jurisdiction over these private labs, that there is any regulatory requirement that private labs notify CDC when salmonella is found. I see nothing in your testimony—I am going to be interested to hear from Ms. Meunier with respect to her contacts to CDC where she drew a blank, but she did find somebody at FDA that was able to look at the actual crackers that her child had eaten.

When you take all of this in concert together, there is a huge breakdown in the system here. I don't know whether it is stovepipes at CDC and FDA and the Georgia Department of Agriculture or what is going on here, but there is a total lack of information sharing between all of our food safety organizations that we simply have got to fix. I am not blaming you guys because you are the messengers here. But it is pretty obvious that we have got to make some major changes and we can't do it without significant input from you folks.

So as we move through this and learn a lesson from this, we are going to need to get you all back up here to talk about how we develop this legislatively or how we instruct you to do so from a regulatory standpoint, because, I mean, this was found September 1. November 25, when this child ate those crackers, this should have been well known to everybody in the public health community and it should not have happened.

Thank you, Mr. Chairman.

Chairman HARKIN. Thank you.

I see Senator Johanns has rejoined our committee here. I was trying to get on to the second panel because of time, but I want to be responsible and respect your presence here, Senator, I say Mr. Secretary, but Senator Johanns.

Senator JOHANNNS. Mr. Chairman, I would suggest we go to the next panel. I am learning the challenges of three committee hearings all at once, so let us go to the second panel and I will make sure and review the testimony and the questions. Thank you.

Senator LEAHY. Mr. Chairman, I will waive my second round of questions because we have gone so far over time.

Chairman HARKIN. Thank you very much.

This panel is excused. If you could stay around just in case something comes up for questions in the second panel, I would appreciate it.

So we will call our second panel, Ms. Gabrielle Meunier from South Burlington, Vermont; Ms. Caroline Smith DeWaal, Director of the Program on Food Safety for the Center for Science in the Public Interest; and Mr. William Hubbard, former Senior Associate Commissioner for Policy, Planning, and Legislation for the Food and Drug Administration.

Senator LEAHY. Mr. Chairman, I mentioned something earlier about Gabrielle Meunier. She does come here from South Burlington, Vermont. She is the Controller for Pomerleau Real Estate in Burlington. In my family, we know the Pomerleau family really well. I should mention I married a Pomerleau, so that is why, I should point out the connection.

But that is not why she is here. She is here because she lives in South Burlington with her husband, Darrell, and their children and it was 7-year-old Christopher who became so severely ill. I think Vermonters throughout the State prayed for Christopher's health and have been so aware of what he went through after the salmonella poisoning from peanut crackers. He survived, thank goodness, so I am glad you are here.

But no parent should have to go through this. I think the case proves the FDA has to be given effective inspection oversight and Congress should look at requiring specific inspection frequencies for

all food plants. We have to work from farm to fork to make sure that we improve the safety of food in our country.

Of course, Ms. Smith DeWaal is well known in Vermont. She is a native Vermonter, as I mentioned before. Her late father, Dr. Durwood Smith, was so highly respected in the Pharmacology Department at the Medical School of the University of Vermont. I knew him when I was State's Attorney, and I should quickly add not because he did anything wrong, but he was very helpful to us in a number of areas. Your mother, Sue Smith, still lives in Vermont, is that correct?

Ms. DEWAAL. Yes.

Senator LEAHY. Mr. Hubbard, I am afraid I can't make a Vermont connection for you, but you are welcome in Vermont anytime.

Thank you, Mr. Chairman.

Chairman HARKIN. He probably spent a nice vacation there once sometime.

All of you, welcome. Your testimonies will be made a part of the record in their entirety and I ask you to summarize them in five to 7 minutes, if you would be so kind.

Ms. Meunier, welcome again and please proceed.

STATEMENT OF GABRIELLE MEUNIER, MOTHER OF AFFECTED CHILD, SOUTH BURLINGTON, VERMONT

Ms. MEUNIER. Thank you very much. Thank you, Senator Leahy, Chairman Harkin, and the rest of the committee, for this opportunity to appear before you today and share the story of my son, Christopher, and our experience with the salmonella poisoning and the peanut recall that followed.

On November 25, 2008, my perfectly healthy and robust 7-year-old son, Christopher, started showing signs of what appeared to be the flu. After consulting with our pediatrician, we limited his food and made sure he got plenty of fluids. But just 2 days later, Christopher's health deteriorated dramatically. He became violently ill and was in tremendous pain, a pain that no child should ever have to experience, and one as a mother I will never forget. How in the world could a seemingly perfectly healthy child get so sick in such a short amount of time?

Once the lab results finally came back and he was diagnosed with salmonella, the picture became a little clearer. After six terrorizing days and sleepless nights in the hospital, filled with antibiotics, antifungus drugs, and no food or drink, his wrecked little body finally stabilized to a point where he could come home.

Senators I could spend all day long telling you about our ordeal and Christopher's terrible experience and the lingering questions that we still have about his long-term health, but I would rather use my time here today to help enact progress and change.

Some excellent ideas have been proposed for improving our food safety system and I would like to add a few of my own. Senators, I believe that technology is the key to improving our responses to foodborne illnesses at every step along the way.

First, there should be a national online foodborne illness data base registry that should be used as soon as a foodborne illness has been diagnosed. Such a tool should be utilized immediately when

the patient is in the hospital or the doctor's office, for the patient to record the foods eaten over the last week. This way, the information is still fresh in the victim's mind rather than over a week later, on the phone with a representative from the State health department for a two-and-a-half-hour interview.

In this age of technology, I don't understand why victims could not be given access to one another via a secure website and a chat room to allow them to talk to one another and possibly solve the question of which foods poisoned them. Had I had this opportunity to talk to other mothers whose children were sick and compare what they had eaten, I have no doubt we would have solved this cracker case back in early December.

Those involved in the outbreak response should never underestimate how much the victims crave information. I was kept in the dark for way too long throughout this process. At one point, I had to insist on learning the specific kind of salmonella Christopher had because I was told I didn't need to know. Victims must be kept in the loop with real-time information and there must be a way to reach all victims by phone. An automated phone message system for victims could easily be established for disseminating information. After all, how many people in this room got text messages from President Obama during inauguration weekend? We should have received some sort of alert as soon as there was the slightest possibility that crackers were suspected as being tainted instead of, by chance, in an online article I read.

When I called the CDC, because I had remaining possibly poisonous crackers left in my home, no one would take my call. The FDA was willing to help, but the holiday and the inauguration came first and it delayed any action. In speaking with the FDA, it was made clear to me that the CDC was not sharing information about my child's illness. All the agencies working on this outbreak should have had access to the same data. Technology must be used to share information between all the teams and lines of defense working on the outbreak.

The public needs to be kept informed, perhaps via an alert system similar to those for storm warnings. This system could also be utilized to update the public when it is safe to eat a food. Right now, it is just a guessing game, a game of Russian roulette, and we all have to rely upon the media to keep us up to date, which is inefficient, at best.

Next, I believe there should be a unified procedure for the genetic identification of food poisoning cases. Labs should be regionalized and best practices should be shared. Once identification is made and data entered into this registry, correlations can be made to determine if there is a pattern developing. Victims' information will already be in the registry. They are important. So now, swift action can be taken immediately.

After our experience, I believe there should be one team in charge at the national level. This team should use technology and the registry data base for collecting and disseminating their information to all lines of defense. It is crucial that our local doctors, the hospitals, the State health departments, the CDC, and the FDA all have access to this data base. As the system is now, Christopher's doctors had to ask around on their own of other local pedi-

atricians if patients had similar symptoms. Had there been a national data base that they could have referred to, they would have seen perhaps that there were clusters or similar symptoms in other States in the United States. This information is important for the first lines of defense to have. And were we to have a bioterrorist act in food, this data would be absolutely invaluable.

Finally, I believe there needs to be personal responsibility in manufacturing and growing foods for consumption by the public. The owners of companies must be personally responsible for the safety of the foods they sell. Inspection records should be made on-line and made available to the general public, and owners should personally attest to the safety of their food. Manufacturers must take responsibility for all ingredients in their products and there should be a transparent process to verify that their suppliers are meeting certain standards. Clearly, this did not happen in this case and now the government must ensure this will never happen again.

Thank you to the committee for holding this hearing today. I would like to close by thanking the staff at the Children's Hospital of Vermont. Our family is so thankful that Christopher received the best care in the world, and lucky for us, he was a big boy to begin with. I shudder to think of the possible outcome had he been underweight or sickly to begin, and my heart goes out to all the other victims and the families who lost their loved ones. Thank you, and I welcome any of your questions.

[The prepared statement of Ms. Meunier can be found on page 85 in the appendix.]

Chairman HARKIN. Thank you very much, Ms. Meunier. Right to the point and I appreciate it very much.

Ms. MEUNIER. Thank you, Mr. Chairman.

Chairman HARKIN. We will move to Ms. Caroline Smith DeWaal, who has been before our committee before in the past. We welcome you again, Caroline. Please proceed.

STATEMENT OF CAROLINE SMITH DEWAAL, DIRECTOR, PROGRAM ON FOOD SAFETY, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, WASHINGTON, DC

Ms. DEWAAL. Thank you. Thank you very much, Senator Harkin. And to just clarify for Senator Leahy, my mother did relocate in Michigan a number of years ago to be close to her grandchildren, but I grew up there. I spent the first 20 years of my life there.

Senator LEAHY. Remind your mother that there is a constitutional duty for grandparents to spoil their grandchildren.

Ms. DEWAAL. I will.

Senator LEAHY. Thank you. Tell her I said so.

Ms. DEWAAL. Well, thank you so much, and really, it is as much for parents and grandparents, I think, that you are holding this hearing because it really does impact so many Americans when peanut butter becomes the source of one of these outbreaks.

My name is Caroline Smith DeWaal and I have been Director of the Center for Food Safety at the Center for Science in the Public Interest for many years, working on food safety issues really since 1991. In addition to CSPI, we are joined today on this testimony with Consumers Union, which endorsed the testimony earlier this morning.

The Peanut Corporation of America outbreak, like countless episodes in the previous 2 years, illustrates tremendous gaps, many that you have discussed this morning, in our food safety system. For example, the company had no food safety operating plan and ignored repeated positive salmonella findings. The State of Georgia lacked full access to the plant's food safety records. The FDA failed to provide adequate oversight of the State inspection program and of the plant involved. Finally, the penalties available to FDA to prosecute this company don't match the culpability of the company.

Despite its size and scope, this event is neither rare nor unexpected. In fact, Congress, many committees, including yours, have held nearly 20 hearings in the last 2 years focused on failures in FDA's food program linked to everything from spinach tainted with *E. coli* 0157:H7, pet food containing ingredients which were intentionally adulterated with melamine, and even a previous peanut butter salmonella outbreak.

Now is the time for Congress to take action to fundamentally reform and fully fund our national food safety system. Legislation should focus on making the companies accountable for food safety while giving the State and Federal inspectors better tools to assess the food safety programs and the performance of companies.

The heart of any reform effort lies in prevention, not response. Congress should require every food plant regulated by FDA to have a food safety plan detailing that it has analyzed its operations, identified potential hazards, and is taking steps to minimize or prevent contamination. Former Secretary Johanns knows that, in fact, that is the system we have for meat and poultry today, but it is not similarly applied to FDA-regulated products.

Legislation should set specific inspection frequencies for all food plants and establish clear auditing parameters when States are conducting inspections on behalf of the Federal Government. Specific authority should allow inspectors to have access to the results of tests conducted by the plant as well as all food safety reports that support the written plan. Without this check, a company can follow the practices of this Georgia peanut company, which instead of fixing its salmonella problem, it fixed the tests. Congress needs to strengthen the State inspection and surveillance systems by providing assistance through training and grants.

CSPI also believes that giving FDA authority to require better ingredient tracing and to order a recall are critical tools for responding to future outbreaks. Today, when you see notices of the recall, they often mention that it is voluntary, and that is true. But this type of language may not compel consumers to act with the requisite urgency because consumers might think, well, you know, if it were serious, FDA would have mandated the recall.

These are a few of the elements already included in legislation before Congress that could have prevented the PCA outbreak and the massive recall which is still ongoing. President Barack Obama promised us a government that works. These new authorities and increased funding will certainly help FDA improve. But to deal with the root of the problem, Congress and the Obama administration will need to go beyond making a few quick fixes. Structural reforms are also essential.

Although FDA is responsible for the safety of approximately 80 percent of the food supply, the FDA's Commissioner must divide his or her attention among drugs, medical devices, foods, and cosmetics. And frankly, food issues frequently fall to the bottom of the pile. There is no single food safety expert in charge of the policies, the budget, and the enforcement staff, and no credible voice communicating to the public and the industry what can be done to prevent outbreaks.

It is time to elevate food monitoring functions within the Department of Health and Human Services. With both the public and the regulated industries clamoring for change, there is no reason to delay. Preventing future outbreaks and recalls like the one you are investigating today is within our grasp. Thank you very much.

[The prepared statement of Ms. DeWaal can be found on page 48 in the appendix.]

Chairman HARKIN. Thank you very much, Caroline.

Now we will turn to Mr. William Hubbard, former Senior Associate Commissioner for Policy, Planning, and Legislation at the Food and Drug Administration. Mr. Hubbard?

STATEMENT OF WILLIAM HUBBARD, FORMER SENIOR ASSOCIATE COMMISSIONER FOR POLICY, PLANNING, AND LEGISLATION, U.S. FOOD AND DRUG ADMINISTRATION, CHAPEL HILL, NORTH CAROLINA

Mr. HUBBARD. Thank you, Mr. Chairman. I have a written statement, but I will just make a few extemporaneous remarks.

I was at FDA for 27 years and the last 14 as an Associate Commissioner. I have dealt as frustratingly with this issue for many years, as you are expressing. I want to agree with your opening remarks, Mr. Chairman, about the fact that we don't have an operating system, which I think is absolutely true. Despite all of the advances we have made in science and technology, we have not brought them to bear on this problem. We simply haven't. In fact, FDA has a food safety system that is a relic of the 19th century. It is outmoded, outdated. It does not use modern scientific techniques. And it clearly needs a serious examination, in my view, by the Congress and the new administration.

There are two particular areas I would like to focus on. One is FDA's capacity to work under the current paradigm. The current paradigm was developed over a century ago and it would have inspectors randomly go into food facilities and look around and see if they find a problem. They might get in every few years, and they would attempt to correct the problem.

That has clearly failed, but one of the reasons it has failed is that FDA's food program has largely disappeared. When I came to FDA in the 1970's, there were 70,000 food firms. FDA inspected 35,000 times a year, so they got to everybody every couple of years, generally. Today, there are 150,000 registered firms with FDA and FDA does 7,000 food inspections. That basically means there is no "there" there.

Now, the FDA believes there are about 6,000 high-risk firms, so they do try to get into those with some frequency, and they should, firms, for instance, that make canned goods that could result in botulism. But they don't get to the vast majority of the other firms.

And you can correlate, Mr. Chairman, that as FDA inspectors left those facilities, stopped going in the 1970's and 1980's and 1990's, recalls went up and adverse findings in the inspections they did do also went up. So you clearly had a correlation between the regulators going away and the problems going up.

Now, I want to reiterate, I think most of our food supply is very safe. But we clearly have these kinds of problems that keep on happening. I just think we have to look at a new paradigm, and that new paradigm exists. The meat program at USDA has shown it. The juice and seafood programs of the FDA have shown that you can build a system of preventive controls, where a firm is asked to identify the hazards that can affect their food and then prevent them from ever happening. So you are not relying on FDA to catch someone after the proverbial horse has left the barn and then fix it. The firm would have a food protection plan, a food safety plan where they would identify hazards like salmonella, make sure it never gets in the food, and then you just simply won't have these problems to the degree we have them.

I will mention a few other things. FDA does need recall authority. As Dr. Sundlof said, they can often cajole a firm into a recall, but firms often stall. They like to talk to their lawyers. They like to think about it. They like to take a day or two. If FDA could order a recall, I think we could get things moving more quickly.

And clearly, when you go into a firm, you need to get to those records very quickly. The bioterrorism act's record access provision is seriously flawed. FDA can't even, as Dr. Sundlof said, when they do a routine inspection, ask to see the records, even if the firm has the records, because you have got to have evidence that there is such a big problem, FDA has to pull that trigger on the Bioterrorism Act. So that clearly doesn't work.

I will end my remarks by answering Senator Leahy's question. Yes, we are going to be here again, over and over again, unless we find a solution to this problem, because the outbreaks have tripled for FDA foods in the last 15 years, or almost tripled. That is a huge increase. So the problems are going up and FDA's ability to deal with them is going down. So we need to give the agency some resources and some authority to fix this problem, in my opinion.

Thank you for your time.

[The prepared statement of Mr. Hubbard can be found on page 59 in the appendix.]

Chairman HARKIN. Thank you. Thank you very much, Mr. Hubbard. Very good testimony. Thank you.

Senator Leahy, I know, has to get back to the floor and I am going to yield to him for opening questions.

Senator LEAHY. Thank you, Mr. Chairman.

Ms. Meunier, I have read your testimony. I have talked with you personally, as have my staff. I still think of this almost as a Kafkaesque thing you went through. You described a little bit in your testimony about the coordination interaction between the Vermont State Health Department and the CDC and the FDA—

Ms. MEUNIER. Yes.

Senator LEAHY [continuing]. At the same time when you were trying to get information yourself as a concerned mother. Do you

want to tell me a little bit more about that? What went right? What went wrong?

Ms. MEUNIER. Yes. Well, there was no one place I could go, and I have to say, I was not even aware that the FDA was involved. I thought this was between the CDC and my State health department. So I was never told that there was this FDA website that I could go to.

Furthermore, it should be one website when there is a foodborne illness, not two, so I would just like to make that clear because people are totally confused as toward who is in charge. Is it my State? Is it the Federal Government?

Senator LEAHY. Especially in an era where we are all used to going on the Internet—

Ms. MEUNIER. Yes.

Senator LEAHY [continuing]. To find out everything from—

Ms. MEUNIER. Yes, we are. So when I actually talked to an FDA representative—and I do appreciate that, absolutely, that the FDA took my call where the CDC would not and refused to speak to me—I said, I didn't even know you guys were tracking this information. I didn't even know you were involved. But then when I found out that the FDA asked me all the same questions that the CDC asked me, I said to the representative, why don't you already have this information? Are you not allowed to share the same data base? My interpretation of her response was that she did not have that information.

The health department working with the CDC, we are talking about days' and days' delay. She has to track me down by the phone. You know, I am a busy mom. There were so many gaps which were common sense not smart practices, the time delays getting from the CDC to the State, from the State to me, all via phone.

Senator LEAHY. If you ran your real estate business this way, it wouldn't last very long.

Ms. MEUNIER. No, because you have to grow with the times. They are using 20th century techniques in a 21st century society.

Senator LEAHY. Thank you.

Ms. MEUNIER. And also, can I just add that the statistical extrapolations that they used in this PulseNet I reviewed, and I can't correlate that to what I went through because it seems to me that I could have determined the outbreak long before the statistical correlations did.

Senator LEAHY. And it is one thing to just go through and recount everything you did, but also at the same time you had the very frightening experience of Christopher being in the hospital.

Ms. MEUNIER. I did. It was an awful thing to go through. He was extremely ill, and for days, we had no idea. Neither did the hospital. Salmonella is not common where I live. I don't know anybody who has ever been food poisoned. And so we thought that he had terrible internal injuries. We thought—never once did anyone mention, and I called the best doctors in Vermont, salmonella poisoning. And never once did we ever fathom that a cracker could contain poisoning, ever. It never dawned on anyone.

Senator LEAHY. Especially the crackers that end up in kids' lunch pails or—

Ms. MEUNIER. Absolutely, and he happened to eat a special lot that day, but—

Senator LEAHY. Ms. Smith DeWaal, in your testimony, you mentioned that, and I think I am quoting you correctly, FDA's infrequent inspections and the agency's oversight of State contracted inspections contribute to illness outbreaks. Could you speak a little bit more about mandatory inspection frequencies? How often should they be done?

Ms. DEWAAL. Thank you, Senator Leahy. This is a critical issue, I think, that will need to be resolved for any legislation to address problems at FDA. Let us look for a moment at the meat and poultry inspection system, which was passed in 1906 based on some scandals and problems that were happening at that time. They required a daily inspection at meat plants. For slaughter plants, they can't even start operations until the USDA employees are in the plants, in their position, really. And for even processed meat products, they have inspection on a daily basis.

Now restaurants are another food venue very important to consumers. Those are inspected by States. The best advice to the States and the one States try to follow is to inspect restaurants twice a year, at least twice a year, and if they are having problems, they should get in there more often.

The FDA inspection—first of all, the FDA has no mandatory inspection frequency today for food plants. They do have a mandatory inspection frequency for drugs, drug plants, which means they are going to go to the top of the list when they get to the inspection system. So today, there is no requirement. The average inspection rate is about once every 10 years, and as we heard, so much of the job is now being done by the States with inadequate coordination with the Federal Government.

So I think there is a lot of room for improvement in these systems and we would be happy to work with your staff on the exact elements that could help improve it. Thank you.

Senator LEAHY. Thank you very much. Ms. Meunier, Ms. Smith DeWaal, Mr. Hubbard, thank you very much. I know all of you have concern in this area. I appreciate you taking the time.

Mr. Chairman, thank you for holding this hearing.

Chairman HARKIN. You are welcome.

I now yield to Senator Chambliss.

Senator CHAMBLISS. Thank you, Mr. Chairman.

Ms. Meunier, first of all, we are glad your son is doing better.

Ms. MEUNIER. Senator Chambliss, I would like to address that. In my experience, when you have such a bad infection—the salmonella causes an infection called *C. diff*, which is *Clostridium difficile*. He got those both at the same time. Is there a possibility *C. diff* was in the food? I ask this question to you and I ask it to the CDC. We do not know enough about the growing concern of *C. diff*, and it is an awful, awful, nasty infection.

Christopher had both as a result of eating these crackers. He was extremely ill and it is going to take a long time for full recovery from this illness. I don't know how other people deal with salmonella, but one of my beefs with keep saying that these salmonella patients have recovered is that is not the truth. Many people have lingering arthritis as a result. My son has arthritis now,

a 7-year-old. It comes and goes. I don't know if he will fully recover from that ever.

So food poisoning, while in some cases can be absolutely intermittent and somebody be totally healed within a week, but not in all cases and certainly not in the case of my son.

Senator CHAMBLISS. Did you have occasion to go online to the CDC website at all during this process, and if so, at what point in time would you have gone on to check for salmonella?

Ms. MEUNIER. I went into the CDC website later on in the process. I was not aware that there was a website. I was doing nationwide searches on my own, just data searches through the web to find out what was going on. So had I known there was a CDC website that I could get information from, I would have gone first and foremost to that website.

Senator CHAMBLISS. OK. So you didn't obviously find out anything about PulseNet early in the process.

Ms. MEUNIER. I read about PulseNet, yes. I also read that I am not sure that every State—I don't know how it interacts in every single State, all 50 States.

Senator CHAMBLISS. OK. Ms. Smith DeWaal, Mr. Hubbard, I appreciate your comment about recall. We can get ourselves into a very difficult situation if we go too far, but yet to not give FDA some authority here more than what they have got, I am just not sure that is the right thing to do, either, and here is my dilemma.

We talked a little bit about this tomato issue last year. FDA identified tomatoes as a source of salmonella last year and issued a warning to all of America, don't eat tomatoes. And this went on for a period of weeks. A month after FDA issued that warning to the American consumer, they made a determination that it wasn't tomatoes at all, that it was peppers that came out of Mexico. If FDA had the authority to recall product on its own, they would have done so immediately, I am sure, and they would have recalled all tomato products.

During that month, the tomato industry in my county and in my part of the country was devastated, lost hundreds of millions of dollars that they haven't received a dime from, and it was not the farmers' fault. Obviously, it was a reaction on the part of FDA, right or wrong. In this case, it was wrong. They used the best information they had.

So my question to you is, how do we really go about thinking from a recall standpoint how much authority we give the FDA and how much leeway should they have relative to this issue of recall?

Mr. HUBBARD. Could I, Mr. Chambliss, defend FDA on that tomato point, if I may? The CDC determines what food they link with a foodborne outbreak, and so CDC instructed FDA that they had determined it was tomatoes through their epidemiological findings and their questionnaire process, which is not an exact science.

About midway through the outbreak, as I understand it from FDA officials, the FDA field folks recognized that there was a disconnect between the growing patterns in Florida and Georgia and other States and the epidemiological findings, and so they went to CDC and asked if they could see the raw epidemiological data so that they could confirm that, in fact, it was tomatoes, because FDA did not believe it was tomatoes at that point. FDA was denied that

information, and so they continued to chase tomatoes fruitlessly for several more weeks. Finally, when they were allowed to turn to peppers, I think it took about 2 days to find the contaminated peppers on the Mexican border.

So the system is clearly flawed in the sense that you don't have the communication and cooperation between State health departments, the CDC, and the FDA to identify the right food quickly. Now, I am sure if CDC were here at this table, they would be explaining that circumstance very differently than I just have. But the point is there was not agreement that it was tomatoes. It turned out it wasn't tomatoes, but a lot of effort went into it.

But to your question on recall, I think if FDA could recall only so-called Class I products where you have a risk of serious illness or death, then I think even the food industry would agree that a recall in those conditions would be acceptable. A recall for, say, a labeling violation would be perhaps something that they would not agree with.

Ms. DEWAAL. Thank you, Senator Chambliss. I think your question really illustrates the importance of prevention to really be our first line of defense. Any time one bad actor, whether they be in Mexico in that case or in the U.S., has a problem, it impacts the entire industry. I mean, I am sure in Georgia right now, they are very concerned about the impact of this one outbreak and this one bad actor on what is happening to sales of their products in the future. So the key is prevention.

When you get to the point of responding to an outbreak, the public health officials have to take the most conservative approach to protect public health and FDA did use the best epidemiology that they had. There is a possibility that tomatoes were grown in that part of Mexico early in the season and then it changed over to peppers. I mean, that is a possibility I have discussed with officials at FDA. So it is possible that there was an early—that tomatoes may have been implicated early because there was actually a link.

But the reality is these investigations are very complex. They are a lot like criminal investigations. They have got to go out and do gumshoe detective work. And the key to legislation that we are promoting in Congress is prevention. Let us get all of these plants, even to the farm level, let us get written food safety plans in place so they can be audited by the State, by the Federal Government, maybe even by the customer. But let us get these plans in place and let these records, the records that support the plans, be accessible to CDC, FDA, USDA when they need them for an outbreak. Thank you.

Senator CHAMBLISS. Your point, Mr. Hubbard, about the fact that this is not an exact science, I mean, you are exactly right. In addition to that, you throw in the complications of the fact that those peppers came across from Mexico and we have got an inspection process, but obviously we are not doing a good enough job there or we would not have had that issue back at that point in time.

I appreciate the testimony of all three of you. You have been very—

Ms. MEUNIER. Senator Chambliss, can I say one more thing? I am sorry for interrupting you. On PulseNet, anything I have read

and anything I heard, and I believe I just heard a doctor say something, there is a huge lag time before something gets to PulseNet and genetically typed, and then afterwards when you get the description of what the foods have been eaten that created the type that went into the PulseNet. And anything I have read speak up to a two-week lag time, and then you are asking people who have been poisoned what they ate 2 weeks ago. And what I have proposed will put a shortening to that time period.

Senator CHAMBLISS. Well, the particular reason I asked you about that is that on November the 10th, there was this monitoring of clusters of salmonella outbreaks around the country that was on PulseNet. Sixteen States were involved. I don't know whether Vermont was one of them or not. But if you had had access to PulseNet, or better yet, your doctor had had access to PulseNet and had gone in and looked at that, or if nothing else put your child's information on there, just imagine what that could have done—

Ms. MEUNIER. Absolutely, and if we were able to have put into PulseNet what he had eaten, everyone would have that information instantaneously.

Senator CHAMBLISS. Yes. Well, I think whether it is recall or whether it is after we discover an outbreak, that there is a huge disconnect and a lack of information sharing. Everything every one of you have said highlights that. We wrestle with this in the intelligence community and we are doing a better job. We have just got to do a better job in the food safety area. So thank you very much.

Chairman HARKIN. Thank you very much, Senator.

Senator Johanns?

Senator JOHANNNS. Just a couple of questions and maybe an observation. I will start with the observation. Having worked with FDA on some really complex food safety issues—melamine would be a good example—I have to tell you my impression was that they were doing as much as they could with the resources available. I really think it is important to focus on how much they can do and how far they can go with the resources at their disposal.

You point out the resources have lessened. I certainly don't debate that at all. That is something we have got to pay attention to on this committee. But that is the observation.

The second thing is a question. I was reading the testimony, and this actually comes from the written testimony of Dr. Sundlof, but I must admit, it gave me a very, very deep concern. Here is what it says. "Peanut butter is sold by PCA in bulk containers ranging in size from five to 1,700 pounds. The peanut paste is sold in sizes ranging from 35-pound containers to tanker trucks. However, through its investigation, FDA has determined that PCA distributed potentially contaminated products to more than 300 consignee firms, many of whom then further distributed products, for consumption as peanut butter or for use as ingredients in hundreds of different products, such as cookies, crackers, cereal, candy and ice cream."

So my question today, what I would ask of you, Ms. Smith DeWaal, where do you feel we are at with the recall? What is your level of comfort with it? Give me a sense of that.

Ms. DEWAAL. Well, thank you, Senator Johanns. We have been expressing concern since the recall was first announced about the

shelf life of these products. I brought in these recalled peanut butter crackers that came out of the pantry of our receptionist at CSPI who is over 60 and was very happy to give them to me. Luckily, she had not eaten them. These products can be in people's kitchens, on their shelves for a long period of time.

We are urging—earlier this week at CSPI, we asked—we are sending an open letter to retailers that have customer loyalty programs to actually send out alerts to people who purchased these products because it is really important that we get them out of people's kitchens, get them out of their pantries.

Peanut butter isn't like spinach or ground beef or many other products which have a natural shelf life. These things seem to last forever. I mean, they probably don't and there is probably a technical shelf life answer, but the reality is for a lot of consumers you buy a jar of peanut butter and you use it for however long until it is empty. So it is critically important that the actions continue.

I mean, a lot of the media alerts, and FDA, I think, and CDC have been trying to do a good job at doing regular media updates and telling the media they are relying on them to get the information out, and I have seen a lot of responsible media. But we have to overcome the fact that consumers don't—consumers think food is safe and they will see a package like that and say, oh, this couldn't hurt me.

So we really have to get it off the shelves. We have to get it out of vending machines. I have more concern in some ways because this outbreak has already killed eight people, caused huge numbers of illnesses, and it could go on. I have got the epidemiologic curve here which many of you have been referring to during your questions, but this could go on for a long time unless we can get—really actively get these products out of—off the retail shelves, but also out of people's homes.

Senator JOHANNIS. There are so many things in this hearing—I am running out of time already—that we can focus on, but I have to tell you, I see it as kind of a triage situation. You are right, this has a long shelf life. We have got product out there. I guess if there is anything I would ask of, whether it is your group, FDA, or whatever, is just to be kept apprised of what we think we are accomplishing in terms of getting dangerous product taken care of and consumers protected.

Senator CHAMBLISS IS RIGHT. You are always trying to figure out the best course of action. These are complex issues. But your testimony indicates how dangerous this can be. A healthy, very young man and all of a sudden is in very, very serious trouble very, very quickly, and you are trying to figure out what the heck went wrong. You can only imagine how dangerous this is for an elderly person that enjoys peanut butter on their toast in the morning. It is deadly.

Thank you.

Chairman HARKIN. Thank you very much, Senator, and again, I thank all of you. This has been very good.

Dr. Sundlof, I am going to have you come back up because I want to ask you some questions about what Ms. Meunier has said and to see if that tracks with some of the things we might want to do.

But I just, both for Caroline and also for you, Mr. Hubbard, I just wanted to—it seems in both of your testimonies, what I get out of that is that we simply have an outdated system here, that whatever worked 50 or 100 years ago just simply isn't working now and it needs to be updated, both in terms of inspections, requirements for reporting, and in your case, Ms. DeWaal, in terms of fines. You pointed out when you have a \$1,000 fine, that is not much of a deterrent at all.

But what I would just like to cover with both of you, and you both kind of covered it in your testimonies, and that is right now, the current method as we have had in the past for FDA inspection involves an inspector showing up at the plant, which just basically is a snapshot in time as to what is really happening. Now we know from what we have done at FSIS with the HACCP system. Should we change that whole paradigm of how FDA operates? You kind of hit on that a little bit, Mr. Hubbard. I wonder if you could just follow up a little bit more on that. Do we need HACCP to go beyond seafood and—

Mr. HUBBARD. Juice.

Chairman HARKIN [continuing]. Juice? Do we need it to go beyond that?

Mr. HUBBARD. Absolutely. I think that is the No. 1 key. These other things, like recall authority, are very helpful. But if we could move toward universal HACCP across the food supply, I believe we would have an exponentially safer food supply, and you would have firms with the incentive to protect their food much more. FDA could then become more of an auditor and not so much of a punisher.

I absolutely believe that, and I think the proof is in the pudding for meat and juice and seafood. We have seen outbreaks going down in those commodity areas. We are seeing better inspection results when the inspectors do go in. And the industry has accepted that as the way to go. In fact, HACCP was developed by the food industry. So in my view, that is clearly the way to go.

Chairman HARKIN. Now, there are some other things you mentioned, also, and that was enforcement activities. Both of you mentioned that. Annual registration of all food facilities. Accreditation of private laboratories. You asked about the private labs and stuff out there. I mean, who are these people? Do we know, and do they report to FDA at all? I am asking that question. Do these private laboratories, when they do something, do they report to FDA? We know now that the plants don't have to report to FDA. I earlier stated that as a big loophole. Maybe there is another loophole here if all these private labs out there don't have to report, either. Is that the case?

Ms. DEWAAL. That is correct. The labs are actually working for the plants, and so there are—unless the government is actually drawing the samples, and those samples would be done by government labs—the sampling that is done by companies, it is all voluntary and they hire the lab and in this case, they seem to send the—if they didn't like the test results the first time, they send it back for retesting and ship the product when the retest was negative. So basically the companies—these are private contractual re-

relationships and the labs have no responsibility to report findings of potentially dangerous products to the government.

In legislation that at least is being discussed on the Senate side, there would be a laboratory accreditation component that has certainly been discussed, and that is something that would certainly help. But we need to build all these records in. These testing records should become part of this mandatory HACCP system or a written food safety plan, however you want to frame it, to make sure that they capture the records that are part of the ongoing food safety monitoring in the plant itself.

Chairman HARKIN. Let me ask one other question. It has been floating around for a long time. It gets introduced as a bill now and then—I think I may have even been on it periodically—and that was to set up a single food safety agency. Some people have said that the FDA, the Food and Drug Administration, really ought to be named the Drug Administration. They spend more of their time on drugs, certifying drugs, overseeing drugs in this country, but very little on food. Maybe we just need one single food safety agency. Do you have any thoughts on that, any of you?

Ms. MEUNIER. I think it is a great idea, sir.

Mr. HUBBARD. Ms. DeWaal will certainly endorse it. I actually spent a lot of time thinking about that in my time at FDA and there are clearly two points of view. The programs used to be together many years ago, and they diverged, and many argue that the drug emphasis in FDA is one of the reasons for the resource shortfall in the food area at FDA, that the commissioners and secretaries and Presidents over the years have made sure drug review got taken care of and it came out of the food side of FDA. And there is actually some empirical evidence to support that point of view.

On the other hand, the FDA is a significant brand name in the United States and if you break it up and create this new thing, is it going to have the credibility and all that the FDA has?

It is a tough call in many ways, and there is also the issue of if you do do it, would you spend all your time moving boxes as opposed to fixing the problem.

Ms. DEWAAL. Let me give you the current thinking on this issue. Ms. Meunier and myself were actually at a bill introduction yesterday on the House side. The current thinking right now is that it wouldn't make sense to create a single unitary agency until we modernize both sides of the house.

Right now, the USDA law is significantly different from the one the FDA is operating under. So it really makes sense to modernize both FDA's legal structure for food and eventually, though it is not really before you right now, the USDA model. And then after that, if it makes sense, you might create a single agency. But it is critically important, and the bill that was introduced by Chairman of House Agriculture Appropriations Rosa Delauro yesterday would take the food components, which you had two people testifying from FDA here today. That is because no one is really in charge of all of the components of food. You take all the components and put them under a new Commissioner of Food Safety or Nutrition who reports directly to the Secretary of Health and Human Services.

Chairman HARKIN. Well, why not just—since the food component at FDA, and I will ask Dr. Sundlof, maybe he doesn't know, it is a smaller part of FDA than the whole drug regime is—why don't you just move that over to the Food Safety Inspection Service? They have a history. They know how to do HACCP. We have been doing it for some years now. Why not do that?

Ms. DEWAAL. Again, it would swallow—you have got two competing legal structures. So for USDA, they have got a lot of resources, but that is because they are required by law to inspect every meat plant every day, and that law is—I mean, I am not hearing that that law is going to change anytime soon. So simply taking the two existing laws and combining the agencies wouldn't actually fix the problems and wouldn't necessarily prevent the peanut butter outbreak.

So what we have got to do is actually build the system at FDA, and you can either do that by keeping everything together at FDA—the brand name is important, and in the proposal the FDA brand will retain, will remain, but it will be the Federal Drug and Medical Device Agency. The FDA will regulate drugs and medical devices and there would be an FSA, the Food Safety Authority or Administration, that regulates on the food side. FSA is actually the name of an agency also in Britain that was formed after BSE really destroyed consumer confidence in their system.

So you really have a proposal that is a very interesting one on the House side. On the Senate side, the legislation that we saw introduced last year, which was bipartisan, did not make that shift. It tries to fix things just within FDA. But I am concerned, Senator, that unless you address this structural problem where Dr. Sundlof is in charge of policy, but you have got someone over at the Office of Regulatory Affairs who actually manages who gets inspected in the food industry, the Commissioner's office manages the budget, until you address the fact that food is really divided into all these different units, we are going to see these problems continue.

Chairman HARKIN. Well, I don't know. I am not certain I have a firm view on that myself, either. It just seems to me that there are just too many pieces out there and no one is really paying much attention to food safety in the beginning, aside from the recall problems and public knowledge right away of outbreaks and things that you pointed out, Ms. Meunier.

Are you familiar with—the FDA has advanced the Food Protection Plan as a framework to improve food safety. The GAO has expressed concern that the plan does not contain enough specific information to assess whether it would improve FDA's food safety program. Are you familiar with it, and what do you think, any of you?

Mr. HUBBARD. Well, it is a broad sort of road map for improving food safety. I think it is fine. It is not—there is no money attached to it to do anything more. There are no specifics, as you say. There are no particular regulations that would be promulgated or new procedures. So it is fine as a very broad general goal, but it would need a great deal of implement to implement, in my opinion.

Ms. DEWAAL. The one element that I would want to bring to your attention in the plan, because I think it is a fine plan, but it really focuses on what FDA considers high-risk facilities. I can tell

you, PCA was not considered a high-risk facility because peanut butter generally isn't. So it is—and FDA also really doesn't have the data that it would need. I mean, you know there has been controversy on this concept of risk-based inspection over at USDA. Well, they have a much more robust data set to support that than FDA has to support its decision about high-risk versus low-risk facilities.

Chairman HARKIN. One last thing. If there had been a HACCP plan in effect at this plant, how confident are you that that would have prevented this salmonella contamination?

Mr. HUBBARD. If there was a functioning HACCP plan, I think it would absolutely have because the firm would have identified salmonella as one of the likely risks to peanuts and peanut butter. The firm would have made sure the peanuts were roasted to a high enough level so that they were clean at the time they went into the processor to make the peanut butter. And their equipment would have been cleaned periodically. The skylights would not have leaked. The roof would not have leaked. The roaches would not be there. The rodents would not be there. And you would not have had the contamination. And therefore, in my opinion, a functioning HACCP plan would absolutely have prevented this problem.

Ms. DEWAAL. It also would have given the State inspectors a lot more to go on during their inspection. They could have walked in. They could have seen the plan. They hopefully would have seen the test results. But they also could have looked at the plant itself and seen that it wasn't actually living up to its HACCP plan.

Chairman HARKIN. Thank you. Thank you all very, very much. I appreciate your coming here, your testimony, and you are right. *C. diff* is—I have been looking at this for some time now—

Ms. MEUNIER. It needs to be looked at further, I think.

Chairman HARKIN. I will tell you, it is getting more and more around the country—

Ms. MEUNIER. Yes. There is something called community-acquired *C. diff* out there, and I read some analog yesterday that said it may possibly be in food now. So my concern is, was it in this cracker? I don't know. We do not know how he got it.

Chairman HARKIN. Thank you all very, very much.

I would like to ask Dr. Sundlof if you could just come back to the table, please. I just want to follow up just on a couple of things with you here.

Senator CHAMBLISS. Let us get Dr. Khan.

Chairman HARKIN. Oh, yes, Dr. Khan, Admiral Khan from CDC.

I just wanted to cover again, you heard the testimony of Ms. Meunier. I have been reading it over and I can just sense the frustration that she must have had at that time. You have this sick child, and trying to get information and trying to find avenues of accessibility.

Now, she did say that when she found the FDA, she said, "thankfully, I found someone willing to listen. Unfortunately, it was the weekend and that Monday was a holiday, so no one could pick up the crackers until Tuesday. However, in a shocking twist, the woman I spoke with at FDA then also wanted to give me a questionnaire about all the foods Christopher had eaten, all the same information I had already given to CDC. I don't understand why

the various agencies working on this outbreak did not already have this information and how they can share it.”

And then it was all phone call. I wrote a note here, no e-mail? Is there any way that you can get e-mail out on this? It seems to me such a simple thing. How do you respond to that? Is this something we should be thinking about doing at FDA?

Mr. SUNDLOF. We are always looking for better ways of communicating, and every time we go through one of these situations, we find more ways. So we are taking advantage of a lot of new technologies, things that I don't even know what they are, but we are doing something called Twitter. We have bloginars. All of these are strange terms to me. But we feel it is extremely important to get the information out to people who need it.

When we had the melamine situation, we were trying our best to reach out to the Asian community in the event that infant formula from China came into the United States. Since the salmonella St. Paul in peppers outbreak, we have held high-level meetings with CDC just to talk about how we can communicate better and how we can get our message out.

In this particular outbreak, we were concerned about people who didn't have access to the Internet, and that is especially prevalent in our senior citizens, who have not grown up with this technology, and how do we reach out to those people? CDC has an information hotline where they are actually encouraging people who don't have Internet access to call their information hotline so that they can look up the list of recalled products.

I certainly agree that communication in these situations where we need to get information out quickly to people is paramount in limiting the scope of the disease and we will continue to work toward that.

Chairman HARKIN. Well, it just seems to me that Christopher's doctors, they now have salmonella. They have asked for the—I don't know if they did, but they could ask if there is any outbreak of a possible foodborne pathogen, what did you eat, and all they have got to do is enter that into a data base someplace. There should be software that would take that. All of a sudden, it flares up on your system. Oh, Christopher may have eaten five or six or seven things that day, and someone in Minnesota ate five or six or seven things and somebody else ate, but all of a sudden they all ate something dealing with peanut butter and that would flag it right away. It seems to me a software program like that is not very difficult to design. I ask both of you that.

Mr. SUNDLOF. I don't disagree. I would defer to Admiral Khan because these are the kinds of information that CDC handles.

Chairman HARKIN. This is something that I would think CDC would have out there.

Admiral KHAN. Thank you, Dr. Sundlof, and thank you, Mr. Chairman. A couple of comments.

First, let me clarify dates. So even though there were cases in September and October, we didn't hear about them until November in PulseNet, and that again goes back to these delays.

Now, back to Ms. Meunier. I really want to thank her, what as an epidemiologist I call as a case or as a doctor, I call a patient

really as a person, an individual who got sick with a disease and tragically, it sounds like, has some complications from that disease.

I also want to congratulate her and you on the comment about the solution. We really need to get better with this time line. How do we shorten these delays? And it is really about these new tools that allow us to do it, and there are numerous new tools, as I outlined before, communication, information tools that would allow us to do it.

And finally, I am quite disturbed that she tried to contact somebody at the CDC and was not able to. We do have a system that allows people to do so.

But the heart of this issue is communications, and we are doing a lot of innovative things with communications, such as you have said, blogs and Twitter and widgets that go onto websites, podcasts, and it is disturbing that people do not recognize that the CDC website is available for information. We have been careful about centralizing information. All the recall information is at one site, so you don't need to go to 100 different sites. You are not getting different messages. You are getting a single consistent message every time.

Chairman HARKIN. OK. Is there—is this site someplace where a local pediatrician or doctor could go in there right away and input some information right away and it goes into a system that is colated with all the other information that is coming in? Is there such a site?

Admiral KHAN. No, sir, and that goes back to the tools we need. Those would be tools at the State and local level that currently do not exist so that if there is an individual who has an unfortunate diagnosis of one of these illnesses, right away, while their memory is fresh, you can get a full history questionnaire completed on them, and then as you log many of those together, you can look for the association then amongst the people who are ill and connect that to your laboratory patterns in PulseNet and go, voila, this is what the connection between those two are. So these are new tools that are needed at the local, State, and national level.

Chairman HARKIN. Well, I am going to be interested in following up on that with CDC. Would you be in charge of that at CDC? Would that be under your jurisdiction?

Admiral KHAN. Sir—

Chairman HARKIN. I want to know who is responsible. Who can I continue to talk with about this?

Admiral KHAN. You can continue to contact us in the National Center for Zoonotic, Vector-borne, and Enteric Diseases.

Chairman HARKIN. Well, because I am. I am going to write a formal letter to you at CDC outlining this and asking how you would structure such a system and when it could be implemented, how much would it cost, do you have the wherewithal to do it.

Admiral KHAN. We would be glad to respond to that request, Senator.

Chairman HARKIN. That really gets to the heart of what Ms. Meunier was talking about, is getting information in immediately, making sure it is correlated with all other information from other parts of the country, to flag these as soon as possible. And then

they could go on that site and see, well, are there other people having the same diagnosis, for example,

That is really what I wanted to cover with them. I don't know if you want to go into anything.

Senator CHAMBLISS. I just have one quick question. Admiral Khan, do you know whether or not on November 10, when PulseNet revealed this cluster of outbreaks within those 16 States, whether or not Vermont was one of those 16 States?

Admiral KHAN. Sir, I do not have that in front of me, but I will be glad to get back to you.

Senator CHAMBLISS. If you could explore that information. And just to further one of Senator Harkin's points there, it ought to be pretty easy to have some sort of software system there to where a physician in any emergency room that is treating a patient for a potential salmonella poisoning or infection could go to a CDC or an FDA, there ought to be some centralized website, but could pull up other cases that might be taking place around the country, and most importantly, to input information that they pick up in that emergency room from that patient.

This is one of the things that it ought not take legislation to do. There is no reason CDC and FDA, and you may need to involve some other agencies, I don't know off the top of my head who, but maybe the VA or somebody that is within the government that is a health care system, but there just ought to be some sort of central data bank for information like this. It just looks like it would go a long ways toward preventing a nationwide outbreak that extended from 13 States to 43 States.

Thank you.

Chairman HARKIN. Well, thank you very much, Senator Chambliss.

Thank you all very much for being here. Again, I hope we don't fall into what Mr. Hubbard said, we just continue to have these hearings and have these hearings and not much seems to happen. Something has got to happen here. I am encouraged by what President Obama said on Monday. He promised, quote, "a complete review of FDA operations." Quote, "I think that the FDA has not been able to catch some of these things as quickly as I expect them to catch," Mr. Obama said in an interview on the "Today" show.

So hopefully, with the executive branch and with Congress, we can make some changes that will both, again, prevent—that is why the HACCP thing. We have got to think about prevention first. Even with that, once in a while things are going to happen and then we need the quickest possible information to parents and to our medical community out there to get that information out and then to get it to FDA as soon as possible so that recalls can happen.

But I also think there are some of these other loopholes, in terms of accreditation of these private labs that are doing it, a requirement that they have to report to you if they find any foodborne pathogens, that they have to be required to report that to FDA along with any other State agency. If they have to report it to the State agency, they can send a copy to FDA.

These are things, at a minimum, that we ought to be doing, I think. The broader picture, of course, is resources for the FDA and

what that is going to require. That is another thing we are going to have to wrestle with.

But thank you all very much. This has been a very enlightening hearing. You have been great witnesses and we appreciate your being here and your testimony and we look forward to working with you in the future. Thank you very much.

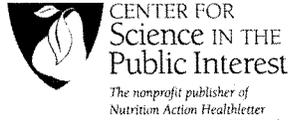
The committee will stand in recess.

Admiral KHAN. Thank you, Senator.

[Whereupon, at 12:37 p.m., the committee was adjourned.]

A P P E N D I X

FEBRUARY 5, 2009



Testimony of Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest
before the
Senate Committee on Agriculture, Nutrition, and Forestry

Washington, DC
February 5, 2009

Good morning Mr. Chairman, Ranking Member Chambliss and Members of the Committee. My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 950,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

The Time to Repair our Food Safety System Is Now

Thank you for asking me here today to discuss the lessons learned from the latest food-borne disease outbreak linked to peanut products produced by the Peanut Corporation of America (PCA). Let me say that the first lesson we have learned is that the American public cannot wait any longer for solutions to address a seriously broken food safety system.

Over the last two years Congress has conducted seventeen oversight and legislative hearings on food safety that followed outbreaks caused by spinach tainted with *E. coli* O157:H7, peanut butter contaminated with *Salmonella* Tennessee, canned chili sauce with deadly botulism spores, and pet food containing ingredients intentionally adulterated with melamine. In every case, the hearings revealed flaws both in the food manufacturers' processes and in the Food and Drug Administration's oversight. With evidence of both unintentional and intentional

contamination leading to large-scale outbreaks, it is little wonder the Government Accountability Office has highlighted the inadequate state of our food regulatory system and placed food safety in its high risk category three years in a row.¹

Successive outbreaks caused by tainted spinach, lettuce, salad mixes, tomatoes, peppers, pot pies, peanut butter, ground beef, chili sauce, and now numerous products made with contaminated peanuts have demonstrated that our hundred-year-old legal foundation and outdated strategies are inadequate to protect our citizens. Twenty-month-old “CJ” Minto from Mobile, Alabama, contracted *Salmonella* poisoning after eating peanut butter cracker sandwiches that are now part of the recall.² CJ’s symptoms continued for two weeks, including one week when the child was unable to eat. He was treated with antibiotics for nearly constant diarrhea and vomiting until he resumed eating. Believe it or not, CJ was luckier than some. Shirley Mae Almer was a 72-year old survivor of cancer surgery and radiation therapy. Her family planned to bring her home from a nursing home for Christmas, but she died on December 21 from salmonellosis linked to the peanut butter. A family member said that the death seemed so ironic, “With all the battles she overcame- to have a piece of peanut butter toast take her.”³

The evidence that FDA reform is needed has been crystal clear in Congressional hearings, victims’ stories, and stakeholder agreements. I think you will hear from all the witnesses today that the time for reform is now. Let’s begin. And, let’s get it right.

¹ Gov. Acct. Off., *High Risk Update: Revamping Federal Oversight of Food Safety*, Rep. No. GAO-09-271, Jan. 2009.

² Jane Akre, *Salmonella Victim Speaks Out*, Injuryboard.com, Jan. 30, 2009, at <http://www.injuryboard.com/national-news/salmonella-victims-speak-out.aspx?googleid=256366>.

³ David Shaffer, *Heartbreak Lawsuit: The Family of a Perham, Minn., Woman Who Died of a Salmonella Infection is Suing a Peanut Butter Manufacturer and Asking for Safer Food*, Minn. Star Tribute, Jan. 27, 2009.

Peanut Corporation of America Is the Latest Proof of a Broken Food Safety System

The outbreak of *Salmonella* Typhimurium started in September 2008. The illnesses peaked in December 2008, affecting consumers in 43 states. Though the illnesses have declined since the first announcement on January 10, 2009 that the suspected cause was peanut butter, they have not abated. The *Salmonella* strain has been linked to contaminated products from Peanut Corporation of America. As of January 29, 2009, there have been eight deaths and 550 illnesses linked to PCA's products.⁴

The Peanut Corporation of America supplied peanut butter to nursing homes, schools, hospitals and other institutions, and made peanut paste which became an ingredient in many products. Starting in June 2007, PCA's Blakely, Georgia plant began detecting *Salmonella* in its products and over the next year had 12 occasions when it shipped products that had initially tested positive for *Salmonella*. In each of these 12 separate occasions, instead of addressing the source of the contamination, PCA retested its products to obtain a negative result and then shipped the product.

During this same period, Georgia state inspectors, acting under contract with the FDA, detected a number of violations, but the tests conducted by the state in 2007 failed to detect any contaminants. Georgia inspectors were apparently unaware of the company's own positive tests.

In April 2008, Canada rejected a shipment of peanuts from PCA as unfit for food. PCA attempted to clear the peanuts for sale in the U.S., but FDA rejected its test results and eventually the peanuts were destroyed. FDA did not follow up with an inspection of the plant.

During this period, PCA distributed the contaminated products to more than 100 consignee firms. The peanut paste was used as an ingredient in hundreds of different products,

⁴ Centers for Disease Control, *Investigation Update: Outbreak of Salmonella Typhimurium Infections, 2008–2009*, (accessed Feb. 3, 2009) at <http://www.cdc.gov/salmonella/typhimurium/update.html>.

such as cookies, crackers, cereal, candy, and ice cream.

What Must Be Done to Repair Our Food Safety System

The PCA outbreak – like countless episodes in the previous decade – illustrates numerous failures and areas where improvements are needed. The company seemed to have had no food safety operating plan. The company did not respond appropriately to repeated positive *Salmonella* findings. The state of Georgia failed to provide effective inspection, in part because they lacked full access to the plant's food safety records, and FDA failed to provide oversight for the state inspection program. In fact, even when FDA received a clear signal of problems in the plant from its own import alert system, the agency failed to send out inspectors to conduct a review of the plant. Finally, the penalties available to FDA to prosecute the company are not adequate to deter future violations of the Act.

1. Absence of a Food Safety Plan and Response to Positive Test Results

The heart of any effective reform effort lies in prevention, not response. Congress should require every food plant regulated by FDA to have food safety plans detailing that it has analyzed its operations, identified potential hazards, and is taking steps to minimize or prevent contamination. This Hazard Analysis and Critical Control Points (HACCP)-style planning is already a requirement for all meat and poultry plants, and it should be a prerequisite for all food processors that want to sell food in the U.S. This establishes the industry's fundamental responsibility for ensuring food safety and provides a foundation for the government audit inspections. However, the history of these programs in the seafood area demonstrates that Congress must also give FDA the authority and funding to enforce compliance through regular inspections and access to company records.

Additionally, FDA needs the authority to set performance standards for the most

hazardous pathogens and to require food processors to meet those standards. The standards are used to ensure that food is produced in a sanitary manner that limits the likelihood of contamination by pathogens, chemicals, or physical hazards, like glass or metal. In the case of PCA, performance standards would have provided inspectors with a benchmark for regular sampling of products.

The approach of HACCP planning combined with performance standards would focus food safety activities on prevention and would permit more efficient and effective government oversight through analysis of records as well as visual and laboratory inspection.

2. The State of Georgia and FDA did not provide effective inspection oversight

The failures to detect and correct the unsafe practices at PCA highlight how FDA's infrequent inspections (averaging one visit in 10 years)⁵ and the agency's oversight of state-contracted inspections contribute to illness outbreaks. FDA hadn't inspected the PCA plant in eight years. Meanwhile, press reports show inspections by the Georgia Department of Agriculture found minor violations that may have pointed to larger problems. It's particularly troubling, though, that the FDA didn't seek either the company's records or the Georgia inspection reports – information that might have prevented the outbreak from occurring - even after it found that some of the products had been rejected by a firm in Canada.

To address these problems, legislation should set specific inspection frequencies for all food plants. Higher-risk foods should be inspected at a greater frequency, preferably no less than annually, with lower risk food facilities being inspected at least once in any two year period. Those inspection rates would still be well below the rate established for restaurant inspections of

⁵ House Comm. on Gov't Reform, *Fact Sheet: Weaknesses in FDA's Food Safety System*, (Oct. 30, 2006), at <http://oversight.house.gov/documents/20061101115143-67937.pdf>.

once every six months.⁶ Setting frequencies will require a commitment to fund the agency or find new resources, and some legislative proposals have established a modest registration fee to offset the costs associated with increased inspection oversight. Current FDA funding shortfalls have reached a critical level, leaving the agency with fewer inspectors, even as the workload continues to increase. Since 1972, domestic inspections conducted by FDA declined 81 percent.⁷ Just since 2003, the number of FDA field staff dropped by 12 percent, and between 2003 and 2006, there was a 47 percent drop in federal inspections.⁸ Just those declines in inspectors and inspections can be traced to an ongoing funding shortfall in the food safety program estimated in the hundreds of millions of dollars.⁹

FDA and state inspectors are also hampered in conducting inspections by restricted access to plant records that could have identified problems at PCA. After the outbreak, FDA obtained records of 12 tests that were positive for *Salmonella* in the year leading up to the outbreak that had not been disclosed to inspectors. PCA was within its rights under current law to refuse to disclose the tests even if asked by inspectors in the plant. This is because inspectors cannot access records unless the requirements of the Bioterrorism Act are met and the inspector presents a written demand.¹⁰ We saw this same situation play out in the 2007 Peter Pan peanut butter outbreak where, had inspectors been given access to test records, they would have been alerted to test the plant for *Salmonella*.¹¹ Even after the PCA outbreak was ongoing, the FDA

⁶ Center for Science in the Public Interest, *Dirty Dining: Have Reservations? You Will Now.*, 2008, at <http://cspinet.org/new/pdf/ddreport.pdf>.

⁷ *Id.*

⁸ Andrew Bridges & Seth Borenstein, *AP Investigation: Food Safety Inspections Languish*, Associated Press, Feb. 29, 2007, at <http://abcnews.go.com/Health/wireStory?id=2905819>.

⁹ FDA Science Board Subcommittee on Technology, *FDA's Mission at Risk: Estimated Resources Required for Implementation*. Feb. 25, 2008.

¹⁰ 21 U.S.C. § 374(a)(1)(B); FDA, Regulatory Procedures Manual 2008, § 10-4-3.

¹¹ Two years before the outbreak, the plant manager refused an oral request from FDA inspectors to see company records of a positive *Salmonella* test telling them they would need a written request. Marion Burros, *Who's Watching What We Eat*, N.Y. Times, May 16, 2007, at <http://www.nytimes.com/2007/05/16/dining/16fda.html>.

had to invoke the Bioterrorism Act to access PCA's records. This is unacceptable. To fix this, the law needs to be changed so that inspectors during routine inspections have access to the results of tests conducted by the plant. The ability to access plant food safety records during inspections is an essential tool to identifying problems. As it turned out, PCA, instead of fixing the problem, fixed the tests, something FDA could have determined had it been given access to the records.

With regard to the shortcomings in state inspection, we must avoid drawing the wrong conclusions. Instead of illustrating that Federal/State cooperation is unreliable, the PCA example argues for improving federal oversight of and assistance to state inspectors who are used to leverage resources for inspections.

In addition to leveraging inspection resources, state health departments are the front line for detecting outbreaks. The Minnesota Department of Health with its innovative approach to epidemiology determined that peanut products were the source of the outbreak. Yet, many states do not have the resources to establish programs modeled on Minnesota's. Congress needs to strengthen the state inspection and surveillance system by providing assistance through training and grants.

While federal and state inspections and surveillance can be improved, they will never be perfect. Congress also should consider leveraging concerned citizens as a means of detecting and preventing situations that can lead to outbreaks. We should protect responsible citizens who come forward to reveal hazards that could affect public health. Whistleblower protections would prevent bureaucratic and corporate hazing of workers to prevent them from coming forward with information about misconduct. We cannot know whether a concerned worker may have come forward in the case of PCA to reveal the positive tests had he or she been protected from

retaliation. But all necessary tools to prevent a similar outbreak should be considered.

3. FDA does not have effective penalties for PCA and for deterring similar actions by other companies

The punishment for committing a prohibited act under the Food, Drug and Cosmetic Act is up to a year in jail, a \$1,000 fine or both.¹² This punishment, which may have been substantial in 1938, has not kept pace with the modern commercial world. Compared to PCA's annual revenues of \$17.5 million¹³ it is hard to see how a misdemeanor fine serves as an incentive for companies to improve their food safety practices. With over 500 people reported sick, more than 100 hospitalized and eight dead as a result of PCA putting contaminated product on the market, such trivial fines – even if found for numerous violations – do not appear fair.

Criminal liability is also a burden on the agency inspectors, as it must conduct a criminal investigation, coordinate prosecution with the Justice Department, and then go through a criminal trial to recover a fairly modest fine or sentence a culpable individual to a misdemeanor jail term.¹⁴ Another approach Congress should consider is to provide the agency with authority to impose substantial civil penalties that can get the attention of managers and be sustained if violations are continuous. Civil liability provides a flexible deterrent to corporate misconduct that can be tailored to the violation. These remedies are available for addressing violations on the drug and device side of FDA, but not the food side except for illegal pesticide residue.¹⁵ It is time to bring FDA's penalties for food violations in line with what is used for drugs and medical devices.

¹² 21 U.S.C. § 333(a)(1).

¹³ Peanut Corporation of America Company Profile, Bizjournals.com, (accessed Feb. 3, 2009), at <http://www.bizjournals.com/gen/company.html?gcode=904819E282CB4C8B9DAE476F9A3F632D>.

¹⁴ For a description of FDA's procedures for prosecuting a case see section 6-5 of the Regulatory Procedures Manual, *supra*, note 9.

¹⁵ Civil penalties for pesticide residue are found at 21 U.S.C. § 333(f)(2).

4. FDA does not require effective traceability systems, and lacks adequate authority to protect consumers by detaining and ordering recalls of unsafe food.

The ability to trace products and their ingredients is essential to speeding up response when an outbreak occurs. Under the Bioterrorism Act, food companies must maintain a record of the immediate previous source and the immediate subsequent recipient of food.¹⁶ The effort to identify the source of the PCA outbreak illustrates areas where traceback could be improved.

The process of determining the source of an outbreak is difficult and time consuming. The Minnesota Department of Health has one of the best epidemiology programs in the country. Faced with nine reports of *Salmonella* poisoning in the State, the department began interviewing victims and comparing data to find a source. The interviews turned up peanut butter, but because PCA provided ingredients to many manufacturers, the epidemiologists could not identify a single brand. As one investigator said, “We had a lot of peanut butter eaters, but none of the brand names were matching up well.”¹⁷ A traceability systems that requires processors to recorded the sources of ingredients and provide those records to investigators could have turned up the correlation between the various brands and their single supplier, PCA.

While all of the companies involved in the peanut recall have acted responsibly, CSPI continues to believe that giving FDA authority to order a recall if necessary is a critical tool for responding to future outbreaks. Today, when you see the notices of the recall, they often mention that it is voluntary. Unfortunately, while true, this may not compel consumers to act with urgency, because they might reason “If it were serious, FDA would issue a mandatory recall.”

¹⁶ 21 U.S.C. § 350c(b).

¹⁷ Gardiner Harris & Pam Belluck, *New Look at Food Safety After Peanut Tainting*, NY Times, Jan. 3, 2009.

Conclusion

President Barack Obama has promised a "government that works," and recently promised a complete review of the FDA's food safety program. Luckily for the President and the public, Congress has been investigating problems at the FDA for several years, and many elements of a reform plan are "shovel ready" – they could be accomplished quickly and deliver real benefits to consumers.

But to deal with the root of the problem, Congress and the Obama Administration will need to go beyond giving the FDA more authority and funding. Structural reforms are also essential. Although the FDA is responsible for the safety of 80 percent of the food supply, the FDA's commissioner must divide his or her attention among drugs, medical devices, foods and cosmetics – and food issues frequently fall to the bottom of the pile. Food responsibilities are divided among at least three centers within the FDA, and there is no single food safety expert in charge of the policies, budget and enforcement staff. This means there is no credible voice communicating to the public and the industry what can be done to prevent outbreaks.

It is time to elevate the food monitoring function within the Department of Health and Human Services, which oversees the FDA. The agency needs to be divided in two, with a new Commissioner of Food and Nutrition Policy who reports directly to the HHS Secretary. Food safety functions under the Department of Agriculture have this sort of direct reporting, leading to greater involvement by the Secretary of Agriculture when problems arise in the meat area.

Now is the time for Congress to fundamentally reform and fully fund our food safety system. Enactment by the end of this year should be the goal. Two years ago, Congress expressed its commitment to adopt a modern regulatory oversight program and fund it adequately to fulfill its mission in the Food and Drug Administration Amendments Act of

2007.¹⁸ Bipartisan legislation introduced in the Senate in the last term of Congress further demonstrated readiness to address problems with FDA's food program. That bipartisanship emerged at the same time coalitions of traditionally estranged consumer and industry organizations, like the Alliance for a Stronger FDA, are appealing to many in Congress to rebuild the agency. With both the public and the regulated industries clamoring for change there is no reason to delay. Preventing future illnesses and deaths – future CJs and Shirley Maes – is within our grasp.

¹⁸ Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85 § 1005, 121 Stat. 823, (2007).

Statement By

William K. Hubbard

Alliance for a Stronger FDA

Before the

Committee on Agriculture, Nutrition and Forestry

United States Senate

Washington, DC

February 5, 2009

INTRODUCTION

Mr. Chairman and members of the Committee, I am William K. Hubbard. Before my retirement after 33 years of Federal service, I served for many years with the U.S. Food and Drug Administration, and for my last 14 years was an FDA Associate Commissioner responsible for, among other things, FDA's regulations and policy development. Today, I serve as an advisor to The Alliance for a Stronger FDA, a consortium of patient, public interest, and industry organizations whose mission is to urge that FDA's appropriations be increased. The Alliance and its constituent members are greatly concerned that FDA's resource limitations have hampered the agency's ability to ensure the safety of our food and drug supply. Today's hearing is focused on the recent salmonella outbreak that been so costly to the public, and on what directions our food regulatory system might go to prevent further such outbreaks. I commend the Committee for your effort to shine light on this problem and possible solutions.

BACKGROUND

As you know, Congress established the Food and Drug Administration in 1906 as a result of concerns about the safety of our food supply. In those days, it was common for foods to be subjected to all manner of problematic practices—filthy, unsanitary conditions were common in food processing facilities; talcum powder, sawdust and many other contaminants were added to deceptively increase the weight or value of foods; and chemical preservatives were used in food that were untested and often highly toxic. As the 20th Century progressed, FDA's scientists and those in the emerging food processing

industry slowly built a food safety infrastructure for the United States that enabled us to claim that we had the safest food supply in the world. And the standards established by the FDA for the production of safe foods became the model for protection around the globe. Throughout the last century, there was steady progress in the food safety system – in learning how to protect food from contamination and in implementing procedures to translate that knowledge into safer food production. But, unfortunately, that record of progress appears to have largely ground to a halt, at least when it comes to the ability of FDA to effectively oversee improvements in food safety, and the limitations under which FDA attempts to do its job have been dismayingly exposed.

And that slowdown in FDA's role –some would even say reversal – has come at the worst possible time. That is because today the need for effective management of food safety is greater than ever before, as evidenced by:

- The emergence of new pathogens, some unknown to science in years past, such as E Coli 0157:H7, that are especially lethal when they contaminate our food;
- The substantial public health and economic costs imposed on our society from the steady – and increasing – numbers of foodborne disease outbreaks in the United States;
- The steady growth in the number of domestic food producers and, even more importantly, the tremendous increase of imported food from other countries --

particularly developing countries in Latin America and Asia, where food safety standards are often lax or unenforced; and

- The increasing complexity of our system of food production and distribution, which often necessitates the movement of food across long distances and through many hands and into many finished products.

THE SALMONELLA IN PEANUT BUTTER OUTBREAK

The occasion for this hearing is, of course, the recent (and perhaps ongoing) series of cases of Salmonella Typhimurium linked to peanut butter. With hundreds of illnesses, and several deaths, reported, and many more likely not documented; the recall of a wide variety of food products made by many different producers; and widespread consumer anxiety about a food commonly consumed by our children, including our new President's daughter, it is a significant event in our national life.

The questions raised by this outbreak are numerous:

- 1) Is the Federal government properly organized to manage an outbreak of this nature?
- 2) Are the various governmental entities involved in foodborne disease outbreaks – Federal, state, and local – adequately coordinated?
- 3) Does FDA have the necessary authorities and resources to prevent such contaminations and outbreaks from continuing?
- 4) Are state food inspectors properly trained and managed to insure effective partnership with Federal food safety efforts?

5) Are FDA and industry processes for tracing the source and destination of food products adequate to ensure rapid recall of contaminated food?

I suggest, Mr. Chairman, that we, as a nation, have not demonstrated that we take the threat to our food supply seriously. We talk a great deal about the need to improve food safety, and wring our hands over each major outbreak that occurs, costing lives and industry resources. But our actions have not been consistent with our rhetoric. Let me explain.

TOLL OF FOODBORNE ILLNESS

As you know, the Centers for Disease Control estimate that 76 million Americans contract a foodborne illness each year. Of those, 350,000 are hospitalized, and 5,000 die. That means that we are losing the equivalent of the World Trade Center attack every 8 months, yet many, if not most, of those deaths are preventable. And beyond the obvious human suffering, and the associated economic costs to sickened consumers, there are tremendous economic costs to food producers. The 2006 spinach outbreak, for example, resulted in the destruction of much of that year's spinach crop and cost producers an estimated \$100 million; and last year's tomato/pepper outbreak resulted in producer losses in the hundreds of million of dollars. In fact, it is estimated that the overall negative economic impact of foodborne illness in the United States may be as high as \$83 billion per year. Worse yet, these repeated outbreaks and their attendant publicity paint a picture, erroneously I believe, of a food industry that cannot assure safe products. Indeed, after the spinach outbreak, the government of Mexico – a nation derided in the

past as the home of Montezuma's Revenge – announced it would evaluate whether American produce was safe to import into Mexico. And this is happening at a time in which one of America's few remaining sources of a positive trade balance is our food exports.

FDA'S FOOD SAFETY SYSTEM – BROKEN BEYOND REPAIR?

"FDA does not have the capacity to ensure the safety of food for the nation." Those are not my words, but rather the summation last year of FDA's Science Board, an advisory committee of experts from many fields of study. And that conclusion has been echoed by a cascade of expert reports in recent years, by the Institute of Medicine, the Government Accountability Office, the HHS Inspector General, the National Academies of Science, and several Congressional committees. All of those studies have concluded that the FDA regulatory system, as currently constructed, simply cannot adequately oversee a large and diverse food production system within its current structure and resources.

Let me give you just a flavor of the metrics by which FDA's inability can be counted. When I arrived at FDA in the 1970s, the Official Establishment Inventory of food facilities subject to regulation was about 70,000, and FDA was able to inspect each of those facilities every other year (that is, 35,000 inspections per year). Today, the OEI is 150,000, and FDA conducts about 7,000 inspections per year. This means that FDA can realistically inspect only the 6,000 or so facilities that are designated as "high risk," meaning that most food facilities never see an FDA inspector. [Peanut butter has not

been considered a high risk food.] Attached is a chart illustrating the dramatic decline in food inspections since the 1970s.

This also means that in the days when FDA's food program was adequately resourced, FDA would have likely inspected the Blakely, Georgia peanut butter processor with some regularity, but today the chances of FDA routinely visiting that facility are virtually nil. And, of course, it further means that there could be, and likely are, many other facilities around the country with similar problems awaiting their turn in the limelight.

The more recent history of FDA capacity is even more disheartening. In 2003, FDA had just over 4000 field investigators and compliance officers to inspect our food facilities and track down problems like the current salmonella outbreak (as well as inspect drug and medical device facilities). Entering 2008, that force had been reduced to 3354, a loss of almost 700 inspectors. The cadre of food scientists in FDA headquarters underwent a 20% reduction during that time (from 950 to 782). And this occurred as the number of foodborne disease outbreaks more than doubled. These recent trends are part of a larger scenario over many years, in which we have declined to provide the FDA with robust capacity to oversee the safety of our food. And, of course, none of this counts the 216,000 foreign facilities making food for our market, of which FDA inspects only about 100 per year.

AN INEFFECTIVE PARADIGM

I will not dwell on FDA's resource woes; they have been well documented and are indisputable. The more important point is that the resource shortfalls are secondary to the real problem, which is that FDA's food safety system is a relic of the 19th century, one that should have been discarded years ago.

Let's look back to FDA's origins, in the dawn of the 20th century. Americans grew much of their food, and food that was purchased tended to come from a nearby source, such as a farm near the consumer's home. Processed foods were relatively few in number, and tended to be staple goods, such as molasses, flour, and sugar. Some of the most lethal bacterial "pathogens" that worry us today, such as E Coli 0157:H7, were unknown to nature and thus no threat to humans. The "state of the art" method of ensuring food safety was the visual inspection by a government official of food processing facilities and the products emanating from them. Imports were few, and were also mostly staple goods. An inspector could easily open a barrel of flour and examine it for insect or rodent infestation, mold and mildew, and other signs of contamination. So Congress embodied that concept into the original Pure Food and Drug Act. Itinerant Federal inspectors could visit facilities and examine their overall sanitation as an indicator of safe food production. With new provisions added in 1938, those inspectors were given enforcement tools believed to be adequate for the day – prosecution of the business's chief executive, an injunction against the business to stop it from selling contaminated food, and authority to seize food found to be contaminated.

Meat, on the other hand, was considered a far riskier food in those pre-refrigeration days. That concern, combined with the need to assure export markets that U.S. beef was free of brucellosis and hoof and mouth disease, prompted Congress to require a continuous inspection model for slaughter facilities, in which Federal inspectors examine and provide a Federal stamp to every meat product as it is processed; that system remains largely unchanged today.

While the meat inspection program also has its critics, the FDA food safety system has been determined to have severe flaws in its conception and implementation, in the context of the modern world, viz.,

- It is a system with random success. That is, it relies on the infrequent inspection by FDA (or perhaps a state inspector) to identify and correct deficiencies in a processing facility;
- Each FDA inspection is only a “snapshot” of the condition of the food processor the day of the visit, thus it cannot assure that the facility is operating safely at all times;
- There are few true standards by which most food processors can be judged. FDA has general “sanitation” regulations, but has not been empowered to set food-specific requirements to which producers should adhere;
- It does not take advantage of state-of-the-art food protection mechanisms (e.g., HACCP) that industry leaders have developed and implemented in recent years;
- Food safety inspections and oversight by state and local authorities are inadequately coordinated with the FDA; nor are training of state and local

inspectors done jointly with FDA inspectors, resulting in differing inspection procedures and varying thoroughness;

- It lacks enforcement tools common to modern regulatory agencies, such as authority to recall contaminated food, to require periodic registration of food facilities, to fine firms failing to comply with requirements, and to require detailed records of a food's movement through commerce (so that contaminated food can be found and recalled promptly); and
- FDA lacks a modern and robust laboratory system that can effectively and rapidly test food samples for the hundreds of possible contaminants that can attack our food.

WHAT IS NEEDED – A MODERN, RISK-BASED FOOD SAFETY SYSTEM

Despite the considerable gloom we have been seeing in recent years related to the failures of our food safety system, there is great reason to be optimistic that we can successfully fix its many flaws. The key will be to move from the current reactive, fragmented system to one that is focused on prevention. FDA and the industry have already demonstrated the possibilities, through development of procedures for preventive controls for low-acid canned foods, seafood, and juice. Known generally as Hazard Analysis Critical Control Points, or HACCP, it is a methodology under which producers undertake four steps to assure the safety of their food, and whose complexity is based on the risks posed to the food:

- 1) Analyze hazards, that is, understand what hazards their food might be subjected to so that they can eliminate them,

- 2) Develop a food safety plan under which they will take the necessary steps to control the identified hazards,
- 3) Document the steps the facility takes to implement the plan, thereby creating a record of how they successfully control the hazards, and can thus assure both regulators and their customers that they are always vigilant about food safety, and
- 4) Meet standards for minimizing risk in their food, such as by periodic testing for hazards to assure that the finished product is indeed uncontaminated.

These are often fairly simple, common sense steps, but they have shown a remarkable capacity to effectively prevent food contamination. In the case of a peanut butter processor, for example, the four steps might be implemented as follows:

- 1) Hazard identification would likely be focused on bacterial contamination,
- 2) The food safety plan would identify the need to a) roast the raw peanuts at sufficiently high temperature to ensure that any bacteria arriving from the farm is killed, then, b) keep the processing equipment clean so that the peanut butter is not exposed to bacteria while being processed and packaged. This would also include the need to guard against rodent and insect infestation, leaky roofs, and any other threat to equipment sanitation.
- 3) Documentation might include only temperature recording of the roaster while it is in operation and the recording of regular, thorough cleaning of the processing equipment; and, finally,
- 4) Performance Standards could be met by periodic sampling and testing of the final product, to confirm that it is free of bacteria.

Under such a new paradigm, FDA's role would shift from its current "gotcha" mode via random inspections to one in which they set the requirements for preventive controls and any necessary quantitative tolerances for contaminants, train and educate processors in the use of such controls, assess the adequacy of firms' food safety plans, and oversee an inspection regime under which FDA, state, local, and other third-party inspectors can confirm the proper implementation of food safety plans.

WHAT IS NEEDED FROM CONGRESS

FDA cannot move to the type of modern food safety system that is needed without statutory change. Specifically, I believe the Congress should enact legislation with the following elements:

First, empower FDA to mandate preventive controls for all food. Many, if not most, large processors have already adopted some form of preventive controls, but such a system will only be as strong as its weakest link, and FDA must be specifically charged with requiring universal HACCP-like processes.

Second, give FDA the resources to be successful in a new food safety system. In the 1970s, when FDA's food program was at its zenith, its budget was one-half of the agency's budget, and that could be a goal for restoring the program to health. It would require additional funding of about \$500 million, or about 2 cents a week for each American. Without the resources to strengthen the FDA, no authorities can or will bring the change that is needed, but I believe the vast majority of Americans would gladly pay a penny every few days for a safer food supply. Indeed, the cost to the taxpayer would

likely be recouped by savings to consumers through the elimination of just one major outbreak a year.

Third, enact long overdue enforcement authorities for FDA, such as mandatory recall authority, annual registration for all food facilities, a revised administrative detention authority, accreditation of private laboratories, and a stronger traceback authority.

Fourth, direct the Secretary of Health and Human Services to develop an effective crisis management system that coordinates the response to foodborne disease outbreaks among CDC, FDA, and state and local government; cuts through the current bickering and turf battles among those entities; and effectively shortens the response time and resolution of future outbreak.

And, fifth, authorize and fund a food safety training academy that will provide uniform, science-based training for all food inspectors, at all levels of government and in the private sector.

A NEED TO MOVE FROM TALK TO ACTION

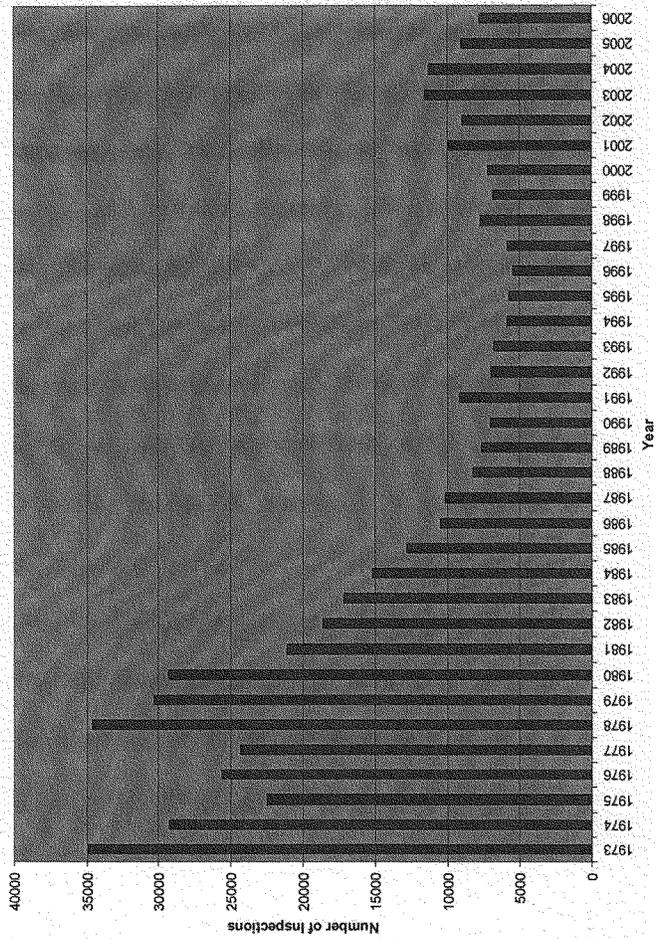
In conclusion, Mr. Chairman, today's hearing is another in a series that Congress has held to highlight instances where FDA needs to improve, and I agree with your concerns that FDA is not as effective as it can and should be. In the case of food, we have a real dichotomy between our rhetoric and our action. As I noted earlier, we say we want a strong FDA and a strong food safety system, but our actions belie that stated objective. We have not given FDA the authority and resources it needs to be the agency we want it to be, and then we are critical of it when it fails to meet expectations. Meanwhile, as

report after report recommends dramatic change in our food safety oversight, the number of foodborne disease outbreaks have risen from about 100 per year fifteen years ago to 350 per year more recently. That is a record for which we should be truly embarrassed, and I sincerely hope that you and your colleagues will agree with my conclusions and resolve to act upon them.

Thank you for giving me the opportunity to provide my views on this subject.

Food Inspections 1973-2006

FDA Inspections (1973-2006)



	<p>Testimony before the Committee on Agriculture, Nutrition, and Forestry</p> <p>United States Senate</p>
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**CDC Response to the Multistate Outbreak of *Salmonella*
Typhimurium**

Statement of

Ali Khan, MD, MPH

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Introduction

Good morning, Chairman Harkin and Members of the Committee. I am Ali Khan, an Assistant Surgeon General and Deputy Director of the National Center for Zoonotic, Vector-Borne, and Enteric Diseases, at the Centers for Disease Control and Prevention (CDC). Thank you for the invitation to address the Committee on CDC's activities related to the prevention of foodborne disease and CDC's role in the response to the current outbreak of *Salmonella* Typhimurium infections associated with peanut containing products.

Background

Diseases spread by contaminated foods continue to challenge the public health system. Large foodborne outbreaks now often are attributed to fresh produce and processed foods, as well as foods of animal origin. Numerous factors are responsible for these large outbreaks such as the complexity of evolving microbes and changing food consumption patterns. In addition, CDC relies on local and state health departments, which have varying capacity to detect and respond to food-related illnesses

As an agency within the Department of Health and Human Services (HHS), CDC leads federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts. CDC is not a food safety regulatory agency, but CDC works closely with the food safety regulatory agencies, in particular with HHS's Food and Drug Administration (FDA) and the Food Safety and Inspection Service within the United States Department of Agriculture (USDA/FSIS). CDC also plays a key role in building state and local health department epidemiology, laboratory, environmental health, and

communication capacity to support foodborne disease surveillance and outbreak response. Importantly, CDC data can be used to help document the effectiveness of prevention interventions.

Everything that CDC does depends on critical partnerships with state and local public health departments that collect surveillance data, conduct laboratory testing, investigate most outbreaks, and take public health action. CDC has worked with the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE) to develop networks for foodborne disease surveillance. For example, PulseNet, the national network for molecular subtyping of foodborne bacteria coordinated by CDC, allows every state health laboratory to test strains of bacteria from sick persons in that state and to compare them with DNA “fingerprint” patterns in the national database at CDC. This has greatly improved the ability to detect clusters of illness that may be related, even if they are dispersed across multiple states. There are similarly other related systems that coordinate the investigation of the large, multistate clusters detected by PulseNet [OutbreakNet team], facilitate state reporting of outbreaks to CDC [National Outbreak Reporting System], develop baseline information on what foods are commonly consumed and trends in foodborne illness [FoodNet], and assess policies and practices of retail foodservice establishments that could lead to or prevent foodborne outbreaks [Environmental Health Specialist Network].

CDC also works with a broad range of other partners to improve capacity and knowledge regarding foodborne disease control and prevention. In collaboration with the National Environmental Health Association (NEHA), CDC conducts team training programs for local and state health department officials including specialists in environmental health, laboratory science, and epidemiology. CDC works with the World Health Organization (WHO) and a variety of

other international partners to conduct similar training programs in other countries. CDC supports the Council to Improve Foodborne Outbreak Response (CIFOR), which was created to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. CSTE and the National Association of County and City Health Officials (NACCHO) are co-chairing CIFOR, and it includes representatives from CDC, FDA, USDA, APHL, NEHA, the Association of State and Territorial Health Officials, the Association of Food and Drug Officials, and industry.

Salmonella

Salmonella is a group of bacteria that is widespread in the intestines of birds, reptiles, and mammals. *Salmonella* is the most commonly diagnosed bacterial cause of foodborne diseases in the U.S., causing 15 reported laboratory-confirmed infections per 100,000 persons in 2007, as measured in FoodNet. There are many different kinds, or serotypes, of *Salmonella* bacteria. Serotyping is a classification system based on differences in structures on the surfaces of bacteria or other disease-causing agents. Serotyping performed by public health laboratories around the nation divides *Salmonella* into more than 2,500 different serotypes, some common and some rare. Serotype Typhimurium is the most common serotype in the U.S. and causes 15-20 outbreaks every year. In 2006, Typhimurium represented 19% of reported *Salmonella* illnesses. Each serotype can be further sub-divided into many more subtypes based on additional laboratory tests of their DNA.

Salmonella infections have often been associated with meat, poultry, eggs, and raw milk; these products are derived from animals that can carry *Salmonella*. *Salmonella* has also been associated with fresh produce and other plant-derived foods and can be transmitted through

processed foods, like pot pies, breakfast cereal, snack foods, and peanut butter. *Salmonella*, like other pathogens that are commonly foodborne, can also be transmitted in other ways besides food, such as from contact with reptiles or other animals, between children at a child care center, or in water.

Many foodborne infections, including *Salmonella*, occur in persons without obvious connections to each other. These are called sporadic cases; determining the source of a single sporadic case can be very difficult. Cases of similar infections can also occur as a group or “cluster.”

Epidemiological investigation of clusters of possibly related cases permits public health officials to determine if the cases were connected and, specifically, if they were linked to food. A cluster of foodborne illnesses is considered an outbreak if an investigation demonstrates that two or more infections caused by the same agent are linked to the same food.

In general, for a foodborne illness to be recognized by the public health surveillance system, a patient must seek medical attention; the physician must decide to order diagnostic tests; and the laboratory must conduct the test using the appropriate procedures and report the results to a health department. Many ill people do not seek medical attention, and of those who do, many are not tested for *Salmonella* or other agents causing food borne illness. Therefore, many cases of foodborne illness are neither diagnosed nor reported. For example, *Salmonella* infection has been estimated to cause about 1.4 million foodborne illnesses annually; however, only about 40,000 laboratory-confirmed cases of *Salmonella* are reported to CDC each year.

Regular reporting about detection of *Salmonella* serotypes and subtypes from ill persons is critical in determining whether a surge in incidence has occurred signaling a possible outbreak. Each serotype can be further divided by DNA analysis into subtypes that are distinguished by

different DNA fingerprint patterns. The fingerprint pattern is determined with a test known as pulsed-field gel electrophoresis (PFGE). PFGE is a very good method for differentiating among epidemiologically unrelated isolates of many serotypes.

Public health laboratories determine the serotype and PFGE patterns for *Salmonella* strains and share the patterns through PulseNet. The laboratories participating in PulseNet are in state health departments, some local health departments, USDA, and FDA. When a clinical laboratory detects *Salmonella* from an ill person, a sample is sent to a State or local PulseNet laboratory where it is serotyped and DNA fingerprinted. The laboratory compares the fingerprint pattern to that of other *Salmonella* strains from people in that area and uploads the pattern electronically to the national PulseNet database maintained at CDC, where it can be compared with patterns from all over the country. This gives us the capability to detect an unusual number of *Salmonella* cases with the same pattern in a single area or in multiple states. The system can identify patterns even if the affected persons live far apart, which is important given the widespread U.S. food distribution systems. Thousands of different fingerprints have been described, and it is not unusual to find some matches in the system, and at any given moment, the PulseNet system may be tracking many small clusters. When the number of matching strains in a cluster increases, and the number of states reporting the matching pattern increases, then the cluster is flagged for investigation at the national level. The current outbreak is caused by *Salmonella* with two closely related patterns that had not been seen in PulseNet before this outbreak.

The current outbreak represents a typical timeline for detecting and investigating foodborne illnesses. There is an inherent time lapse between when a person becomes ill with *Salmonella* infection and when the results of testing are reported to PulseNet. It takes time for a person to

become ill, seek medical care, and submit a sample for testing. It then takes time for the clinical laboratory to detect *Salmonella* and send the strain to the public health laboratory; finally, the public health laboratory must perform serotyping and DNA fingerprinting and then submit that finding to PulseNet, which is when CDC becomes aware of the illness.

The Current Salmonella Typhimurium Outbreak

On November 10, 2008, CDC's PulseNet staff noted a small and highly dispersed multistate cluster of 13 *S. Typhimurium* isolates with an unusual PFGE pattern reported from 12 states, and the OutbreakNet team began monitoring it. On November 25, CDC worked with state and local partners to begin an epidemiologic assessment of that cluster, which had increased to 35 isolates reported from 16 states. On December 2, CDC and state and local partners began an assessment of a second cluster of 41 *S. Typhimurium* isolates from 17 states. The PFGE patterns of the second cluster were very similar to the patterns in the first cluster. This second cluster had been first noted by PulseNet on November 24, as a cluster of 27 isolates from 14 states. Neither of these patterns was seen previously in the PulseNet *S. Typhimurium* database. In December, the two clusters were being investigated in parallel because they appeared to be similar. On January 7, 2009, after *Salmonella* from the two patterns were shown to be indistinguishable by other advanced laboratory tests, the two patterns were grouped together as a single outbreak strain, and the investigations were merged.

The initial steps in an epidemiological investigation are to collect information from which hypotheses can be generated about the possible source of the outbreak. As cases with the same DNA fingerprint pattern were identified, CDC collaborated with public health professionals in local and state health departments who were interviewing patients to determine what specific

foods or other exposures they may have had in common. Many affected state and local health departments, including the Minnesota Department of Health (MDH), conducted intensive investigations of patients infected with the outbreak strain and shared the findings with CDC. These interviews did not immediately point to a specific product, but raised the possibility of peanut butter and chicken products, without suggesting a particular brand.

By December 28, the Minnesota Department of Health had learned from patient interviews that some patients infected with the outbreak strain lived or ate meals in one of at least three institutions (two long-term care facilities and one elementary school). A review of menus and invoices by MDH and the Minnesota Department of Agriculture (MDA) revealed that the institutions had a common food distributor in North Dakota, and the only food common to the three institutions was King Nut creamy peanut butter. By January 9, 2009, six additional cases in six other Minnesota institutions were identified by MDH; each of those institutions had received King Nut peanut butter. On January 9, the MDA laboratory reported isolation of *Salmonella* from an open container of King Nut peanut butter. This was confirmed on January 12 as *S. Typhimurium* of the outbreak strain.

On January 3 and 4, 2009, data were gathered for a study by CDC and state and local health departments to identify whether illness was associated with eating specific food items. Preliminary analysis found that ill persons were significantly more likely than non-ill persons to have eaten peanut butter, though illness was not associated with eating national brands of jarred peanut butter sold in grocery stores. By January 9, when an opened jar of King Nut peanut butter collected at a nursing home in Minnesota was reported to be growing an as yet

uncharacterized *Salmonella*, the FDA had identified a Peanut Corporation of America (PCA) factory in Blakely, Georgia, as the sole producer of King Nut brand peanut butter.

On January 16, the Connecticut Department of Public Health Laboratory isolated the outbreak strain of *S. Typhimurium* from a previously unopened 5-pound container of King Nut creamy peanut butter, suggesting that contamination occurred during production. However, CDC's ongoing collaboration with states indicated that many cases did not eat peanut butter in institutions, but had eaten various other peanut butter-containing products. FDA investigators reported that the PCA facility in Blakely produced peanut butter and also peanut paste (made from ground roasted peanuts) and other peanut products, which were sold to many food companies for use as an ingredient in peanut butter-containing foods.

To better determine the association of illness with other peanut-butter containing foods, a second study was conducted by CDC and state and local health departments January 17-19 to further assess exposures in persons who did not live in institutions and had become ill since December 1. Preliminary analysis found that ill persons were more likely than non-ill persons to have eaten specific brands of prepackaged peanut butter crackers. Both brands of peanut butter crackers are made at one plant, which is known to receive peanut paste from PCA.

Intact packages of peanut butter crackers that had been purchased in the United States were obtained from the home of a patient in Canada by the Canadian Food Inspection Agency. Culture of a composite sample of the crackers yielded the outbreak strain of *S. Typhimurium*. Other testing of three intact packages of peanut butter crackers obtained from a patient's home in Oregon showed similar *Salmonella* contamination.

Throughout the investigative process, to ensure that information was disseminated to the public as accurately and quickly as possible about health threats and other information related to this outbreak, CDC and FDA coordinated their communication strategies and messages and discussed these strategies in daily calls with state health officials. We balance the rapid release of information on sources of illness against the potential negative consequences to consumers, food growers, producers, and industry. Continued collaborations and communications between federal agencies, state and local health departments, and all relevant stakeholders are essential.

Status of Investigation

As of February 1, 2009, 550 persons from 43 states and one person from Canada had been reported infected with the outbreak strain. Confirmed, reported onset of illness dates have ranged from September 1, 2008, to January 17, 2009. A total of 120 patients were reported hospitalized, and the infection may have contributed to eight deaths. The epidemiologic, laboratory, and traceback findings from this continuing investigation indicate that peanut butter and peanut paste produced at the PCA plant are the source of the outbreak. More specifically, the outbreak was caused by contaminated peanut butter used in institutions, and by peanut butter and peanut paste used as ingredients in food products. The second case-control study indicated a particular risk with peanut butter crackers, but this does not exonerate other peanut-containing products.

After one brand of peanut butter served in institutions was implicated by epidemiologic and laboratory evidence, the investigation was expanded to include food items that use peanut butter and peanut paste made in the same factory as ingredients in peanut butter-containing products. This was an ingredient-driven outbreak, in which a contaminated ingredient affected many different products that are distributed through various channels and consumed in various settings.

Peanut butter and peanut paste are common ingredients in cookies, crackers, cereal, candy, ice cream, pet treats, and other foods. Mass food distribution can lead to widely distributed nationwide outbreaks.

Conclusion

The large number of products and brands recalled already, and the large quantities of some products recalled, makes this one of the largest recalls in the United States. The outbreak appears to be slowing, but we are not able to say that the outbreak is over at this point. Because of the time lag in reporting, we expect reports of new cases to continue for 2-3 weeks after the outbreak actually ends. The event illustrates how a large and widespread outbreak can occur, from distribution of a single item to hundreds of foods. It also highlights the continued need for robust disease detection systems at all levels—local, state, and federal—to ensure prompt recognition, response, and investigation of these outbreaks. CDC will continue its efforts to:

- focus on research, education, and training that will assist with Federal strategies to prevent foodborne illnesses before they happen;
- incorporate food industries into prevention, response and information sharing; and
- bolster state health infrastructures to effectively and promptly identify and respond to outbreaks.

This will entail continuing to work with regulatory authorities, state and local partners, food and environmental microbiologist scientists, and the food industry to prevent future food borne illness outbreaks. Thank you again for the invitation to testify before you today. I will be happy to answer any questions you may have.

Gabrielle Meunier, Mother of *Salmonella* Typhimurium victim

Testimony to the Senate Committee on Agriculture, Nutrition & Forestry
Examination of Federal Food Safety Oversight in the Wake of Peanut Products Recall

February 5, 2008
Washington, DC

Thank you Senator Leahy and Chairman Harkin, and the rest of the Committee for the opportunity to appear before you today and share the story of my son Christopher and our experience with the recent *Salmonella* outbreak and the peanut recall that followed.

On Thanksgiving night, November 25, 2008, my perfectly healthy and robust seven-year-old son, Christopher, spiked a very high fever, started throwing up, and having diarrhea. His father and I suspected it was the flu, as did our Pediatrician, so we limited his food and made sure he got plenty of fluids. Two days later Christopher's health deteriorated dramatically, he was severely ill and in tremendous pain; a pain that no child should ever have to experience and as a mother one that I will never forget as I sat by his bedside. We immediately called our Pediatrician who instructed us to bring him to the hospital.

We asked ourselves how in the world could a seemingly perfectly healthy child get so sick in such a short period? However, once the lab results finally came back and he was diagnosed with *Salmonella*, the picture became clearer. Thankfully, after days of antibiotics, anti-fungus drugs, and no food or drink, his wrecked body finally stabilized to a point where he could come home. This, after six days and nights filled with fear and unanswered questions.

Senators I could spend all day telling you about Christopher's terrible experience and the questions that still linger about the long-term ramifications for his health, but I would rather use my limited time here today to help make change and progress for the future. Some excellent ideas have already been proposed for improving our food safety system and I would like to add a few of my own, while highlighting some of the mistakes I witnessed firsthand during Christopher's ordeal. I must start by praising the first line of defenders in the fight against foodborne illness. Senators it is my experience that this is the only part of the foodborne illness safety system that works well.

Technology and Information

First, and foremost I believe that technology is the key to making our foodborne illness response work better and in a cohesive manner. I believe there needs to be a national online foodborne illness database/registry that can be used by victims as soon as a *Salmonella* or other foodborne illness has been diagnosed. Such a tool would allow patients or their caregivers to log on to the registry and fill out a questionnaire about food eaten in the seven days prior to illness onset. This can be done while the patient is still in the hospital or in the Doctor's office. By doing this step immediately, the information is still fresh in the victim's mind rather than on the phone for a two and a half hour interview over a week after the initial diagnosis.

In this age of technology, text messages, and instant messaging; I do not understand why victims could not be given access to a secure website and chat-room to allow them to talk to one another and possibly solve the question of which food poisoned them. In Christopher's case, he is a very picky eater. I am chagrined to say that my son mostly eats cheese, milk, yogurt, peanut butter, and snacks like chips, peanuts or crackers. Had I had an opportunity to talk to other mothers whose children were sick, and compare what they had eaten I have no doubt we could have cracked this case back in early December.

In addition to using technology to get information from victims, I feel that it can be used better for sharing information with victims and the public. In my opinion, the agencies involved with any outbreak should never underestimate how much victims and the public crave information. I was kept in the dark for way too long throughout this process, at one point having to insist that I be told what specific kind of *Salmonella* Christopher had, even though the health worker I was speaking to said that "I didn't need to know." The victims must be kept in the loop with real time information and there needs to be a way to reach all the victims by phone. I believe that a computerized phone message to victims could easily be established for disseminating information -- after all how many people in this room got text messages from the president during the inauguration weekend?

In this case, as soon as there was the slightest possibility that crackers and other foods were the culprit, we should have received a message telling us to remove any peanut butter crackers from our house. Thankfully, a coworker of mine read that tainted Crackers possibly contained *Salmonella*. Then it all made sense, Christopher had eaten a package of cheese and peanut butter crackers but no one else in our family had. This is where our case hit another roadblock, when I called the CDC about the crackers, which we still had in our pantry, no one would take my call. Thankfully, when I called the FDA, I found someone willing to listen, unfortunately it was the weekend and that Monday was a holiday so no one could pick up the crackers until Tuesday. However, in a shocking twist the woman I spoke with at the FDA then also wanted to give me a questionnaire about all the foods Christopher had eaten, all the same information I had already given the CDC. I do not understand why the various agencies working on this outbreak did not already have our information. Technology must be used to share information between all the teams and lines of defense working on an outbreak.

In addition to notifying victims, the public needs to be kept informed as well, perhaps with an alert system similar to those for storm warnings. This system could also be utilized to update the public when it is safe to eat a certain food again. Right now it has is a guessing game for the public -- and sometimes just a game of Russian roulette.

Identification

Next, I believe there should be a unified procedure for the identification of all *Salmonella* cases. If one state does this best, then they should share their procedures and best practices with the rest of the country for the fastest turn around possible. Once identification is made and the data entered into the registry, the correlations can be made to determine if there is a pattern developing. If there is, then there is already a litany of information regarding foods eaten, already provided by the victims so swift action can be taken.

National Team

After our experience, I believe that there should be one team involved at the National level in charge of the follow up. Such a national team could again use technology and the registry/database for all their information dissemination to all lines of defense and data gathering. It is crucial that four lines of defense have access to the information on the database, this includes the local Doctors and hospitals, the State Health Departments, the CDC, and finally the FDA. With one team involved in tracking and organizing the investigation, if any sort of clusters or patterns are identified by that team, this information can be shared to all parties through the registry database.

As the system is now, Christopher's doctors had to ask around on their own if other local pediatricians had patients with similar symptoms. Had there been a national database, they would have seen that on the date that Christopher was diagnosed, that there was already a cluster of Salmonella elsewhere in the U.S. They could have then seen if there were any other cases in Vermont. This information is important for the first lines of defense to have – even if does not effect their specific region of care. If we were to have a Bioterrorist act through food, this data would be invaluable information to all lines of defense.

Personal Responsibility

Finally, I believe there needs to be personal responsibility in manufacturing and growing foods for consumption by the public. The owners of companies must be personally responsible for the safety of the foods they sell. Inspection records should online and made available to the general public, owners should have to log-on to a database at regular intervals, depending on the amount of products produced, and personally attest to the safety of their food.

Manufacturers must take responsibility for all items that go into their products, and therefore if they are purchasing supplies and ingredients from other companies, they need to attest and be equally responsible for that ingredient as well. If their supplier is listed on a public database and personally attesting for the safety of their product then their liability for that supplier is lowered if their supplier is meeting all required standards. In this particular case, there has rightfully been a lot of blame placed on the plant where the contaminated product originated, however I believe that large suppliers of food products, should have a clear process to verify that their suppliers are meeting national standards. Clearly, that did not happen in this case, and now the government must ensure this will never happen again.

Thank you again to the committee for holding this hearing today. I would like to close by thanking the Staff at the Children's Hospital of Vermont for treating Christopher so promptly. Our family is so thankful that he received the best care in the world and lucky for us he was a big boy to begin with. I shudder to think of the outcome had he been an underweight or sickly child to begin with and my heart goes out to all of the other victims and their families.

Again, thank you and I welcome any questions you may have.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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STATEMENT OF
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CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE
COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
UNITED STATES SENATE

FEBRUARY 5, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning Mr. Chairman and members of the Committee. I am Dr. Stephen Sundlof, Director of the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services. FDA appreciates the opportunity to provide you with information on our ongoing investigation of the foodborne illness outbreak associated with *Salmonella* Typhimurium, which has been found in peanut products produced by the Peanut Corporation of America (PCA). Because our investigation and the accompanying recall of suspect product continues as we speak, our final conclusions and recommendations are necessarily pending the outcome of our investigation.

Let me begin by providing a brief description of the typical traceback process employed by FDA and our sister agency, the Centers for Disease Control and Prevention (CDC). Once CDC, through its epidemiological investigation which involves working with state and local health departments, identifies the possible food(s) associated with a foodborne illness outbreak, CDC notifies FDA. At that point, FDA considers the strength of the evidence implicating the suspect food or foods and determines the appropriate level of regulatory response. To start our traceback investigation to identify the source of the contamination, we work with the food industry and with state and local regulatory partners, and, when needed, with foreign governments. We do this by tracing the food suspected of being the vehicle for transmitting the pathogen back through the supply chain from the retailer, restaurant or institutional setting and inspecting or investigating points throughout the supply chain to determine where the contamination most

likely occurred. Tracing food requires us to find and examine documentation (such as bills of lading and invoices) for the product throughout the supply chain. We also obtain information on the practices and conditions under which the product was stored and handled at each point to better determine shipments of interest and whether contamination may have occurred at each point. The records we need are not always in an electronic format, and records review often can be a time-consuming, resource intensive process.

In the current case, FDA began its investigation prior to having a strong epidemiological link to a particular food, both to inform the epidemiological study and to shorten the time required to get potentially contaminated foods off the market. Because institutionally-served peanut butter, in five-pound containers, was identified by the state of Minnesota as a potential vehicle, our investigation had a strong lead: the brand name of a company and the address to begin our trace. But allow me to explain a few components of the epidemiological work, the first step in our collaborative efforts.

EPIDEMIOLOGICAL INVESTIGATION

Since early December 2008, FDA has collaborated with CDC, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), and public health officials in various states to investigate the multi-state outbreak of human infections due to *Salmonella* Typhimurium. Early epidemiological efforts to identify a likely food vehicle were inconclusive. While initial efforts focused on the potential for chicken to be the illness vehicle, peanut butter was first identified as a possible source in mid-December. On January 7 and 8,

after conversations with CDC, FSIS, and the Minnesota Department of Health about the strength of association between illness and exposure to chicken or peanut butter, FDA decided to begin to investigate institutional food service sources of peanut butter despite the inconclusive epidemiological data.

On January 7, based on preliminary information from CDC's multi-state case control study that explored other possible food sources in addition to peanut butter, and before Minnesota had identified the *Salmonella* strain, FDA made its initial contact with the King Nut Company in Ohio. King Nut distributes peanut butter manufactured by the Peanut Corporation of America (PCA) at its Blakely, Georgia, plant to institutional facilities, food service industries, and private label food companies in several states. On January 9, FDA initiated an inspection of the PCA plant in Blakely, and Minnesota reported that they had isolated *Salmonella* from the open container, though the type of *Salmonella* was not yet known.

As part of its epidemiological investigation, the Minnesota Department of Health tested an open five-pound container of King Nut peanut butter obtained at a nursing home where three patients were sickened by the outbreak strain of *Salmonella* Typhimurium. By January 10, Minnesota health officials had determined that the peanut butter contained the same strain of *Salmonella* Typhimurium associated with the illnesses linked to the outbreak. However, because it is always possible that the open container was contaminated by someone or something else in the environment, these results did not definitively confirm PCA as the source. FDA and other state health departments expanded the testing of unopened containers of the same brand of peanut butter.

On January 19, testing by the Connecticut Department of Health of an unopened container of King Nut peanut butter showed that it contained the same strain of *Salmonella* Typhimurium associated with illnesses linked to the outbreak. The fact that the *Salmonella* Typhimurium was confirmed in an unopened container of peanut butter indicated that the peanut butter was contaminated when it left the Blakely processing plant.

Peanut butter is sold by PCA in bulk containers ranging in size from five to 1,700 pounds. The peanut paste is sold in sizes ranging from 35-pound containers to tanker trucks. However, through its investigation, FDA has determined that PCA distributed potentially contaminated products to more than 300 consignee firms, many of whom then further distributed products, for consumption as peanut butter or for use as ingredients in hundreds of different products, such as cookies, crackers, cereal, candy and ice cream.

As of February 1, CDC reported that 550 persons infected with the outbreak strain of *Salmonella* Typhimurium have been reported from 43 states, plus one person from Canada, and that the infection may have contributed to eight deaths.

PLANT INSPECTION

After visiting King Nut on January 8 to determine where its peanut butter was manufactured and to collect samples, FDA initiated an inspection of PCA's Blakely plant on January 9, shortly after preliminary information indicated that this firm might be linked to the ongoing *Salmonella* outbreak. FDA completed its inspection on January 27.

A document listing observations by FDA investigators during their inspection, known as a List of Inspectional Observations, or Form 483, has been posted on FDA's website at www.fda.gov/ora/frequent/default.htm. This list is not a final Agency determination regarding compliance. The list of observations includes matters relating to cleaning programs and procedures as well as failure to implement steps to mitigate *Salmonella* contamination in the facility.

FDA's environmental sampling at the plant found two *Salmonella* strains, neither of which were *Salmonella* Typhimurium, the outbreak strain. As of now, CDC is not aware of any illnesses definitely connected to these other *Salmonella* strains. We are confident, however, based on the investigations by the states, CDC and FDA, including product testing, that the Blakely plant is the source of the contaminated foods related to the current *Salmonella* Typhimurium outbreak. State sampling and analysis of unopened finished products indicate that PCA-shipped product from the Blakely plant was contaminated with the outbreak strain.

Further, FDA's review of the firm's testing records -- which were not disclosed to FDA and state inspectors during earlier routine inspections -- revealed that there were instances in 2007 and 2008 where the firm distributed product in commerce which tested positive for *Salmonella*.

As you may be aware, FDA has recently confirmed that our Office of Criminal Investigations (OCI) is conducting an ongoing criminal investigation.

PRODUCT RECALLS

After discussions with FDA, the first product recall related to the outbreak was initiated on January 10, 2009, by the King Nut Company of peanut butter distributed under the King Nut and Parnell's Pride labels. On January 13, PCA initiated a voluntary recall of certain lots of peanut butter and peanut paste produced on or after July 1, 2008, due to the risk of *Salmonella* contamination. PCA expanded this recall on January 16 to include peanut butter produced on or after August 8, 2009, and peanut paste produced on or after September 26, 2008. This was followed by yet another expansion on January 18, 2008, when PCA announced it was recalling all peanut butter and peanut paste manufactured on or after July 1, 2008, at its Blakely processing plant.

On January 28, PCA issued another expanded voluntary recall of all peanuts and peanut products, including all peanuts (dry and oil roasted), granulated peanuts, peanut meal, peanut butter and peanut paste processed in its Blakely facility since January 1, 2007. All of these recalled peanuts and peanut products were made only at the company's Blakely facility.

Many companies that received peanuts and peanut products manufactured by PCA's Blakely facility have, in turn, conducted voluntary recalls. A user-friendly, searchable list of the products being recalled, with corresponding photographs, when available, can be found at www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm. The searchable list currently includes approximately 1,000 entries in 16 categories representing products that have been

recalled by more than 75 companies. FDA is updating this list on a daily basis, as new information becomes available.

FDA has been working with purchasers of PCA's peanuts and peanut products to identify affected products and facilitate their removal from the market. FDA initiated inspections at the direct consignees of PCA and King Nut and continues to follow the distribution points for products. FDA and state officials have contacted hundreds of firms throughout the entire distribution chain that may have purchased or further distributed PCA products. This work is continuing and includes the additional products in the expanded recall.

Companies nationwide that received product made by PCA have issued voluntary recalls of their products. As FDA gathers additional information about these products, the list of recalled products has expanded, and will likely continue to do so. FDA urges all affected retailers to immediately stop selling recalled products. Directors of institutions and food service establishments are also strongly urged to ensure that they are not serving recalled products.

We would like to emphasize, as we have stated numerous times, that major national brands of jarred peanut butter found in grocery stores are not affected by the PCA recall. Further, FDA has no evidence to suggest that the *Salmonella* Typhimurium contamination originated with any manufacturing facility other than PCA's Blakely plant. The facility is not operating at this time.

RECOMMENDATIONS FOR CONSUMERS

FDA has established a web page to provide constantly updated information on the contamination and recall at www.fda.gov/oc/opacom/hottopics/salmonellatyph.html. This web page has already been viewed more than 19 million times. The web page includes a searchable database to assist consumers in quickly identifying recalled products, found at www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm.

Consumers are urged to check this web page to determine which products have been recalled and to become aware of new recalls as they are announced. Any product that is on the recall list should be disposed of in a safe manner. Consumers are also urged to wash their hands after handling potentially contaminated products. If consumers are unsure whether a peanut-containing product is potentially contaminated, they should avoid consuming it until they obtain more information about the product. Persons who think they may have become ill from eating peanut products are advised to consult their health care providers.

Product recalls include some pet food products that contain peanut products made by PCA. Although the risk of animals contracting salmonellosis is minimal, there is risk to humans from handling these products. It is important for people to wash their hands -- and make sure children wash their hands -- before and, especially, after feeding pets. Further information for consumers is located in the Frequently Asked Questions section located on this web site. The pet food products are also included in the searchable data base of recalled products.

For information on products containing peanut butter from companies not reporting recalls, consumers may wish to consult the company's website or call the toll-free number listed on most packaging. We note that information consumers may receive from the companies has not been verified by FDA.

PRODUCT MANUFACTURERS AND DISTRIBUTORS

FDA urges manufacturers and distributors of products containing peanut-based ingredients to inform consumers about whether their products could contain peanuts or peanut products from PCA Blakely. If a manufacturer knows its products do not contain peanuts or peanut products from PCA, it may wish to provide this information to consumers.

FDA is continuing to work with the firms on the details of their actions, conducting follow-up audits and inspections, monitoring the progress of the firms' actions, working with state and local regulatory authorities, and notifying our foreign regulatory counterparts of products that have now been confirmed as having been distributed internationally. FDA is continuing its work to identify products that may be affected, and to track the ingredient supply chain of those products to facilitate their removal from the marketplace.

CONCLUSION

FDA is working hard to ensure the safety of food, in collaboration with its Federal, state, local, and international food safety partners, and with industry, consumers, and academia. Although

the *Salmonella* Typhimurium foodborne illness outbreak underscores the challenges we face, the American food supply continues to be among the safest in the world. Food safety is a priority for the new Administration.

Over the last year and a half, FDA has made significant progress in identifying food vulnerabilities and mitigation strategies. For example, we have strengthened our response to food safety threats by providing incident command system training to our FDA offices around the country, and to states, and by developing templates to enhance communication during a food recall. We are proud of the collaborative efforts among Federal and state agencies to investigate, analyze samples, monitor the effectiveness of the current recall, and communicate with the public to protect public health. We will continue to strive to reduce the incidence of foodborne illness to the lowest level possible.

Thank you for the opportunity to discuss FDA's response to the recent *Salmonella* outbreak. I would be happy to answer any questions you may have.

DOCUMENTS SUBMITTED FOR THE RECORD

FEBRUARY 5, 2009



Statement for the Record

to the

Senate Committee on Agriculture, Nutrition & Forestry

Regarding "Examination of Federal Food Safety Oversight in the Wake of Peanut Products Recall"

**American Frozen Food Institute
February 5, 2009**

Chairman Harkin, Ranking Member Chambliss and members of the Committee, thank you for the opportunity to submit this statement for the record. We appreciate your commitment to food safety and commend the Committee for holding this important hearing.

The American Frozen Food Institute (AFFI) is the national trade association that promotes and represents the interests of all segments of the frozen food industry. AFFI fosters industry development and growth, advocates on behalf of the industry before legislative and regulatory entities, and provides additional value-added services for its members and for the benefit of consumers. AFFI members manufacture and distribute frozen foods throughout the United States and globally and are committed to ensuring that these products are produced in accordance with strict standards of safety and quality.

Americans spend more than \$1 trillion on food. Consumers have a reasonable expectation that the food products they buy are safe. While much is being done to ensure the safety of these products, safeguards must be continually updated to meet the changing demands of a global economy.

The combined efforts of the food industry and government agencies are credited with making the U.S. food supply among the safest in the world. Recent food safety incidents, however, have spurred debate about whether our regulatory agencies have adequate resources to do their jobs as effectively as possible, and whether the current federal food safety laws have kept pace with the significant advancements in food production, processing and trade.

While it is impossible to eliminate all potential food safety risks, we can work smarter to reduce risk. It requires the creation of new and innovative ways to protect American consumers and continual improvement in managing the safety of our imports, in addition to our domestic production. Approximately \$2 trillion of imported products entered the U.S. economy last year and experts project this amount will triple by the year 2015. Meanwhile, the major U.S. food regulatory agencies continue operating at budget levels well below amounts needed to keep up with the influx of imports.

U.S. FOOD AND DRUG ADMINISTRATION FUNDING

Food safety always has been and continues to be the top priority for AFFI and its more than 500 member companies. In 2007, the Institute joined the *Coalition for a Stronger FDA* in its efforts to build public support for increased funding for the U.S. Food and Drug Administration (FDA).

The *Coalition for a Stronger FDA* is comprised of consumer and public health advocates, food and medical industry representatives, and more than 50 patient groups working to ensure FDA is well-positioned to protect Americans. Funding for FDA is critical, especially because the agency will be called on to address an increasing array of domestic and international issues in the coming years – including revolutionary food and medical advancements. The Coalition has undertaken a multi-year effort to advocate that FDA receive sufficient resources to protect patients and consumers, and to maintain and build public confidence and trust in the agency.

Although the U.S. food industry has a tremendous track record of supplying the world with safe, high quality food, we certainly recognize the necessary and complementary role that FDA and other regulatory agencies play. These entities ensure public health through the establishment of food safety standards and by carrying out necessary testing, inspections and scientific research. Failure to adequately invest in these programs will have serious long-term consequences for our country and its consumers.

In the wake of recent, highly-publicized food safety concerns, significant budget increases would allow agencies such as FDA to help reassure consumers, speed innovation in food safety, and ensure the U.S. remains competitive in foreign markets. For fiscal years 2007, 2008 and 2009, the FDA will have received an aggregate of \$522M in new monies. These new funds are a good start, but more needs to be allocated to meet the challenges facing the agency.

The increased funding that AFFI and the *Coalition for a Stronger FDA* seek would assist FDA in developing new strategies and continuing important work in the areas of regulatory enforcement, monitoring and inspection, international harmonization, science-based oversight, foreign food safety assessments and technical assistance, and trade. These efforts are intended to enable the agency to remain an effective force in resolving international issues bearing on the safety, quality, and labeling of foods and other products.

Budget increases also would allow FDA to hire the next generation of highly-qualified scientists and other career agency personnel who will be the future recipients of critical institutional

knowledge on a wide range of food safety issues. Without these funds, the agency will face a critical shortage of expertise in the future.

FDA REFORM

Although the food industry has developed and implemented sophisticated food safety assurance methods, federal and state regulatory officials have traditionally depended on spot-checks of conditions and random sampling of final products to monitor compliance with applicable regulations. This approach has tended to be reactive rather than preventive with limited ability to address the many challenges with which an industry as dynamic as the food industry is increasingly faced.

Among the key challenges confronting the industry and regulatory agencies over the years have been the increasing size of the food industry, diversity of products and processes, amount of domestic food manufactured, and the number and kinds of foods imported. The resources of FDA and state and local agencies have not kept pace with these challenges.

In December 2008, FDA released a one-year progress report on the implementation of the November 2007 Food Protection Plan (FPP). This report demonstrated significant progress toward achieving the three core elements of the FPP: prevention, intervention, and response. With continued significant funding increases from Congress, AFFI is confident FDA will be prepared under the structure outlined in the FPP to meet the challenges facing the food safety system.

Providing consumers with safe and nutritious food products is the food industry's responsibility. To achieve this, AFFI members already implement a variety of food safety measures to ensure the safety of their products. But Congress can also take steps to modernize the food safety laws.

Every food company should be implementing measures to reduce safety risks associated with providing their product to the consumer. In addition, companies should document those measures in a food safety plan, which should be available to the FDA for review. Furthermore, importers should oversee the food safety measures being utilized by their foreign suppliers.

A risk-based approach to FDA inspections would maximize the effectiveness of inspections. Products and facilities that pose the greatest potential food safety risk to the consumer should be the focus of FDA's inspection activities. In addition, FDA should establish safety standards for fruits and vegetables, when risk and science demonstrate a need. Finally, FDA should have the authority to order a mandatory recall of products presenting serious adverse health consequences when a company has refused to conduct a voluntary recall.

CONCLUSION

In today's global economy, continued and enhanced cooperation between industry and government is critical to ensure the safety of the U.S. food supply. The regulatory agencies, especially FDA, need adequate resources now, and in the future, to carry out their mission and

mount the challenges of a continually growing global marketplace. Working with FDA, the food industry needs to employ preventive control programs that take advantage of modern technology.

Once again, thank you for the opportunity to submit this statement for the record. We look forward to working with members of the Committee on this and other issues of relevance to the frozen food industry.

**Testimony for the Record
Submitted by**

**Grocery Manufacturers Association
National Association of Manufacturers
National Confectioners Association
National Fisheries Institute
National Restaurant Association
Produce Marketing Association
Snack Food Association**

on

**Senate Committee on Agriculture Hearing
“Examination of Federal Food Safety Oversight in the Wake of
Peanut Products Recall”
February 5, 2009**

Ensuring the safety of our products is the food industry’s most important priority. We agree that Congress should take steps to update the century old food safety laws. Recent events surrounding the Peanut Corporation of America’s recall have highlighted the need for Congress to enact food safety reforms and to increase FDA food-related spending to \$900 million by FY 2012.

In particular, we propose the following reforms:

One, we urge you to require all food companies to have a food safety plan. Every company manufacturing food for the US market should be required to conduct an evaluation of food safety risks, determine appropriate food safety controls, and document those controls in a food safety plan available for FDA review.

Two, require every food importer to police their foreign suppliers and direct FDA to build foreign capacity. In particular, Congress should require that food importers document the food safety measures and controls being implemented by their foreign suppliers. Food importers who demonstrate their products pose no meaningful risk should be eligible for expedited entry at the border so FDA can give greater scrutiny to high risk imports. Congress should also direct FDA to help build the capacity of foreign governments to regulate food safety.

Three, we urge you to give FDA the power to establish safety standards for fruits and vegetables. In particular, Congress should give FDA the power to establish safety standards for certain fruits and vegetables – when risk and science demonstrate that standards are needed. FDA should be permitted to work with states and others to tailor standards to meet local growing conditions and to ensure that standards are being met.

Four, we urge you to authorize mandatory recalls. In particular, we believe Congress should give FDA the authority to order a mandatory recall when a company has refused to conduct a voluntary recall and there is a significant risk to public health. Specifically, where the responsible party refuses to voluntarily recall a product for which there is a reasonable probability that the food will cause serious adverse health consequences or death, the Secretary should be permitted to order the company to conduct a recall.

We support efforts to continually improve the safety of America's food supplies and urge Congress to continue to make the prevention of contamination the foundation of our nation's food safety strategies. We urge Congress to quickly enact food safety reforms that will give FDA new powers to reduce the risk of food-borne illness, and we urge Congress to increase FDA food-related spending to \$900 million by FY 2012.

QUESTIONS AND ANSWERS

FEBRUARY 5, 2009

Examination of Federal Food Safety Oversight in the Wake of Peanut Products Recall hearing

Chairman Harkin written questions for FDA

Please provide for the record the timeline of the FDA's involvement with the Peanut Corporation of America in the inspection and recall events from the time that FDA learned of the problem to the present. What is the date of FDA's first action in this investigation? What are the dates of each action and communication with PCA? When did discussions regarding the recall begin with PCA? What is the date of each communication to companies that may have used product produced by PCA? When did these food companies and retailers act to recall or stop selling product? Of special interest would be when certain companies initiated recalls if they were prior to the first one by PCA.

In the years leading up to the current outbreak, the Blakely, GA Peanut Corporation of America plant had been inspected by the state of Georgia under contract by the FDA. Between the FDA inspection in 2001 and the recent one in January 2009, on what dates was that plant inspected and by whom? Were there entities other than the state of Georgia inspecting the plant in that time period as well, such as inspectors/auditors from companies that purchased products from PCA?

**Senator Robert P. Casey, Jr.
Questions for the Record
Food Safety Hearing, February 5, 2009**

Panel I:

Sundlof: Can you elaborate a bit upon what a standard FDA inspection entails for a facility like the Peanut Corporation of America's Blakely Plant? What are field inspectors trained to look for, and what would constitute a "red flag" or an otherwise serious violation?

Khan: What practices or capabilities should states have in place to alert CDC as soon as possible about a potential outbreak? What allowed the Minnesota Department of Health officials, for instance, to report on this outbreak before any other state?

Khan: How specifically does CDC plan to increase its coordination with state and local health agencies to expedite the response to outbreaks? Is CDC in a position to provide greater technical assistance or other support?

Panel II:

Hubbard and DeWaal: How would you envision a more comprehensive record keeping system to function? Who should be responsible for tracking a food product's movement through the food supply system?

Hubbard: How would you propose that laboratory facilities be expanded? Are there ways that such an expansion could take place that would leverage existing federal, state, and/or local capabilities?

Hubbard: You made mention of "turf battles" existing between officials at FDA, CDC and state and local health agencies. Can you describe examples of this? In your opinion, did these battles result in a delayed response to a report of foodborne illness?

DeWaal: Can you elaborate on your recommendations for increased food safety training? Who should receive this training, and what specific skills should it seek to develop?

Senator Charles E. Grassley
Examination of Federal Food Safety Oversight in the Wake of Peanut Products Recall
Question for the record
02/05/2009

Question for Dr. Stephen Sundlof and Mr. William Hubbard

- 1) It seems like every day we are hearing about more recalls of foods. Does FDA have any sense what is the pre-dominate problem? Are lab results inaccurate? Is the greatest threat from imported products? In essence, if the FDA received limited new resources, where would they be best directed?

Senator Debbie Stabenow

QUESTIONS:

Training

Mr. Hubbard –

It is critical for the safety of our nation's food supply that we plan ahead so that this type of illness outbreak does not happen again. The Department of Health and Human Services has raised concerns about the quality and uniformity of state food inspections, yet nothing has been done to address this major flaw in our food safety network. In this regard, I would like to draw my colleagues' attention to the National Center for Food Protection, now underway in Battle Creek, Michigan, which addresses the lack of adequate training for state food safety officials. This new center will begin training state food officials this summer to a level commensurate and consistent with our federal standards, thereby providing a new level of protection for consumers. Mr. Hubbard- is it your impression that developing a National Training center with a unified curriculum for state and Federal inspectors will address the inadequacies and discrepancies amongst inspections?

Equivalency/Trade

Mr. Hubbard –

Question #1: As globalization continues, food imports into the U.S. continue to grow. In fact, according to the FDA, more than 80% of seafood consumed in the U.S. is imported. While we face many challenges with our domestic food supply, we also need to address the mounting concerns regarding unsafe food coming from abroad. We have seen many examples of this in the past few years, specifically in pet food and dairy products. As we improve our food inspection system within our own country, we need to hold other countries to the same standards. Do you believe that establishing rules of equivalence between countries is the best way to ensure that we hold all countries to the same food safety standards?

Question #2: In regards to food imports, there are many unsafe products coming into our country. However, there are already a number of laws on the books that would protect us from this unsafe food. Do you think FDA and other agencies who oversee food safety are doing an adequate job of enforcing these laws in imported products? What more can we do to make sure we enforce these laws internationally?

Dr. Sundlof –

Question #1: According to your agency: "Cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market." FDA also claims that both the agency and industry share an interest in removing unsafe and/or defective products from the marketplace. However, given the recent situation regarding peanuts and the criminal investigation that is now taking place, do you believe FDA needs broader authority to recall products, rather than relying on a voluntary system?

Question #2: Due to the recent failures of the food safety system to protect the public health against salmonella, many now believe the FDA lacks the resources to fully perform. What are the key activities in need of substantial increases in funding, in order to make the FDA operate to its best ability?

Ms. Smith-Dewall –

Question #1: Some industry groups and food safety advocates support the creation of a single food safety agency, rather than continuing to administer food safety activities in a number of different agencies. Opponents argue that the reorganization process would compromise food security. Do you believe that food safety activities should occur under a singular agency? If so, how would you recommend reorganizing without compromising food security in the interim?

Question #2: As you know, some members of Congress have proposed splitting the Food and Drug Administration into two separate agencies. Do you believe that the separation of food safety from the FDA would enhance their ability to perform?

Questions submitted by Senator Stabenow

Q: Some industry groups and food safety advocates support the creation of a single food safety agency, rather than continuing to administer food safety activities in a number of different agencies. Opponents argue that the reorganization process would compromise food security. Do you believe that food safety activities should occur under a singular agency? If so, how would you recommend reorganizing without compromising food security in the interim?

A: A single agency would provide the best solution for improving Federal oversight of food safety. In February 2005, GAO released a report on the experiences of seven countries that consolidated their food safety functions into a single agency. GAO Rep. No. GAO-05-212. The countries reported that the transition was or would likely be positive for improving protection of the food supply. A key lesson to take from the experiences of these countries is that transition will be accompanied by some disruptions, but that the benefits of consolidation far outweigh the costs of continuing our current dysfunctional food safety system.

One approach that would minimize disruption would be to phase in the transition by first updating the food laws and consolidate FDA food safety functions in a separate Food Safety Administration (FSA) within the Department of Health and Human Services (HHS). This is the approach proposed in the Food Safety Modernization Act introduced in the House of Representatives by Rep. Rosa DeLauro. Then begin modernization of the legal structure that underpins USDA's Food Safety Inspection Service (FSIS), the agency that provides oversight of meat, poultry and some egg safety. Once the FSA is established and modernization of the meat and poultry sectors is begun, it would be possible to consolidate the FSA and FSIS functions into a single agency, preferably standing alone. This phased approach would minimize disruptions that could compromise food safety.

The controversial issue raised in the consolidation approach has been whether the agency should be independent, like many other modern agencies such as the Environmental Protection Agency, the Consumer Product Safety Commission, and the Commodities Future Trading Commission, or whether the consolidation should be done either in the Department of Agriculture or Health and Human Services. There are strong advocates for each of these ideas, but the reality is that the decision does not have to be made at this point. Modernization of both primary food regulatory laws is a critical prerequisite to creating the single agency and should be done expeditiously.

Q: As you know, some members of Congress have proposed splitting the Food and Drug Administration into two separate agencies. Do you believe that the separation of food safety from the FDA would enhance their ability to perform?

A: Yes, with the benefit of updated laws and authorities for the agency to administer. Separating food safety from drug and device approvals would raise the profile of food safety and provide it with dedicated expert leadership.

Currently, there is no one official with responsibility for the food safety program. Instead, the Secretary looks to the FDA Commissioner, who is not a food expert, and the Commissioner must rely on the Director of the Center for Food Safety and Applied Nutrition, the Director of the Center for Veterinary Medicine, and the National Center for Toxicological Research for guidance on food safety issues. Furthermore, inspectional duties are managed through the Office of Regulatory Affairs, which is responsible for inspecting not only food facilities but also drug, device and cosmetic manufacturers. Too often food safety has suffered because it is buried within FDA where the focus is more on the agency's role in approving and overseeing medical products.

A separate agency would put an expert in charge of the program with a direct path to the Secretary. It would bring food expertise to the various

divisions and consolidate functions so that the inspectors could develop appropriate specialization and provide appropriate monitoring of state contracted food inspections.

Questions submitted by Senator Robert P. Casey, Jr.

Q: How would you envision a more comprehensive record keeping system to function? Who should be responsible for tracking a food product's movement through the food supply system?

A: A comprehensive traceability system is the responsibility of the food manufacturer who is best positioned to know who its suppliers and customers are. This is the philosophy that underpins the one-up/one-down system that is required under the Bioterrorism Act. 21 U.S.C. § 350c(b). Congress has also enacted a requirement for country of origin labeling that goes all the way to the final purchaser, so records documenting the origin of products are already a legal requirement. 7 U.S.C. 1638a.

Unfortunately, these systems have not proven adequate in outbreaks linked to produce items to track the items quickly and with the specificity to prevent broad scale recalls. Consumers frequently shun product categories for months after these large recalls, so developing a more effective traceability system will result in less market disruption.

A number of systems are being developed that would provide a comprehensive tracking record through the use of alpha-numeric trace codes, bar coding, RFID, and computer database systems to create a trace record that travels with the product and provides its complete history to investigators when an outbreak occurs. Many of these systems are already in use commercially or are being developed by industry associations (such as the Produce Marketing Association). Congress should consider giving the Secretary of Health and Human Services authority to develop

comprehensive traceability requirements for the food industry, based on existing technologies already being used in the private sector.

Q: Can you elaborate on your recommendations for increased food safety training? Who should receive this training, and what specific skills should it seek to develop?

A: As the Peanut Corporation of America case has illustrated, state inspectors failed to detect problems that FDA inspectors later found. Training programs are needed and should focus on techniques for inspecting, identification of hazards, sample collection, testing processes and, as HACCP becomes more common across the food industry, HACCP processes.

FDA today lacks an inspection force that is specialized in food safety. The Office of Regulatory Affairs has inspectors that one week may be in a food plant and the very next, may be inspecting a drug or medical device plant. So the first order of business should be specialization of the food inspection work force such that they can readily identify the hazards specific to food plants.

Standardized training should be provided to both federal and state food inspectors. Calibration inspections should be done, that provide a check that the federal and state inspection are looking for the same hazards in food plants.

Question submitted by Senator Charles E. Grassley

Q: It seems like every day we are hearing about more recalls of foods. Does FDA have any sense what is the pre-dominate problem? Are lab results inaccurate? Is the greatest threat from imported products? In essence, if the FDA received limited new resources, where would they be best directed?

A: All of the above. In my view, there are two basic problems: 1) FDA is massively under-resourced to deal with the scope of the food safety challenge, and 2) the agency is forced to regulate using a statutory template created over a century ago, that is outmoded. If FDA were to receive new resources under the current statutory construct, it would clearly want to inspect more frequently, but it needs more resources in conjunction with statutory authority to oversee a modern food safety system predicated on the use by manufacturers of preventive controls (which the food industry, food science experts, and consumer groups all agree is the way to regulate food in the future).

Questions submitted by Senator Stabenow**Training**

Q: It is critical for the safety of our nation's food supply that we plan ahead so that this type of illness outbreak does not happen again. The Department of Health and Human Services has raised concerns about the quality and uniformity of state food inspections, yet nothing has been done to address this major flaw in our food safety network. In this regard, I would like to draw my colleagues' attention to the National Center for Food Protection, now underway in Battle Creek, Michigan, which addresses the lack of adequate training for state food safety officials. This new center will begin training state food officials this summer to a level commensurate and consistent with our federal standards, thereby providing a new level of protection for consumers. Mr. Hubbard- is it your impression that developing a National Training center with a unified curriculum for state

and Federal inspectors will address the inadequacies and discrepancies amongst inspections?

A: Yes. The concept of a national training academy for food inspectors is, in my opinion, a much needed approach. I understand that FDA food safety officials also agree that a consistent, national training program is needed.

Equivalency/Trade

Q: As globalization continues, food imports into the U.S. continue to grow. In fact, according to the FDA, more than 80% of seafood consumed in the U.S. is imported. While we face many challenges with our domestic food supply, we also need to address the mounting concerns regarding unsafe food coming from abroad. We have seen many examples of this in the past few years, specifically in pet food and dairy products. As we improve our food inspection system within our own country, we need to hold other countries to the same standards. Do you believe that establishing rules of equivalence between countries is the best way to ensure that we hold all countries to the same food safety standards?

A: The concept of equivalence has worked very well for USDA's meat and poultry inspection program, under which that Department can require that foreign countries virtually duplicate USDA's inspection system and standards. However, relatively few countries are deemed equivalent and relatively few processors in those countries are approved by USDA.

For FDA-regulated foods, there are over 130 countries shipping food to the U.S. , and there are over 200,000 foreign food facilities registered with FDA. So, for FDA to undertake equivalence process similar to USDA's would likely require a very large additional staff and many years time. Thus, FDA officials have generally believed that an equivalence approach for the foods it regulates would not be practical.

There are some less ambitious measures that can be taken, however. For example, FDA cannot now "embargo" foods from countries that are

believed to have inadequate food safety standards. Giving the agency the authority to suspend shipments from countries that have repeatedly sent food that is found in violation would be a powerful message to exporting countries that they need to take greater care with the food they export to the U.S. Such authority could allow FDA to 1) suspend shipments of a given food from a given country, such as milk from China following the melamine contamination last year, 2) suspend shipments from a given foreign producer, such as particular seafood processors found to repeatedly use illegal drugs in their fish, and 3) suspend, in extraordinary cases, all food imports from an entire country if that country's system was found to be so faulty as to pose a serious risk to American consumers.

Q: In regards to food imports, there are many unsafe products coming into our country. However, there are already a number of laws on the books that would protect us from this unsafe food. Do you think FDA and other agencies who oversee food safety are doing an adequate job of enforcing these laws in imported products? What more can we do to make sure we enforce these laws internationally?

A: While I believe there should be more aggressive enforcement of the current laws governing food imports, I also believe that the greatest need is for statutory change. FDA's authority dates to the turn of the 20th century, and essentially allows an FDA inspector to deny entry of a food import if the inspector finds contamination in a given food shipment. That system has two fundamental flaws: 1) it relies upon an inspection of each and every shipment, but FDA is resourced to inspect only 6/10s of 1 percent of imported foods, certainly not enough to be a credible deterrent; and 2) it does not give FDA explicit authority to require foreign governments and food producers to demonstrate that they are following safe food production guidelines. The end result means that foreign food processors, even in undeveloped countries, can send virtually anything of any quality to the U.S. with little fear of being caught or punished.

Questions submitted by Robert P. Casey, Jr.

Q: How would you envision a more comprehensive record keeping system to function? Who should be responsible for tracking a food product's movement through the food supply system?

A: Some industry segments, such as the large tomato producers, have demonstrated systems that are highly effective. Using technology such as bar codes and RFID (radio frequency ID), firms are able to track foods from their initial source, say, a farm, all the way to the retail outlet that sells the food to consumers. This means that, if a problem is suspected, they can give FDA the necessary information to track a contaminated food to its source rapidly and accurately, and can effectuate a recall without causing widespread disruption for innocent farmers and distributors. As last year's tomato/pepper contamination, and this year's peanut butter case, demonstrated, FDA's need rapid access to complete records of a food's movements, and electronic record keeping is extremely valuable. The agency also needs authority to require some technical details, such as lot numbers and nomenclature [for example, during the tomato search last year, some distributors called a particular type of tomato "red rounds," while others described the same tomato as "cooking tomatoes," meaning that FDA investigators going through invoices were misled and delayed in finding the eventual source].

Q: How would you propose that laboratory facilities be expanded? Are there ways that such an expansion could take place that would leverage existing federal, state, and/or local capabilities?

A: There are a number of questions that should be addressed with regard to laboratories; I will address two of them here:

1) Many public health officials believe there needs to be an expansion of the net work of state and Federal laboratories capable of analyzing food for

contamination; but also, that a system of improved coordination be developed to ensure that the lab system communicates well among various labs and does not duplicate effort.

2) FDA's laboratories are a valuable resource for the agency and the nation, but most are in dire need of facility repairs, equipment upgrades and modernization. I was told recently of a case in which an FDA lab received a discarded analytical machine from the National Institutes of Health, which regarded the equipment as antiquated. Yet the FDA scientists were delighted to receive a piece of equipment they felt was a significant upgrade to their facility. Such stories are not uncommon at FDA, and reflect the overall lack of adequate funding for the agency over the past 15 years.

Q: You made mention of "turf battles" existing between officials at FDA, CDC and state and local health agencies. Can you describe examples of this? In your opinion, did these battles result in a delayed response to a report of foodborne illness?

A: There are a number of studies and report about the need for better coordination and collaboration among CDC, FDA, and state and local health departments, to which I would refer you for more information. One serious student of the issue is Michael Taylor, a former FDA and USDA official who is now a professor at George Washington University's public health school.

One serious example that I am aware of in this regard deals with last year's search for tomatoes contaminated by Salmonella St. Paul. The epidemiological findings by state health officials and the CDC targeted tomatoes as the culprit in that outbreak. Thus, FDA was advised by CDC to search for tomatoes with that specific contamination, and FDA did so for many weeks. However, mid-way through the Salmonella St. Paul investigation, FDA investigators became doubtful that tomatoes were the cause – because they were unable to find contaminated tomatoes despite

extensive inspections and testing, and the tomato “theory” did not match well with the growing and harvesting patterns in certain states. So, as I have been informed, FDA officials asked CDC for the raw epidemiological data upon which CDC relied to determine that tomatoes were the problem – so that they could attempt to mate the “epi” data with the harvesting and distribution information FDA had. But I’m told that CDC denied FDA access to that data, insisting that FDA continue to search for contaminated tomatoes. As it later turned out, as you know, the FDA suspicions were correct, and peppers were later determined to be the cause of the Salmonella St. Paul cases. If this account is accurate, the results were widespread: FDA was accused of incompetence in “chasing” the wrong food; confidence in the Federal government’s ability to respond effectively to a major outbreak was diminished; consumers were misled about a potential health threat; and the tomato industry suffered economic losses.

Of course, epidemiology is not an exact science, and I’m sure CDC officials were making their best judgment at the time. Whoever was “right” or “wrong” in that instance is less important than the recognition that the Federal government needs a single senior official with the authority and responsibility to ensure that state and Federal oversight of food safety outbreak investigations are conducted rapidly and are well coordinated. There was an attempt during the Clinton Administration to have such a mechanism (known as “FORCG”), but it was not perfected at the time and was not continued by the Bush Administration.

Questions submitted by Robert P. Casey, Jr.

Q: What practices or capabilities should states have in place to alert CDC as soon as possible about a potential outbreak? What allowed the Minnesota Department of Health officials, for instance, to report on this outbreak before any other state?

A: To detect and investigate potential outbreaks more quickly, states and local health departments need to be able to rapidly and routinely 1) collect and "fingerprint" all *E. coli* O157, *Salmonella* and *Listeria* patient isolates; 2) interview those patients about likely exposures, such as food, water, animal exposure and person-to-person transmission with a standard questionnaire; 3) identify potential outbreaks by linking interview data with laboratory "fingerprint" data, and then, re-interview those patients in much greater detail; 4) conduct identical detailed interviews of healthy persons to compare their exposures to those of patients who are part of the potential outbreak; and 5) conduct detailed environmental assessments of small clusters of related illnesses associated with institutions or restaurants.

We understand that Minnesota is able to rapidly confirm and "fingerprint" every *Salmonella* or *E. coli* O157:H7 isolate that is submitted and also rapidly interview every *Salmonella* and *E. coli* O157:H7 patient with a detailed questionnaire to conduct investigations of potential outbreaks. Other health departments and public health laboratories tell us they cannot do this with their current resources. While the national "fingerprinting" network called PulseNet has greatly increased the detection of clusters for *E. coli* O157, *Listeria*, and *Salmonella* that may represent widespread outbreaks, rapid detection and early assessment of potential outbreaks depend on the capacity within state and large city health departments to conduct such surveillance and investigation.

Q: How specifically does CDC plan to increase its coordination with state and local health agencies to expedite the response to outbreaks? Is CDC in a position to provide greater technical assistance or other support?

A: CDC plans to increase its coordination with state and local health agencies by developing standard methods and tools for health departments to use during multi-state outbreak investigations, such as guidelines for multi-jurisdictional outbreaks, standardized food questionnaires, program performance indicators, standardized protocols for environmental investigation of restaurants and grocery stores, and an on-line Food Safety Clearinghouse. CDC has also supported FDA in its efforts to promote the use of the *Voluntary National Retail Food Regulatory Program Standards* by state and local agencies. Among other things, these Standards provide guidance on what an agency can do to improve foodborne illness outbreak investigations and communications between retail food regulatory programs and the state epidemiologists and public health laboratories.

CDC is well positioned to expand coordination by building upon its existing efforts and relationships. CDC has a long-standing partnership with the Association of Public Health Laboratories, which has allowed CDC to deliver standardized methods, training and equipment to the PulseNet laboratories. Through the Council of State and Territorial Epidemiologists and OutbreakNet, CDC coordinates and collaborates with state health department epidemiologists through regular conference calls and an annual meeting. CDC also works with the National Environmental Health Association (NEHA) to deliver multi-disciplinary outbreak training. In 2006, CDC began a multidisciplinary collaboration with the Council to Improve Foodborne Outbreak Response (CIFOR), to identify barriers among components of the food safety system and to develop a variety of practical recommendations, “best practices” and products that address these barriers. CIFOR membership consists of a broad array of disease control and regulatory stakeholders, including FDA, USDA, CDC, state and local

regulators, epidemiology, laboratory, and environmental health
representatives.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Tom Harkin
Chairman
Committee on Agriculture, Nutrition, and Forestry
United States Senate
Washington, D.C. 20510-2587

Dear Mr. Chairman:

Thank you for providing an opportunity for the Food and Drug Administration (FDA or the Agency) to testify at the February 5, 2009, hearing before the Committee on Agriculture, Nutrition and Forestry, which examined the recent *Salmonella* Typhimurium outbreak in peanut products. This letter provides responses for the record to questions forwarded by the chief clerk on February 10, 2009.

We have restated each question below, in bold type, followed by FDA's responses.

Questions submitted by Senator Harkin

Please provide for the record the timeline of the FDA's involvement with the Peanut Corporation of America in the inspection and recall events from the time that FDA learned of the problem to the present.

We have provided a timeline in the enclosure.

What is the date of FDA's first action in this investigation?

On December 3, 2008, FDA's liaison at the Centers for Disease Control and Prevention (CDC) began monitoring the *Salmonella* Typhimurium outbreak; no vehicle had been identified at that time. On January 7, 2009, FDA discussed peanut butter as a possible source of the outbreak with CDC and the Minnesota Department of Health. On January 8, based on preliminary data from CDC and Minnesota's investigation, FDA initiated an inspection and collected samples at a peanut butter distributor, King Nut.

What are the dates of each action and communication with PCA?

Throughout the *Salmonella* Typhimurium investigation, FDA has communicated with the Peanut Corporation of America (PCA). As is the usual practice when firms are willing to provide FDA the opportunity to do so, FDA reviewed and commented on PCA's recall press

releases before they were issued on January 13, 16, 18, and 28. As the recall expanded, FDA arranged discussions with PCA as necessary to communicate FDA's concerns. Following PCA's January 28 press release, as information was provided to FDA indicating that PCA may have sold products that were distributed at the retail level under PCA labels or by PCA's customers, FDA discussed this issue with PCA.

When did discussions regarding the recall begin with PCA?

On January 9, 2009, based upon the information gathered at King Nut, a distributor of peanut butter made by PCA, FDA initiated an inspection of the PCA plant in Blakely, Georgia. The information that was gathered during this inspection and investigation led to PCA's decision to initiate a voluntary recall on January 13 of 21 specific lots of peanut butter produced on or after July 1, 2008. PCA subsequently expanded the recall related to its Georgia facility on three separate occasions.

What is the date of each communication to companies that may have used product produced by PCA?

Recalling firms bear the principal responsibility for conducting recalls, including notifying affected companies that may have received the recalled product. Subpart C of Part 7, Recalls, contained in 21 *Code of Federal Regulations* (CFR) 7.40-59, provides general guidance to industry for the voluntary recall of FDA-regulated products.

PCA notified its customers on or about January 13, January 16, January 18, and January 28 to inform them of its initial and expanded recalls. FDA staff subsequently initiated contact with these consignees to verify that they had received PCA's notification and were taking all appropriate action.

When did these food companies and retailers act to recall or stop selling product? Of special interest would be when certain companies initiated recalls if they were prior to the first one by PCA.

The first product recall related to this outbreak was initiated on January 10, 2009, by the King Nut Company in Solon, Ohio, of peanut butter distributed under the King Nut and Parnell's Pride labels. As previously noted, PCA initiated its recall on January 13 and subsequently expanded this recall on January 16, January 18, and January 28 to cover additional products and production dates.

Food companies throughout the entire distribution chain that received these recalled products and/or incorporated these recalled products as ingredients into further-manufactured food products have subsequently stopped selling and recalled these products.

FDA has established a Web page and searchable database to provide constantly updated information on recalls at: www.fda.gov/oc/opacom/hottopics/salmonellatyp.html and www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm.

These Web pages have already been viewed more than 35 million times. The searchable database assists consumers in quickly identifying recalled products.

In the years leading up to the current outbreak, the Blakely, GA, Peanut Corporation of America plant had been inspected by the state of Georgia under contract by the FDA.

Between the FDA inspection in 2001 and the recent one in January 2009, on what dates was that plant inspected and by whom? Were there entities other than the state of Georgia inspecting the plant in that time period as well, such as inspectors/auditors from companies that purchased products from PCA?

Between the FDA inspection in 2001 and the recent one in January 2009, the Georgia Department of Agriculture (GDA) conducted independent inspections of PCA's Blakely, Georgia plant in January 2006, May 2006, August 2006, December 2006, February 2007, and December 2007. In addition, GDA conducted inspections under contract for FDA in August 2007 and June 2008.

Questions submitted by Senator Grassley

It seems like every day we are hearing about more recalls of foods. Does FDA have any sense what is the predominant problem?

There are many reasons why consumers are hearing about recalls of foods more frequently. One of the major reasons is that we are identifying multistate foodborne outbreaks earlier and more frequently than previously because of improved laboratory techniques and use of the national laboratory surveillance system, PulseNet. In recent years, large multistate foodborne outbreaks have been detected that previously would not have been identified. Other reasons include communication tools that reach wider audiences and broader and faster distribution of food products across the United States. The current outbreak of *Salmonella* Typhimurium is one example of how one supplier in the food supply chain can have a tremendous impact. The peanut products manufactured by PCA were widely distributed and were manufactured into a wide variety of other products, making this a very large and complex outbreak.

Are lab results inaccurate?

Positive and negative *Salmonella* test results associated with the same lot of food do not indicate that the laboratory results are inaccurate. *Salmonella* is a "low dose" pathogen that is known to be able to cause illness in some persons when as few as one to ten cells are ingested. Thus, a food product can be the source of a large foodborne outbreak and yet have very low levels of *Salmonella*. In foods with very low levels of *Salmonella*, which are not evenly dispersed throughout the product, not every sample taken from the lot will test positive. In fact, our experience is that a majority of samples from a contaminated lot will typically test negative. Thus, it is not unusual to see a positive sample from a lot and then retest that lot and get a negative result. The negative result does not establish that *Salmonella* is not present in the lot.

Is the greatest threat from imported products?

Not necessarily. We have seen significant outbreaks stemming from both imported and domestically produced products, and we have had recalls of both imported and domestic products. We do have better knowledge of the manufacturing conditions of food products manufactured in the United States and can more easily follow-up on reports of potential problems at domestic facilities. However, we also have a number of relationships with foreign governments that allow for sharing of information when they find problems in their industries that could impact U.S. consumers.

In essence, if the FDA received limited new resources, where would they be best directed?

The President's Fiscal Year (FY) 2010 budget invests over \$1 billion for FDA food safety efforts to increase and improve inspections, domestic surveillance, laboratory capacity, and domestic response to prevent and control foodborne illness.

Questions submitted by Senator Stabenow

According to your agency: "Cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market." FDA also claims that both the agency and industry share an interest in removing unsafe and/or defective products from the marketplace. However, given the recent situation regarding peanuts and the criminal investigation that is now taking place, do you believe FDA needs broader authority to recall products, rather than relying on a voluntary system?

Mandatory recall authority would be a useful tool that in some circumstances could result in a faster removal of implicated products from commerce.

Due to the recent failures of the food safety system to protect the public health against salmonella, many now believe the FDA lacks the resources to fully perform. What are the key activities in need of substantial increases in funding, in order to make the FDA operate to its best ability?

The President's FY 2010 budget invests over \$1 billion for FDA food safety efforts to increase and improve inspections, domestic surveillance, laboratory capacity, and domestic response to prevent and control foodborne illness.

Questions submitted by Senator Casey

Can you elaborate a bit upon what a standard FDA inspection entails for a facility like the Peanut Corporation of America's Blakely Plant?

FDA conducts both limited and full inspections. A limited or directed inspection is one that is designed to focus on a specific issue or obtain limited information, follow-up on a recall, or address a specific question.

A full or comprehensive inspection takes considerably more time and assesses the firm's entire operations. A full inspection is as a careful, critical, official examination of a facility to determine its compliance with the laws administered by FDA. Inspections may be intended to comprehensively evaluate a firm's compliance or they may be directed to obtain specific information on new technologies, good commercial practices, or data for establishing food standards or other regulations. Inspections like those of peanut butter manufacturers follow the process described in FDA's compliance programs and the recent bulletin providing information on environmental sampling and internal testing.

What are field inspectors trained to look for, and what would constitute a "red flag" or an otherwise serious violation?

Investigators are instructed to focus on the following areas during comprehensive inspections:

- Receiving – the source of ingredients, storage, protection from contamination, and microbiological certifications, if applicable;
- Manufacturing and repacking operations – observe process, determine whether critical areas are under control (e.g., temperature and time considerations, cross-contamination, employee practices, handling, pests, sanitation standard operating procedures (SOPs), filling operations, containers);
- Facility environment – adequacy of facility, pest control, structure, water source, waste disposal, cleaning procedures;
- Storage of finished product – environment, temperature, pests;
- Transportation – vehicles, SOPs, cross-contamination, temperature.

Significant deficiencies in any of these areas or evidence of direct contamination could constitute a "red flag" or serious violation.

Inspection and Recall Events Related to Peanut Corporation of America

Timeline (January 9, 2009 to February 5, 2009)

Friday, January 9, 2009

FDA begins the inspection of Peanut Corporation of America (PCA) located in Blakeley, GA. PCA ceases production and shipment of peanut butter and paste.

Saturday, January 10, 2009

FDA investigators collect environmental and product samples at the PCA facility in Blakeley, GA.

Monday, January 12, 2009

FDA initiates an inspection of Tidewater Blanching, a PCA peanut blanching facility located in Suffolk, VA.

Tuesday, January 13, 2009

PCA announces a voluntary recall of 21 lots of peanut butter produced in its Blakeley, GA, facility on or after July 2008.

Wednesday, January 14, 2009

FDA receives PCA customer notification documents (recall lists and letters).

Friday, January 16, 2009

FDA informs PCA that new product samples in unopened containers tested positive for Salmonella. PCA expands the voluntary recall to include all peanut butter produced on or after August 8, 2008, and all peanut paste produced on or after September 26, 2008, at the Georgia facility.

Sunday, January 18, 2009

PCA expands its recall to include all peanut butter and peanut paste produced on or after July 1, 2008, at the Georgia facility.

PCA announces that it has stopped producing all products at the Blakeley, GA, facility as the FDA and CDC continue the investigation.

Wednesday, January 21, 2009

FDA begins inspection of the PCA plant located in Plainview, TX.

Friday, January 23, 2009

FDA concludes the initial inspection at PCA in Plainview, TX.

Saturday, January 24, 2009

FDA makes mandatory request for records to PCA in Blakeley, GA.

Monday, January 26, 2009

FDA concludes the inspection of PCA's Tidewater Blanching in Suffolk, VA.

Tuesday, January 27, 2009

FDA concludes the inspection of PCA in Blakeley, GA, and issues FDA Form 483, Inspectional Observations.

Wednesday, January 28, 2009

PCA expands its recall to include all processed peanuts and peanut products shipped from the Blakeley, GA plant since January 1, 2007.

Wednesday, February 4, 2009

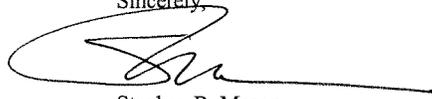
FDA initiates a follow-up inspection of PCA in Plainview, TX, to conduct further microbiological investigation and to investigate the possible link to Colorado cases of *Salmonella* Typhimurium.

Thursday, February 5, 2009

FDA issues an amended Form 483, Inspectional Observations, to PCA in Blakeley, GA.

Thank you, again, for the opportunity to appear before the Committee. We look forward to continuing to work with you and Committee staff on these important public health matters. If you have any further questions or concerns, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Mason', with a long horizontal flourish extending to the right.

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Enclosure

cc: The Honorable Saxby Chambliss, Ranking Member
Committee on Agriculture, Nutrition, and Forestry

The Honorable Charles E. Grassley, Member
Committee on Agriculture, Nutrition, and Forestry

The Honorable Debbie Stabenow, Member
Committee on Agriculture, Nutrition, and Forestry

The Honorable Robert P. Casey, Jr., Member
Committee on Agriculture, Nutrition, and Forestry