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

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

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 eater 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 cor-

rect 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; AC-COMPANIED 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 privatelabel 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 his 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 ZOONOTIC, 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 association 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 inves-

tigation 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 Washington 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, wight?

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 in-

spected 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 Chambles. 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 proc-

essed 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 Chambles. 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 addi-

tional 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 Chambles. 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 Chambles. 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 Chambles. 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

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