THE SALMONELLA OUTBREAK: THE CONTINUED FAILURE TO PROTECT THE FOOD SUPPLY

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BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

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[1] Mr. Parnell did not present an opening statement.
[2] Mr. Lightsey did not present an opening statement.

THE SALMONELLA OUTBREAK: THE CONTINUED FAILURE TO PROTECT THE FOOD SUPPLY

WEDNESDAY, FEBRUARY 11, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:05 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Bart Stupak (chairman) presiding.

Members present: Representatives Stupak, Braley, Markey, DeGette, Schakowsky, Christensen, Welch, Green, Sutton, Barrow, Inslee, Pallone, Dingell, Waxman (ex officio), Walden, Deal, Radanovich, Sullivan, Burgess, Blackburn, Gingrey and Barton (ex officio).

Also present: Representative Bishop.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order.

First I want to take the opportunity to welcome all of our new and returning members to the subcommittee. I am honored to be able to serve as chairman for another term. I want to welcome our new ranking member, Mr. Walden of Oregon, and also Mr. Braley, the vice chair of this subcommittee. You have been on the subcommittee for some time, Mr. Walden. I look forward to working with you in a good, bipartisan working relationship in the 111th Congress like we had in the 110th Congress.

I welcome Chairman Waxman in his new role as chairman of the full committee. Mr. Chairman, I know you will serve us well and will continue the tradition of aggressive and fair oversight that this committee has become known for. I also look forward to working with your staff along with Mr. Kevin Barstow, who in this case here traveled once again to Georgia to look at the peanut plants in Georgia as he did in 2007. I think Kevin is going to be in every peanut plant in Georgia if this keeps up, so I want to thank Kevin and Scott Schloegel and the whole staff for all their hard work in preparation for today's hearing.

I want to thank Chairman emeritus, John Dingell, the gentleman from my home State of Michigan, for his long and distinguished career in the House and here in the Energy and Commerce Committee. I must note today in fact the first resolution on the floor

today, so members will be moving back and forth in and out of this committee to pay tribute to Mr. Dingell as being the longest-serving Member in the history of the U.S. House of representatives. He served more than 53 years and 2 months. As was noted in the ceremony honoring Chairman Dingell last night, we will honor him for the time he has served and we honor him more for what he has done while serving. It is truly a pleasure and a privilege to serve with Mr. Dingell and have him on this committee.

Now the business before us today. This hearing today that we have is "The Salmonella Outbreak: the Continued Failure to Protect the Food Supply." We will begin with opening statements. The chairman, the ranking member, the chairman emeritus will be recognized for 5 minutes for an opening statement, and other members will be recognized for 3 minutes for their opening statements. I should note, there is a lot of interest in this hearing. We already have a statement submitted by the record with unanimous consent. Representative Sanford Bishop is here. He is from Georgia. He has an interest in this. And also Mr. Barrow is here, again not part of the subcommittee but he is a member of the full committee. Mr. Green is here, so a lot of interest in this hearing. So I will begin with the opening statement.

Since late 2008, the United States has been in the grips of a nationwide outbreak of salmonella infections that to this date is believed to have caused 550 illnesses and eight deaths in 43 States. In January, public health officials in Minnesota and Connecticut connected the outbreak to peanut butter produced by the Peanut Corporation of America, PCA, at its plant in Blakely, Georgia. This finding triggered a series of recalls that have included all peanut butter and other peanut products produced at the facility for the past 2 years and recalls by over 54 companies of more than 1,900 products containing the ingredients from the Blakely, Georgia, and Plainview, Texas, facilities of PCA. The recalls have cost business and government millions of dollars. The psychological cost has been widespread concern among parents of the millions of children nationwide who daily enjoy peanut butter sandwiches, cookies, crackers and other snacks. The President of the United States has expressed the view of parents across America when he said that his 7-year-old daughter eats peanut butter probably three times a week and that, "I don't want to have to worry about whether she is going to get sick as a consequence to having her lunch."

Today's hearing will examine how this contamination was allowed to grow unchecked and the collective failure of multiple players—the peanut butter manufacturer, the Food and Drug Administration, State regulators and private industry—to take steps that might have prevented the outbreak. This subcommittee is well versed on the issues we address today. In the last Congress we held eight hearings to examine the safety and security of the Nation's food supply including one in April of 2007 in which we specifically examined a similar outbreak arising from salmonella contamination of peanut butter manufactured by ConAgra.

Although we continue to learn new facts about the outbreak in the Georgia facility at which it all started, the facts we already know paint a very disturbing picture. When the FDA inspectors entered the plant in Georgia, they found a facility riddled with un-

sanitary and unsafe conditions according to the inspector's preliminary report. Mold was observed growing on the ceiling and walls in the cooler used to store peanut butter products. A live roach and several dead roaches were observed in the washroom adjacent to the production/packaging area. Most importantly, salmonella was found in two separate locations in the plant including the one that was only 3 feet from finished peanut butter products. Even more disturbing is the fact that Peanut Corporation of America knew about salmonella contamination for over a year and a half but did nothing to address it. Internal company records reveal that since June 2007, PCA's products tested positive for salmonella on 12 different occasions but that the company continued to produce and distribute its peanut butter products without consequence.

And we know that the multiple players had opportunities to report or detect the contamination but failed to do so. The FDA had the authority to conduct inspections at the PCA facility and to test for salmonella, but when the FDA sent state inspectors to the plant on its behalf in 2007 and 2008, it did not test for salmonella, even though both visits occurred after the 2007 salmonella outbreak traced to the ConAgra plant just 70 miles down the road from the PCA plant. One of these inspectors occurred just one day after PCA-manufactured product had tested positive for the presence of salmonella. The Georgia Department of Agriculture conducted two inspections of the Blakely plant in 2008 but did not conduct tests for salmonella on either occasion despite an internal goal to conduct such tests once a year. Private laboratories that conducted the tests when PCA had firsthand knowledge of the positive findings of salmonella failed to report those results to anyone but the company. Neither the FDA nor the State of Georgia requested access to those records until after the salmonella outbreak. PCA's largest customers such as Kellogg's engaged contractors to conduct audit of the Blakely plant but they did not conduct their own salmonella test and did not require PCA to show them their internal test results, which would have revealed a consistent pattern of salmonella contamination.

So we appear to have a total systemic breakdown with severe consequences for hundreds of victims for which we need explanation. That is why we have asked representatives from each of these players, the manufacturer, the FDA, the State regulator, the private laboratories as well as victims of this outbreak to testify today. At this hearing we will seek answers to the following questions. What has been the human impact of this outbreak? How could the company, regulators, laboratories and industry let the salmonella contamination remain hidden for over a year before the outbreak? What legislative or regulatory changes can be implemented to prevent such catastrophic failures in the future? On this last question, it bears noting that we already have a vehicle for change in this area, H.R. 759, the FDA Globalization Act of 2009, which I am sponsoring along with Congressmen Dingell and Pallone.

I look forward to today's testimony as an opportunity to gather additional information with which to shape this legislation to address the public health impact of this and similar outbreaks. If there any good that can come from this tragic outbreak, it could

come from long-overdue legislative change to protect the American people from dangers in the Nation's food supply.

Next I would turn to my ranking member, Mr. Walden, for his opening statement, please.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you very much, Mr. Stupak, and Mr. Chairman, I look forward to working with you in my new role as the ranking Republican on the Oversight and Investigation Subcommittee. We have worked together on issues before for many years to protect the safety of Americans in many different ways and to improve security and other things in agencies. So I look forward to our work together.

Ladies and gentlemen, I remember our previous food safety investigations into E. coli in spinach, E. coli in meat, salmonella in peanut butter, salmonella in jalapenos, now salmonella in a variety of peanut-containing products. This container is full of products that less than a month ago people were consuming thinking it was fine to eat, and one of the things I am going to do today is ask Mr. Parnell from Peanut Corporation of America if he would like to open this and sample some of the products that he didn't think were a problem in sending out to the rest of us to eat. Now, there are some recalled products in here and there are some that are probably oK now. Lives were lost and people were sickened because they took a chance and I believe knowingly shipping product that was contaminated.

Yesterday we learned there is another plant in Texas that the FDA didn't even know existed that apparently has never been inspected and now we learn there was salmonella in that plant as well. This is simply outrageous.

The latest outbreak of salmonella has sickened 11 people in my home State of Oregon. It has touched the lives of teenagers in Baker County and toddlers all the way the other side of the State in Medford and in Wilsonville. Pets have now been added to the list of those falling ill from salmonella-tainted products. A dog in Oakland, Oregon, apparently is the first animal illness in the Nation linked to recalled products.

Today we will hear from a witness from one of these affected families, Peter Hurley. Mr. Hurley, I welcome you and your wife and your three children today. Jacob is here. Three-year-old Jacob, do you want to stand up and give a wave there? You are going to hear about Jacob's story. Jacob became sick in January. For about 2 weeks Peter and his wife watched as poor Jacob got sicker and sicker and they consulted their pediatrician and sought counsel and advice and poor Jacob apparently couldn't keep anything down. The pediatrician said well, what does Jacob like to eat because at least maybe we can get him to eat what he likes to eat and help him along. Austin peanut butter crackers is his favorite. So he continued to peanut butter crackers, and eventually as the news came forward that those crackers and other products like those in this container may well be containing salmonella, a State epidemiologist showed up at their house on a Saturday night, took the crackers, and from what I understand, every other package was contami-

nated with salmonella. Can you imagine the tragedy as a parent of knowing that in effect you have been poisoning your 3-year-old child with the help of your pediatrician, none of whom knew this was the problem until the damage was done?

Salmonella is a naturally occurring microorganism. It is usually transmitted to humans by eating contaminated foods. To reduce the risk of contamination, we require food-processing firms to follow the Food and Drug Administration's current Good Manufacturing Practices that serve as the minimum sanitary processing requirements for producing safe food. Failure to comply with the Good Manufacturing Practices is a violation of law, and if noncompliance leads to the distribution of adulterated or contaminated foods, more severe penalties may be applicable. Good Manufacturing Practices also serve as the basis for food-firm inspections conducted by the FDA and by State government inspectors.

Now, the Peanut Corporation of America, whose president and plant manager are invited witnesses today, has been identified as the sole source of this salmonella outbreak. Several of the company's products were tainted with salmonella at the PCA plant in Blakely, Georgia, and shipped to more than 100 consignee firms that serve as suppliers to food producers large and small for use as an ingredient in hundreds of different products such as cookies, crackers, ice cream, cereal and candy. At least two Oregon companies I am aware of have had to recall their products because they included ingredients that were sourced back to PCA. The health implications are all too clear, as our witnesses will testify today. Additionally, there are economic consequences for the food producers that use those ingredients and had to conduct those recalls.

As FDA has reported and as indicated in documents obtained by this committee, the Peanut Corporation of America routinely violated numerous Good Manufacturing Practices and knowingly shipped adulterated products to its customers. In an internal e-mail chain between the plant manager, Sam Lightsey, and the president, Steward Parnell, the two men discussed microbial testing completed on finished product. The e-mails state the company was notified of a confirmed positive salmonella test on a sample conducted by an outside lab. That sample was tested again and a negative reading occurred. Then Peanut Corporation of America shipped contaminated product to another outside lab and received a negative result. In response to getting a negative result, the company president gave instructions to his plant manager to ship the salmonella-positive products, specifically telling them "turn them loose." Another e-mail from Mr. Parnell, the president wants to discuss another positive test of salmonella and the time lapse in the shipment of product as a result. Mr. Parnell expresses his concern of losing huge amounts of dollar sign, dollar sign, dollar sign, dollar sign, dollar sign due to delays in shipment and costs of testing. It appears Mr. Parnell was more concerned about his company's bottom line than the food safety of Americans.

Expert witnesses will explain that a subsequent negative test result for salmonella on a sample never, never negates the initial finding of a confirmed positive. In response to a confirm positive, PCA should have immediately destroyed the entire lot of contaminated product, ceased production and attempted to uncover the root

cause of the contamination. All these steps are part of the FDA's manufacturing requirements that firms are forced to follow, required to follow.

FDA must enhance the GMPs for food and get stronger authority. Food firms should be required to give FDA access to records that show compliance, prove that kill step for pathogens actually works and confirm sanitation and protection against cross-contamination. To help prevent outbreaks in the future, FDA inspectors must have access to internal documents. We must assure the public the food on our grocery shelves is safe and what we put into our mouths and those of our children, elderly parents and even our pets is safe. While Congress moves on legislation, our food safety agencies and food manufacturing firms can take immediate action to improve the production of safe food, and I suggest that we demand those actions now, Mr. Chairman. Thank you.

Mr. STUPAK. Thank you, Mr. Walden. I suggest you keep your contaminated products on your side of the aisle. That would be a new way to get back into the majority but we will pass on that.

Mr. Waxman, opening statement, please, sir.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I am pleased to see you continuing your aggressive oversight on the issues of food safety and I am pleased also to see that you are working with our counterparts on the Republican side, especially Ranking Member Walden, to do this in a bipartisan basis. There is no partisanship when it comes to questions of food safety. We are shocked at what has been going on in this country on food issues, and what this committee needs to do is to find out the truth, hold people accountable and make sure it doesn't happen again.

For too long, people have been worried about this and they want to know what is happening, who is responsible. Well, we are going to hear in this first panel that those who most often pay the price are the young, the elderly and the infirmed because these tainted products distributed by the Peanut Corporation of America were sent to elementary schools, nursing homes, hospitals and even FEMA meal kits handed out in the wake of the Kentucky ice storms. We are going to hear today the results of our subcommittee's investigation and we have obtained documents that I would ask unanimous consent be made part of the record.

Mr. STUPAK. Without objection.

[The information was unavailable at the time of printing.]

Mr. WAXMAN. These documents obtained by our subcommittee are very disturbing because what they show is that this company cared more about its financial bottom line than it did about the safety of its customers. Last September, for example, PCA was notified by a private lab that its products had testified positive for salmonella. This wasn't the first positive test the company received and it may not be the last. In response, the president of the company sent an e-mail. Stewart Parnell was complaining that the positive salmonella tests were costing them huge amounts of money, and I see on the screen that we are flashing up this e-mail.

"There is going to be a huge lapse in time from the time we pick up peanuts until the time we can invoice." Well, even after the FDA began investigating in January and forced the company to recall some products, PCA's first concerns were financial. On January 19, Mr. Parnell sent an e-mail pleading with the FDA officials to allow the company to keep doing business. He wrote that they "desperately at least need to turn the raw peanuts on our floor into money." He assured the FDA that these peanuts would be cooked and further processed by their Texas facility. This Texas facility is the same one that was shut down yesterday after salmonella was found there too.

The subcommittee also obtained documents that appear to show that Mr. Parnell was not forthcoming about his company's past. Despite multiple records showing positive salmonella tests over 3 years, he wrote an e-mail to his company's employees on January 12 asserting flatly that, "We have never found any salmonella at all," and he blamed the news agencies. They are looking for news stories that are going to scare people about the cause of this food sickness outbreak. The subcommittee obtained a statement from an official at one of the private labs used by PCA to test for salmonella. The lab official reported that PCA's plant manager in Georgia, Sam Lightsey, admitted to shipping products before receiving lab results. The official stated, "When I called Mr. Lightsey in early October 2008 to give him the serology reports that JLA obtained from the lab for the confirmed salmonella, he paused and said uh-oh or something to that effect and then told me he had released the product for shipping. When I asked him if he could get it back, he said it was on a truck heading to Utah." This lab official also informed us that PCA stopped using its services because it received too many positive tests. The official stated, "I called Mr. Lightsey to follow up on the recent discussion regarding the confirmed positive and he confirmed that because of the high coliform results, they are going to send samples to a different lab."

Mr. Chairman, I want all these documents in the record. I want them to be made public. I hope that in this hearing, we are going to be able to find out more about the actions of these PCA officials. I look forward to hearing from the labs that conducted these tests as well as the State and federal officials in charge of overseeing this company, and I also want to extend my condolences to the victims and family member, the victims who are here today. We have got to find out the truth. We have got to hold people accountable and we have got to make sure that this doesn't continue in the future.

Thanks for your hard work and the aggressive oversight that I know you are committed to. I yield back the time.

Mr. STUPAK. Thank you, Mr. Chairman.

I next turn to Mr. Barton of Texas for an opening statement.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Mr. Chairman.

Today you are going to see Congress at its best and at its worst. This subcommittee hearing is Congress at its best. We have an issue that affects the public health and safety of American people.

We have a chairman and a subcommittee chairman who have quickly acted to bring it to the country's attention, to bring witnesses forward both from the victims' side and from the regulatory side and also give an opportunity for the affected party, the company in this case, to present their side of the story. That has been done on a bipartisan basis with full cooperation including yesterday a full committee meeting, business meeting, where we unanimously voted to subpoena to compel some of the witnesses that didn't want to voluntarily testify to come before the Congress so that people would know. That is Congress at its best. Mr. Waxman and Mr. Stupak are to be commended for their leadership.

I also want to commend Mr. Walden, the new ranking member on the Minority side, for the best opening statement I have heard in 22 years in an oversight hearing, and that goes back to John Dingell, Billy Tozan, Tom Bliley, Mr. Waxman and others who have always specialized in aggressive oversight. He put the case succinctly. He put the case in personal terms. He did it in a way that we can understand. So that is Congress at its best.

Unfortunately, today we are also going to see Congress at its worst. We have the stimulus package that is in limbo somewhere in conference between the Senate and the House of Representatives, and the House conferees were appointed yesterday. This committee, who has got jurisdiction for approximately $100 billion of that stimulus, including all the healthcare issues, all the telecommunications issues, all the energy issues, all the environmental issue has one conferee, the chairman of the committee. Nobody on the Minority side. It is a very small conference but the Speaker has seen fit that the Minority doesn't count. Our voice doesn't count. Well, I have a prediction to make. By the end of the day or the end of the week, they are going to hear the voice of the Minority on this issue. We need to do something to help the economy for this country, we need to do it cooperatively on a bipartisan basis, but when you shut one side out, it makes it very difficult to work in a positive fashion.

So on a positive note, this is an important hearing. We are totally supportive. Whatever the results of the hearing are, I am sure we will work together to implement those, but on the other issue, it is not democracy when only one side has a voice.

With that, Mr. Chairman, I yield back.

Mr. STUPAK. Thank you, Mr. Barton.

By order of appearance, members will be recognized for 3 minutes for an opening statement. Next would be Mr. Green from Texas.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman. I want to thank you for holding the hearing today. Last year we had many hearings on food safety, but unfortunately, the committee was never able to pass a food safety bill. The recent salmonella outbreak is yet another example of how the FDA and State agencies are unable to protect the American food supply. The committee's investigation has shown that Peanut Corporation of America was operating with blatant disregard for safety standards, which ultimately led to at least

eight deaths and sickened 600 individuals. Investigations by this committee found the Peanut Corporation of America shopped for labs that gave them negative salmonella results after originally testing positive, that they would not wait for the results and would ship the products out for consumption without ensuring they were safe for consumption. Peanut Corporation of America's plants are also in deplorable condition, especially the plant in Georgia with cockroaches near the peanuts, water leakage, mold and unsanitary production line.

On the 3rd we learned that the Peanut Corporation of America was operating an unlicensed and uninspected plant in Plainview, Texas. This plant was never inspected until the FDA began investigating the salmonella outbreak, at least never inspected by the FDA. Unfortunately, my home State of Texas is one of the states where the FDA relies on our State inspectors to oversee food safety. On Monday the Texas Department of State Health Services shut down the Plainview plant after it tested positive for possible salmonella. It is unbelievable that a food-processing plant can deliver possibly tainted products into our food supply without a license and without ever being inspected. One thing is clear: No plant should be able to operate in the manner in which the Peanut Corporation of America has operated.

Congress, myself included, said for years that the FDA is underfunded, and that is still true, but throwing money at them will not solve the problem. We need to overhaul the way the FDA reviews and inspects our food-processing plants and food supply. This committee, Congress and the new Administration must do all we can to shut down those unlawful operators and find a new way to protect the American food supply.

Again, I want to welcome our witnesses here, particularly the children. I have a 4-year-old granddaughter who loves peanut butter and crackers. In fact, as I sit here today, my son, they are having a new baby this morning in south Texas, a little boy, and all of them, all my grandchildren eat peanut butter and I have a jar here, and I didn't bring it to check it for salmonella, but anyway, it is so important for the American people literally from our smallest citizens to our oldest.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Green.

Mr. Deal for an opening statement, please, 3 minutes.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman.

First of all, I would like to welcome the deputy commissioner of agriculture from the State of Georgia, Mr. Terry Coleman, who by the way is a former speaker of the Georgia House of Representatives as a Democrat, Mr. Chairman, and also Mr. Oscar Garrison, who is the assistant commissioner of agriculture of the Georgia Department of Agriculture, who is going to testify on one of our panels.

Mr. Chairman, our Nation has always prided itself on having the safest food supply in the world. This confidence is founded on the hard work of those who grow, process, package and deliver our food

coupled with the oversight and inspections provided by the federal agencies such as FDA and USDA working with their comparable State regulatory authorities. Let no one misunderstand, however, we are all outraged by the alleged violations of law and common standards of safety which are the focus of this hearing, and our sympathy goes out to those who were injured and to those who have suffered losses. Although I am a resident of the State of Georgia where the production of peanuts is a vital part of our State's economy, there will be no statements of provincial protectionism from me for it is those who are closest to the problem that are the most infuriated by it for we know that the vast majority of those who produce peanuts and the resulting products are decent, law-abiding people. Right now peanut farmers are poised to plant this year's crop. The uncertainty created by the actions of Peanut Corporation of America will cost them millions of dollars. They and many more in the chain of production have done nothing wrong but they are suffering the consequences of the questionable actions of one company. These innocent individuals and companies are more concerned than almost anyone that the cloud of suspicion be removed from the peanut industry.

As legislators, we should be asking how we can make the system work better. I am sure we can learn from this unfortunate experience how to reform our inspections system at both the federal and state levels. In fact, the Georgia General Assembly is in session right now and is considering legislation to strengthen the role of our State inspections and oversight. We have the responsibility to shake the scales of justice as it relates to food safety but the architect whose eyes are focused only on the actions of the most egregious will design scales of justice that will not work for it fails to account for the overwhelming weight of the majority who are honest and law abiding. That is our challenge as we go forward to ensure the safety of all without destroying the underlying industry.

I am confident that the peanut industry of my State and the Nation will work cooperatively with this committee, with this Congress and the legislatures of the various States to craft reforms that will restore the confidence of the American people in the safety of peanut products. Toward that end, I pledge my best efforts, for after all, the good health of the American public and in fact the fate of the peanut butter and jelly sandwich lie in the balance.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Deal.

Next we will hear from Mr. Braley, the vice chair of the subcommittee, a new member of the committee. Welcome.

OPENING STATEMENT OF HON. BRUCE L. BRALEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Mr. BRALEY. Thank you, Mr. Chairman. I just want to tell you how honored I am to be serving as your vice chairman. I look forward to working with you and Ranking Member Walden on the important work of the committee.

As I was preparing for the hearing today, I thought of Upton Sinclair and what he must be thinking as we sit hear nearly 100 years after the publication of The Jungle facing the very same food questions that dominated the discussion of this Capitol over 100 years

ago, and that was highlighted by this advertisement that appeared in USA Today where we have the unbelievable aspect of corporations paying thousands of dollars to say "it ain't me", and as we focus on the important topics we are here to talk about today, we need to keep in mind the enormous economic consequences to people who are not involved in this contamination as well.

This recent outbreak of salmonella in peanut products has resulted in the recall of over 1,700 products, one of the largest recalls ever under the jurisdiction of the FDA, but this outbreak is not just disturbing because of its size. It is particularly troubling because of its impact on Americans most vulnerable to tainted food. As noted in the Monday issue of USA Today, salmonella affects people who are most vulnerable depending upon the strength of their immune system and how old or young they are, and we all know that salmonella is most dangerous to very young children. Given that, I think it is outrageous that the contaminated King Nut peanut butter, which was the product in which the source of this salmonella outbreak was first located, was distributed to nursing homes, hospitals and schools.

Yet the serious concerns I have about the severity of the effects of salmonella on children are only compounded by the sheer popularity of peanut butter and peanut butter snacks among children. As President Obama noted recently, peanut butter is very prevalent in the diets of young children like his daughter Sasha. As a parent, I know this firsthand. I am also concerned as a parent that three States have had to remove tainted Peanut Corporation of America products from their school lunch programs. These States receive peanut butter or roasted peanuts from the Federal Government, which bought them from the Peanut Corporation of America. It is completely unacceptable that our Nation's schools could be serving children products that could make them severely ill or kill them and that the Federal Government would be purchasing and distributing these potentially dangerous products to our schools.

There are many questions that need to be answered today about the practices of Peanut Corporation of America, about the FDA and State inspections of their plants, and about the general safety of our food supply. One thing that is clear is that we need to be doing a much better job of protecting Americans, particularly children and other vulnerable populations, from unsafe food products. I look forward to hearing the testimony of the witnesses and hope that this hearing will help to determine what Congress needs to do to prevent these outbreaks in the future and ensure the safety of our Nation's food supply.

Mr. STUPAK. Thank you, Mr. Braley.

Mr. Gingrey for an opening statement, please. I guess he is not there.

How about Mr. Burgess for an opening statement? Order of appearance we have been going by. Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. Chairman, it seems like we have been here before. We have previously established that there are serious problems within the

FDA. In the last Congress we had 16 FDA-related hearings. Now we begin a new session of Congress with a hearing on the Food and Drug Administration and their role in inspecting the Peanut Corporation of America, the source of over 553 salmonella-related illnesses and at least eight deaths. Mr. Chairman, this is like a bad movie and we all have read the script before. In 2007, we investigated the Food and Drug Administration's role with ConAgra and the salmonella illness in their peanut-based products, and just like today, in 2007 it was the State of Georgia which was the source of the salmonella and peanut-based products, so it is not just a bad movie script, it is a deadly one, and it has got the same theme, salmonella, the same actors, the Food and Drug Administration and the State of Georgia, but with one crucial difference: this time there is the possibility of criminal activity by the Peanut Corporation of America. And we know that the Peanut Corporation of America engaged in deliberate misconduct in this case. We know that the Peanut Corporation of America not only retested salmonella-positive batches of peanut products, they intentionally shipped the products to their unsuspecting clients. At least 75 companies, 16 different food categories make over 1,000 types of consumer foods with peanut products made by the Peanut Corporation of America and then they put them in front of the whole world for our consumption. It is no wonder in the past month, it seems like almost on every newscast at the top of every hour we are notified of yet another recall of yet another product creating yet another crisis, a crisis in an already troubled economy.

Mr. Chairman, this is a deliberate act that is almost astonishing in its cruelty. It is a violation not only of the trust of the American consumer but also of their business partners. The president of the Peanut Corporation of America could give us answers, should give us answers, but we won't get them today because it is my understanding, that individual is going to plead his Fifth Amendment rights. Boy, I would love to ask, how did you think this was going to work out for you.

I also continue to be troubled by how much the Food and Drug Administration needs our attention and modernization. They need more powers like the mandatory recall power, which I had previously advocated, as well as the power to retrieve all records for any food company being investigated. But no matter how much demand greater action and accountability from the Food and Drug Administration, we can only hold the Food and Drug Administration accountable for the laws that are there and then businesses like the Peanut Corporation of America, they violate not just the law but the fundamental tenets of their business practices. It is not any longer about following the rules of the FDA. It is just about being a good citizen of the world. So for me, yes, it is time again to focus on the Food and Drug Administration and how we need to work on the Food and Drug Administration and help it in its mission but we also should focus on punishing the bad actors in this case.

Mr. Chairman, now it is a criminal matter, and although we need to work to continue to modernize the FDA by giving them the money and the power they need to continue to protect our citizens, you know, there is not a night that goes by it seems that Lou

Dobbs doesn't end his newscast by saying, "Doesn't anyone deserve a government that works?" and that is not just a rhetorical question, Mr. Chairman.

Mr. Chairman, let me ask that this committee answer Mr. Dobbs in the affirmative. Let us make it unambiguous. Let us make it a bipartisan affirmative and let us also commit that from this hearing forward we will make our actions match our rhetoric, and I will yield back.

Mr. STUPAK. Thank you, Mr. Burgess.

Ms. Christensen for an opening statement. Welcome to the committee.

OPENING STATEMENT OF HON. DONNA M. CHRISTENSEN, A REPRESENTATIVE IN CONGRESS FROM THE VIRGIN ISLANDS

Ms. CHRISTENSEN. Thank you, Mr. Chairman, and good morning, Chairman Waxman, Chairman Stupak, Ranking Members Barton and Walden. This is my first hearing with the Subcommittee on Oversight and Investigations and I am glad to be here but I am really sickened by the reasons that we are meeting this morning.

The recent salmonella outbreak demonstrated clear and serious deficiencies in our country's food safety system, some based on centuries-old legislation, and so this hearing is very important to fixing the problems that cause so much preventable illness and the eight deaths that should not have happened, so thank you for holding it, and thank you also to those who are here to testify, especially the families of those who suffered because of the unscrupulous, likely criminal business practices and the fact that our government failed you. I extend condolences to the Almer and Tousignant families, and to Mr. and Mr. Hurley, we are glad to see that Jacob is well enough to be here with us today.

For the past several months we have heard countless reports about the salmonella outbreaks, and with each story and each investigation we learn a bit more about how many gaps there are in our Nation's processes to ensure food safety. We have also learned how key agencies such as FDA lack the authority, resources and oversight that they clearly should have to ensure the safety of our food and the health of our families and our loved ones. Finally, we have learned about the tragic consequences that these gaps in food safety have on innocent lives, consequences that could have been avoided, should have been avoided and consequences that I look forward to working with you, my colleagues on this committee, to avoid in the future.

Thanks to Mr. Dingell, Mr. Pallone and Mr. Stupak, who have already launched an effort that is heading us in the right direction with the introduction of H.R. 759, the Food and Drug Administration Globalization Act of 2009, which I am proud to cosponsor. Through provisions which empower the FDA with additional resources and mandatory recall authority as well as oversight over and access to the safety plans of food service facility established as well as access to those tests that are conducted to measure safety and inspection records, we are finally on a better path to prevention. We know those measures are too late for the precious lives that have been lost and the others that were put in jeopardy, lives of some of more vulnerable people, those in nursing homes, hos-

pitals and schools, all because we had to wait for a company to initiate the recall of a product that they knew was tainted, that they knew would make people sick just to protect their profit margins.

There is plenty of blame to go around because many balls were dropped. The only blameless ones in all of this are the individuals who died, those who got sick and their families and loved ones. If for no one else, let this hearing be about them and let the lessons we learn and the next steps we take to ensure that their suffering is not forgotten.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. STUPAK. Thank you.

Mr. Radanovich for an opening statement, please.

OPENING STATEMENT OF HON. GEORGE RADANOVICH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. RADANOVICH. Thank you, Chairman Stupak and Ranking Member Walden. Also I want to thank Mr. Waxman and Mr. Barton for holding this important hearing on the outbreak of salmonella in peanut products.

As a representative of one of the largest agriculture producing districts in the Nation, I am keenly aware of the importance of food safety as a public health hazard and also as an issue of national security. However, what truly makes me more concerned about food safety, it is not so much my role as a Member of Congress but as a father of a 10-year-old boy who happens to love peanut butter and jelly sandwiches. Parents these days have so many things to worry about. It is unfortunate that peanut products, which are often a staple in the diet of a 10-year-old boy, have been added to this list. Even with the best parenting in the world, there are some things that are out of our control as parents. My wife and I can choose to avoid packing my son peanut products in his lunch but that doesn't stop him from trading his granola bar for trail mix that has salmonella-tainted peanuts in it.

My condolences go out to those who have lost your loved ones and to those who have been tragically affected by the salmonella outbreak, it was an avoidable situation, and I am looking forward to hearing the testimony from the witnesses and learning how Congress can help prevent situations like this from reoccurring.

So I look forward to the hearing and what we might learn from it, and Mr. Chairman, I yield back.

Mr. STUPAK. Thank you.

Ms. Sutton for an opening statement, 3 minutes. Welcome to the committee.

OPENING STATEMENT OF HON. BETTY SUTTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Ms. SUTTON. Thank you, Mr. Chairman.

On Christmas Day, my local newspaper had a story about a resident in a Summit County nursing home, that she was very ill, and on top of many other medical conditions she suffered from fever, abdominal cramps and diarrhea. Doctors diagnosed this woman with a case of salmonella, and a few weeks later she died. The woman I speak is one of the eight people who died of salmonella

and is among the 550 people nationwide who became sick as a result of this bacteria. According to the Ohio Department of Health, there have been 89 cases of salmonella reported in Ohio in the past 4 months. This figure is much higher compared to occurrences in other States.

Mr. Chairman, this outbreak demonstrates yet again that our food inspection system is broken. The source of the salmonella was traced to a factory in Georgia, we have heard, called the Peanut Corporation of America, or PCA, and on multiple occasions PCA's peanut products have tested positive for salmonella. PCA still shipped their products to schools, nursing homes and stores, despite that. Now there is a document on the FDA Web site with 288 pages worth of recalled products that include peanuts. The negligent practices in this food manufacturing plant are unacceptable and the government must do more to protect Americans. Regulatory agencies like the FDA, they need more power and they must execute more power and oversight to prevent another catastrophe like this. This is why I reintroduced the Protect Consumers Act. This bill is very simple. It would give the FDA mandatory recall authority over food products. Mandatory recall authority is only one of the critical steps, and there are other bills out there that are equally important and more comprehensive but just taking this simple step is a step that we should pursue with haste. Currently, the FDA is forced to rely on the company at issue to do the right thing, and we know that that isn't a good way to operate.

I look forward to hearing from PCA to learn why they continued to sell their contaminated products. I am also eager to hear from government officials to learn about their role in the recall and I look forward to working with my colleagues here on the committee to fix our broken system so that America's families can trust that the food they are eating is safe. That is not too much to ask.

Thank you.

Mr. STUPAK. Thank you.

Ms. Blackburn for an opening statement, please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms. BLACKBURN. Thank you, Mr. Chairman. Thank you for the hearing, and I want to thank our witnesses for taking their time to come before us today.

As you have heard, FDA review and oversight is not new to this committee. This is something that we have gone over and over and over during my 4 years on this committee, and Mr. Chairman, I sit here and I am listening to the opening statements and looking at our witnesses and I think, how many more Americans are going to have to be affected by some type of illness or worse before we get down to the basics on review, reform and accountability that is lacking in the system that is before us. I think it is unacceptable for the American public's health, and indeed, their life in many cases to be put at risk.

Now, peanuts, as you have heard, this is why we are here. This is the latest of our contamination issues in our food supply, and it is so unfortunate that contaminated product was knowingly

shipped to various locations, some in my State of Tennessee, and indeed, we express our sympathies to the families who have been injured, harmed or experienced loss of life because of this. We have 11 cases that are in Tennessee alone. Indeed, this is something that could have been prevented. We all know the source. We have discussed that with Peanut Corporation of America. We are going to look more into that today. And one thing that I am really going to want to know a bit more about is how there could have been 12 known cases of salmonella between June of 2007 and September of 2008, how there could have been 12 times that this was known and appropriate action was not taken. And what the American people are wanting to see is not more rhetoric, they want to see action, and Mr. Chairman, I think that is where reforming this system comes forward as what our next step should be to make certain that the American people can trust us to do our job, to reform the system so that they have trust in the food supply and the product that is placed on their shelves, and I yield back the balance of my time.

Mr. STUPAK. Thank you.

Ms. DeGette for an opening statement. Ms. DeGette is vice chair of the full committee.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Chairman. We spend a lot of time together in these food safety hearings, and I want to welcome our new members of the committee. I have been on this subcommittee for 12 years now, and since I have been on this subcommittee this is our 10th food safety hearing at which the members of the Oversight and Investigation Subcommittee spend quite a bit of time in a bipartisan way wringing our hands.

Now, in the meantime, with the latest problem, over 500 people have been sickened, 15 of them are in my home State of Colorado, half of the sickened people are children, and eight people have died. This is the deadliest outbreak of foodborne illness in decades but we have seen in the last few years jalapenos, peanut butter again, meat, dog food and on and on and on. I guess my question is to Congress in general, how many sick kids does it really take for us to finally act? How many workers need to get laid off before private industry and Congress put resources into protecting the integrity of our food distribution system? And I cannot think of a case that better demonstrates the need for the FDA and USDA to have mandatory recall authority than this case. The Peanut Corporation of America sells in bulk to companies and then those companies manufacture and distribute processed foods. So even though people started getting sick last summer, current federal law does not empower public health officials to issue a recall in response to an emergency like this. My constituents are shocked when they hear this, and instead companies are left to voluntarily decide for themselves if and when to recall their products. And so Mr. Chairman I know this isn't a legislative hearing but I am sure that the parents who are sitting here today would like to know that there are actually legislators working on these issues. I have introduced

legislation again this year, which I have introduced many times in the past, to finally give the government mandatory recall authority, and the good news is, finally this is supported not just by the regulators but also by the industry, and so I think when we pass comprehensive food safety legislation, finally the FDA and USDA will have mandatory recall authority.

The second bill I have reintroduced this year, which I have introduced many times in the past, is the TRACE Act, and what this bill does is creates a comprehensive traceability system so that we can trace from where the peanuts came from to when they are in those little peanut butter crackers that the children are eating, where that came from so that we can recall that right away. That problem was a particular problem last year with the jalapenos in the salsa. I am happy to report that Mr. Dingell and Mr. Stupak have included both my mandatory recall language and some traceability language in their comprehensive bill and I am also happy to report that the regulators support traceability and now again the manufacturers are beginning to understand that situation.

Mr. Chairman, I am eager for this hearing today. We need to shed light on this situation, but once we do that, Mr. Chairman, I look forward to working with you and Mr. Waxman so that we can move legislation and begin to solve these problems.

Mr. STUPAK. Thank you.

Mr. Gingrey for an opening statement, please, 3 minutes.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGREY. Mr. Chairman, thank you for recognizing me on this, my first hearing as a member of this subcommittee, and I look forward to serving under your leadership and that of Ranking Member Walden in the crucial oversight role of the subcommittee. Let me welcome our former Georgia Speaker of the House and now deputy commission of agriculture, Terry Coleman, as well as Mr. Oscar Garrison, the assistant commissioner, who I certainly look forward to hearing his testimony on the third panel

Now, I first want to express my sincere condolences to the families that are here today and those families across the Nation who have either lost a loved one or have suffered illness as a result of this salmonella outbreak. For those testifying today, I appreciate your willingness to come before this subcommittee and share your stories, as difficult as it may be, with us. All of us have a responsibility to learn from this tragedy and to take the necessary steps to ensure that no other family has to ensure what you have experienced.

Mr. Chairman, it is regrettable to see that the facility under investigation today is located in my home State of Georgia and it is also unfortunate that Mr. Parnell and Mr. Lightsey from PCA, the Peanut Corporation of America, will likely refrain from testifying in accordance with their Fifth Amendment rights. And while they are within their Constitutional rights, I would offer this admonition to them and to anyone else who makes the products that our citizens and their families consume: If you circumvent the law or merely take advantage of lax oversight, don't think you have

gamed the system forever because justice will catch up to you and you will pay. Further, if the circumstances as presented and reported to this point bear out to be true, then it seems the decision to achieve shortsighted profits has trumped common sense and morality. For this, there will be an accounting.

Mr. Chairman, as we in Congress move forward, we must also recognize that no matter how high a regulatory wall we erect, there will always be someone who is brazen enough or stupid enough or greedy enough to try and climb over that safety barrier, and though our gut reaction might be to build an even higher wall, we have an obligation to thoroughly evaluate and ensure that current law was properly enforced first. The wall's integrity, after all, comes not from the height, Mr. Chairman, but from its foundation.

So as we proceed with this hearing, I will listen carefully to the witnesses and their statements and their responses to the questions in the hope that we will get to the bottom of this tragedy.

Mr. Chairman, with that I yield back.

Mr. STUPAK. Thank you, Mr. Gingrey.

Again, by order of appearance at the subcommittee, Mr. Welch from Vermont. Welcome to the committee, and you are always welcome to come sit up here on the top row too.

OPENING STATEMENT OF HON. PETER WELCH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VERMONT

Mr. WELCH. I hear the air is pretty good up there.

Thank you very much. I want to echo what Mr. Gingrey said and express my condolences, and believe me, it is very kind of you to come here and it makes a real difference that you are willing to share your story, painful as it is, and I apologize that we have added to your burden by making you sit through so many opening statements. But, you know, I have been listening to them too and there is something that I find quite heartening in this. We all agree that what Peanut Corporation of America did was despicable and outrageous and they should be held to account. But what you as parents, as sons have a right to expect from your government is that we have systems in place that give you the assurance that when you buy food, it is safe. It is as simple as that. And obviously there is nothing worse as a parent to see a child who is sick and we don't know what the outcome is going to be or to lose a parent before his or her time. And I am heartened by what I have heard today from the members of this committee and also I was earlier at the meeting of the whole committee when I heard our chairman, Mr. Towns, and our ranking member, Mr. Issa, both expressed the commitment to having vigorous oversight, and that doesn't change just because we have had a new change in Administration because there are unscrupulous folks out there who for a quick buck will put in peril people that you love, and it is our mutual responsibility to do every single thing we can to have systems in place that give you the assurance that the food you buy is safe, and what you are doing, and we so appreciate, is your coming forward with your personal story that makes it real, that makes it vivid, and that is at some personal inconvenience and pain to you, so I join my fellow committee members in thank you for your service.

Mr. STUPAK. Thank you, Mr. Welch.

Mr. Sullivan for an opening statement, 3 minutes, and welcome to the subcommittee.

OPENING STATEMENT OF HON. JOHN SULLIVAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

Mr. SULLIVAN. Thank you, Chairman. I appreciate it.

As a new member of the Oversight and Investigation Subcommittee, I would like to thank Chairman Stupak and Ranking Member Walden for holding this hearing this morning. It is an honor to be named to this prestigious subcommittee. I am pleased to be part of this important discussion on food safety and look forward to working with each of you as we move forward in the 111th Congress. Unfortunately, the salmonella outbreak has hit my state of Oklahoma. According to the Oklahoma Department of Health, three adolescents contracted salmonella due to the tainted peanut butter. One of those adolescents was from Rogers County which borders my district. Fortunately, they are all recovered but this serves as a reminder that we must take every precaution necessary to keep our food safe.

In late 2008, the Centers for Disease Control identified an outbreak of salmonella affecting 600 people in 43 States with the recent outbreak perhaps contributing to eight deaths. This is an issue that affects each and every one of us, our friends and our families. It is clear that the food companies and the FDA have a shared responsibility in keeping our food supply safe and secure, and I look forward to their recommendations on how to do that in light of the recent salmonella outbreak.

Thank you in advance to our panels before us today, and my condolences to those who have lost loved ones in this unfortunate incident. I look forward to the hearing and testimony of our witnesses to get to the bottom of this incident, and I yield back the balance of my time.

Mr. STUPAK. Thank you, Mr. Sullivan.

Mr. Markey, a member of the subcommittee, for a statement, please.

OPENING STATEMENT OF HON. EDWARD J. MARKEY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF MASSACHUSETTS

Mr. MARKEY. Thank you, Mr. Chairman, very much, and thank you so much for having this hearing.

Peanut butter is a classic American food enjoyed by young and old alike, and when it is contaminated by a dangerous pathogen, it is something that sends chills through every family in America because there are few things more American than peanut butter, perhaps baseball of course, but this week we learned that there too was a positive test for steroids, and salmonella poses a serious health risk as well. So this requires an ongoing effort by this Congress to ensure that in all of these cases that there is no contamination of these things that Americans take for granted as being American. Peanut butter goes well with jelly but not with salmonella. Peanut butter was probably half of my diet as a child. It is one of those foods that is really good for you and tastes great

too, but now mothers and fathers across America are worried about salmonella and don't know what to put in their kids' lunches. This is not good for our country. More than 1,800 food products have been recalled including crackers, snack bars, cookies and all sorts of other items made with peanut butter that may contain the disease-causing bacteria. Salmonella already has had an impact on hundreds of families.

The FDA under the Bush Administration failed to take steps necessary to ensure the safety of our food supply. We learned once again with this recall that mandatory authority is required. When it comes to food safety recalls, we need mandates and not maybes. We cannot run the risk that we will see families across this country once again afflicted with this kind of a problem. The families who testify here today, and we thank you for that, represent millions of other frightened families across this country, and your story is their story. Your story represents this fear that a parent can be lost, that a child can be sickened by a product which they assume is safe because the Federal Government is ensuring that it is safe by putting the fear of the government into the hearts of those that produce products like peanut butter and peanut butter-related products. That did not exist and that is why you are here today. We thank you for your courage in testifying today. I can promise you that your testimony today will result in the changes that will protect millions of families in our country.

I yield back the balance of my time.

Mr. STUPAK. Thank you, Mr. Markey.

Ms. Schakowsky for an opening statement, please.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Peanut butter. Peanut butter. Is there a kitchen that doesn't have peanut butter, is there a lunchbox that doesn't have peanut butter sandwiches at some point? It is actually more American than apple pie. But what I really find amazing is that it was known by the Peanut Corporation of America that their product was tainted with potentially life-threatening salmonella and yet released into the food stream anyway. How could that possibly happen? The only explanation is they thought based on some reality, given the lax regulation of the last Administration, that they would get away with it.

I am so sorry to the testifiers and the families that are here today that were burdened by this, afflicted by this, tortured by this, that your government failed you, and I am grateful to the chairman for holding this hearing today so that we can set in motion those safeguards that will never let that happen again and to hold accountable the people that made the decisions that allowed it to happen. In one of the most developed nations in the world with access to unparalleled technologies and resources, there is simply no excuse that we can offer to you that contaminated or otherwise unsafe food made it all the way to consumers and to your tables.

I have been a food safety advocate since 1969 when I a young group of housewives got together to get freshness dates on food. We led a little housewives' campaign that has resulted in dates, expira-

tion dates, sell-by dates being on food throughout our marketplace, and yet today we find that this could happen. So I thank the panel before us right now for being here to testify.

I want to just mention that one of the laboratories, Deibel, is in my district. I have been told by the committee that they were very cooperative with the committee. I appreciate that and look forward to their testimony as well and want to join with my other colleagues in assuring you that we will act to make your families safe from this kind of potential killer. Thank you.

Mr. STUPAK. Well, thank you. That concludes the opening statements of members of the subcommittee. I noted once for the record Mr. Barrow is here. He is a member of the full committee. Do you have an opening statement you would like to submit?

Mr. BARROW. Well, first off, thank you, Mr. Chairman, for holding this hearing and for allowing me to audit these proceedings as though a member. I have very little to add to what has been said before but I will add very little.

Mr. STUPAK. Very quickly, because you are not allowed opening——

Mr. BARROW. It seems to me that in addition to the provisions that have been talked about before that are part of a comprehensive reform, things like mandatory recall authority, one thing we very badly need is a testing regime in the industry in which folks are required to test and know what they need to know and a mandatory contemporaneous reporting requirement so that the regulators will know what the processors know when they know it. I think that would add great teeth and great effectiveness to any mandatory recall authority, and that is what I look forward to exploring with other members on the panels later on.

Mr. STUPAK. Well, thank you. We discussed that certification of labs and testing before and it is part of our global bill, and we would love to have you on the bill. You will be allowed to ask questions later as we move on.

Mr. Bishop, we already have your opening statement. A valuable Member of the House, while not part of the committee, we appreciate you being here and monitoring the proceedings. Without objection, Mr. Bishop's statement will be made part of the record.

[The information was unavailable at the time of printing.]

Mr. STUPAK. As I said, that concludes our opening statements by members. I would now like to have our first panel of witnesses to testify. First we have Mr. Jeffrey Almer of Savage, Minnesota, whose 72-year-old mother, Shirley, died after eating salmonella-contaminated peanut butter at a nursing home—I should also note he has a photograph of his mother that I am sure he will explain to us as we move on; Mr. Lou Tousignant of Minneapolis, Minnesota, whose 78-year-old father, Clifford, died after eating salmonella-contaminated peanut butter at a nursing home, and Mr. Peter K. Hurley, a police officer from Wilsonville, Oregon, whose 3-year-old son, Jacob, was severely sickened by salmonella after eating Austin crackers.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that you have the right under the rules of the House to be advised by counsel during your testimony. Do you wish to be represented by counsel, gentlemen? OK. Everyone indi-

cates no. I am going to ask you to rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. You are now under oath. We will begin with your opening statement. If you don't mind, Mr. Almer, would you begin, please, 5-minute opening statement, and we appreciate you all being here and coming here.

TESTIMONY OF JEFFREY ALMER, SAVAGE, MINNESOTA; LOU TOUSIGNANT, MINNEAPOLIS, MINNESOTA; AND PETER K. HURLEY, WILSONVILLE, OREGON

TESTIMONY OF JEFFREY ALMER

Mr. ALMER. Thank you, Mr. Chairman and committee members for inviting me to testify today. My name is Jeff Almer and I am here today on behalf of the family of Shirley Almer, my mother, and as a member of S.T.O.P., Safe Tables Our Priority, a nonprofit organization that represents foodborne illness victims nationwide. My sisters, Vickie and Ginger, are also with me today.

Shirley Almer had a lot of Sisu, which in her Finnish heritage describes a person with spunk, fortitude and determination. That is why her death on December 21 from all things salmonella-contaminated peanut butter came as such a shock to our family.

In May of 2007, Mom had a couple of dime-sized spots of cancer diagnosed on her right lung. She decided to have it removed at the University of Minnesota and was subsequently diagnosed cancer-free. She took a family trip to Florida a year later to celebrate with her children and grandchildren, and it was such a joy to see her enjoying life after that terrible scare.

Then in July 2008, she suffered a seizure and was diagnosed with a brain tumor. The prognosis was hopeful and she was determined to do whatever it took to beat cancer for a second time. A second seizure robbed her of movement and speech capabilities. She underwent brain radiation and a gamma knife procedure. She was required to stay at the University Hospital but fought back through rehab and regained the use of her limbs and her speech despite the diagnosis of some doctors. It was sheer determination and a can-do attitude she overcome all of that, never complaining. One of her wonderful rehab nurses told me she was a shining light and said she was absolutely amazed at the recovery. Mom was released in early October to recuperate with her family and was once again declared cancer free. She made plans. She bought Christmas presents. She wanted to get another puppy. She wanted to visit her sister Mary in Arizona and she was looking forward to being around to watch her grandchildren grow up.

Unfortunately, she suffered a urinary tract infection around Thanksgiving and needed to check in short term to a rehab care facility for treatment. Her short stay was supposed to end the Monday prior to Christmas when she would then join the family for the holidays. She began to complain of stomach cramping and had diarrhea. There was a downward spiral from that point on. Our family was absolutely stunned to learn on the day before her scheduled release that doctors were giving her hours to live. It was very unex-

pected and equally hard to fathom how she could have gotten to this point. We were devastated as we ended up saying our tearful goodbyes and watching her last breaths on that Sunday.

It was just after the New Year that my sister Ginger was informed by the Minnesota Department of Health about the positive test for salmonella. A week before her death she had unknowingly consumed salmonella-laced peanut butter while in her immune-compromised state of health. Cancer couldn't claim her but peanut butter did. Now that we understood the cause of her death, our grief was replaced by anger as we struggled to accept this preventable tragedy. Our family feels cheated. My mom should be here today.

Her death and the deaths of seven others could have been so easily prevented if it were not for the greed and avarice of the Peanut Corporation of America. PCA appears to be more concerned with squeezing every dollar possible at the expense of sanitary conditions and sound food manufacturing processes. Every company needs to have a moral and ethical compass when producing the Nation's food supply. In this absence, we need a cohesive regulatory system to serve as our safety net; too often it is reactive, if at all.

While they were not expecting to kill anyone, PCA now has the blood of eight victims on their hands along with the shattered health of a known 600 others, and they have devastating their own community with the unemployment. Their legacy is now that of a company that did what it could get away with until their shoddy practices has led to the Nation's largest recall. Their behavior is criminal, in my opinion. I want to see jail time and I want to see them served nothing but the putrid sludge they have been trotting out. I don't believe anyone in this country buys all the protests of innocence they have been saying.

Shirley Almer loved this country but was terribly let down by a broken and ineffective food system with abysmal oversight. She was let down in the worst possible way by the very government whose responsibility it is to protect its citizens' health and safety. We cannot continue to ignore the public health threat caused by poorly regulated and contaminated foods. We cannot allow food safety to be continually underfunded and expose unsuspecting Americans to deadly pathogens.

This brings up many important questions. How much time and money will end up being spent on the act of recalling over 1,000 food products? What about the lost productivity and medical expenses for the sickened? When we will have a proactive instead of a reactive system? And my last question would be, when will all these painful deaths and sickness stop being collateral damage?

The government and the industry need to work together to correct a multitude of problems. I am proud to be asking for change on behalf of my mother, Shirley, and on behalf of S.T.O.P. Although this country has many important issues right now, I am urging President Obama and distinguished Members of Congress to make the safety of our Nation's food supply a priority. It is imperative that Americans trust that their health is not compromised by the food on their plate.

We love you, Mom, and we miss you every day. Thank you very much.

[The prepared statement of Mr. Almer follows:]

Jeffrey Almer
Along with S.T.O.P.—Safe Tables Our Priority

Testimony before the Oversight and Investigations Subcommittee of the Committee on Energy and Commerce
United States House of Representatives

Salmonella Contamination
February 11, 2009

My name is Jeff Almer and I am here today on behalf of the family of Shirley Almer, my mother, and as a member of S.T.O.P.—Safe Tables Our Priority, a non-profit organization that represents food borne illness victims nationwide.

Shirley Almer had a lot of Sisu; which is what Finnish people call a person with spunk, fortitude and determination. That is why her death on December 21, 2008—from of all things, *Salmonella*-contaminated peanut butter—came as such a shock to our family.

In May of 2007 Mom had a couple dime-sized spots of cancer diagnosed on her right lung. She decided to have it removed at the University of Minnesota, and was subsequently diagnosed cancer free. She took a family trip to Florida a year later to celebrate with her children and grandchildren and it was such a joy to see her enjoying life and laughing after that terrible scare.

Then, in late July 2008, she suffered a seizure and was diagnosed with a brain tumor. The prognosis was hopeful and she was determined to do whatever it took to beat cancer for a second time. She underwent brain radiation. My brother, Mike, and I watched in horror as she suffered another seizure which caused some issues on her right side as well as swallowing and speech hardships. She was required to stay at the University hospital but fought back through rehab and regained the use of her limbs despite the diagnosis of some doctors. It was through sheer determination and a can-do attitude she overcame all that, never ever complaining. One of her wonderful rehab nurses told me she was a "shining light" and said she was amazed. Mom then had a treatment session with a gamma knife, which is a pinpoint precision procedure to zap the remaining cancer cells. She was released in early October to recuperate with our family and in late October she was once again declared "cancer free" by the University of MN.

Unfortunately, Mom contracted a urinary tract infection around Thanksgiving time where once again she needed to check in short-term to a rehab care facility in Brainerd for care and treatment. She couldn't wait to get home and even suggested getting a puppy from an acquaintance. Her short-term stay was supposed to end the Monday prior to Christmas when she would then join the family for the holidays. Unfortunately, she began to complain of stomach cramping and also had diarrhea. There was a downward spiral from that point. The family was absolutely stunned to learn that on the day before her scheduled release from the rehab facility, that doctors were giving her just hours to live. It was very unexpected and equally hard to fathom how she could possibly have gotten to this point. We ended up saying our tearful goodbyes and watching her last breaths on Sunday Dec 21. The holidays were non-existent and mattered little.

It was just after the New Year that my sister Ginger was informed by the Minnesota Department of Health about the positive test for *Salmonella*. A week or so earlier she had unknowingly consumed *Salmonella*-laced peanut butter while in her immune compromised state of health. Cancer couldn't claim her but peanut butter did.

Now that we understood the cause of her death our grief was replaced by anger as we struggled to accept this very preventable tragedy. Our family feels cheated. My mom should be with us today. My mother, Shirley, was a proud mother, a proud businesswoman, and a proud American. She fought hard for the things she believed in. She always liked to fly the US flag along with the Finnish flag, which was her heritage. If it was one of her kids who passed away from *Salmonella*-tainted food, or one of the many other contaminants present in our food supply these days, there is no doubt that she would be as outraged as I am today. She would be doing the same thing her family is doing in her memory right now: telling her story in order to effect change.

Her death and the deaths of seven others could have been so easily prevented if it were not for the greed and avarice of the Peanut Corporation Of America (PCA). PCA appears to be more concerned with squeezing every dollar possible at the expense of sanitary conditions and sound food manufacturing processes. Every company should have a moral and ethical compass when producing the nation's food supply. In this absence, we need a cohesive proactive regulatory system to serve as our safety net; too often it is reactive, if at all.

PCA now has the blood of eight victims on their hands, along with the shattered health of a known 600 others. Their legacy is now that of a company that did what it could get away with until their shoddy practices led to one of the nation's largest recalls.

Shirley Almer loved this country but was terribly let down by a broken and ineffective food safety system. She was let down in the worst possible way by the very government whose responsibility it is to protect its citizens. We cannot continue to ignore the public health threat caused by poorly regulated and contaminated foods. We cannot allow food safety to be continually under funded and expose unsuspecting Americans to deadly pathogens. We need strong laws, regulations, and effective enforcement enacted to protect our families.

Here are some of the key points that an effective revamped system should include:

- A food safety system that is prevention based with companies being mandated to have validated process controls.
- Development and enforcement of mandated performance standards with companies facing stiff penalties for non-compliance.
- Increased inspection by the federal government with less reliance on states policing the same companies that they wish to promote.
- Increased lab capacity in order to diagnose foodborne illness cases faster and not have a back-up at state labs.
- Adequately staffing the PulseNet system so that it can be better used for faster detections, allowing it to become a more active system instead of a passive system.
- Mandatory recall authority for the government regulatory agencies.
- Traceability of ingredients and products.

The government and the industry need to work together to correct a multitude of problems. I am proud to be asking for change on behalf of my mother, Shirley, and on behalf of S.T.O.P.—Safe Tables Our Priority. Although this country has many important issues right now, I am urging President Obama and the distinguished members of Congress to make the safety of our nation's food supply a top priority. It is imperative that Americans can trust that their health is not compromised by the food on their plate.

Jeff Almer
Brothers: Michael, Patrick
Sisters: Ginger, Vickie
Grandkids: Isaac, Madeline, Shelby, Shanice

Mr. STUPAK. Thank you, Mr. Almer.

Mr. Tousignant, your opening statement, please. If you want to submit a longer statement for the record, it will be included. If you would, please, Mr. Tousignant.

Mr. TOUSIGNANT. Before I begin, Mr. Chairman, would you start the video, please?[Video]

TESTIMONY OF LOU TOUSIGNANT

Mr. TOUSIGNANT. Mr. Chairman, members of the committee, my father was a highly decorated Korean War veteran. He fought in many difficult battles in his years in Korea and was awarded three Purple Hearts for his valor. He faithfully served his country for over 22 years and he loved every minute of it. The only thing that he loved more was his family.

He was the proud father of six: Paul, with me here today, Marshall, Susan, Calvin, Jane and myself. As you can see by those photos, he loved spending time with his grandchildren and his great-grandchildren. He had 15 grandchildren and 14 great-grandchildren.

But he was a man that physically and psychologically scarred from Korea, and early on it was difficult for our family, but like most battles in his life, he overcame it, so much so that he became one of the most generous men that many had known. The night of his funeral, I was having a conversation with my brother-in-law, Dan Herrick, almost with me today, and he shared a story with me of when he and my sister were first married. Like most young married couples, times were tight back then and my father knew that, and he would invite them over, make up a story saying my car starter won't work right, something is wrong with the brake, something is wrong with the door, come on over and take a look at it. And he would always give Dan and my sister Jane a little something for the trouble of coming over. He helped a lot of through the years including his own parents when he joined the Army as a teenager. He sent money back home because times were tight then as well. As long as he had a few dollars in his pocket, he was more than willing to help anyone.

His final battle occurred in December of 2008 when he ate some contaminated peanut butter from PCA. He suffered for weeks until he finally died on January 12, 2009. He had just entered a full-time healthcare facility in Brainerd, Minnesota, a month earlier. He had few goals left in life except for one: he wanted to live to be older than his father. He wanted to live to be 80 years old. He was 78 when he died, a year and a half too early.

We can't be certain of how many years Dad was robbed of, and because of the way he died, because of all the media attention, our grieving process has been different than most. We should not be sitting here in front of you today, any of us. We can no longer pick up the phone and ask him what game he is watching today. My nieces and nephews can no longer crawl over to Grandpa and have their photos taken with him. My brother Marshall and my sister-in-law Ann, who were fortunate enough to spend the last 3 1/2 years with him, can no longer go to his house daily and just check in and see how he is doing. My brother Paul, who spoke with him frequently, can no longer call him just when he feels like. He has

trouble sleeping at night now, not just because we lost our father but the senseless way that this happened.

What happened to our father, the seven other families like the Almers, the over 600 others sickened like the Hurleys is not new. Over the years there have been hundreds of similar outbreaks and other heartbreaking stories. Why has this been allowed to happen? Two years ago the Peter Pan outbreak affected more than 600 people in 47 States. Two years later, here we are again asking for change.

I submit to you, ladies and gentlemen, how can we truly be leaders of the free world if we can't keep our own citizens safe from the food that we eat every single day? We have a blind faith that when we go to a grocery store, the food there is also safe. Clearly it is not.

Do not let the death of my father, the seven others and hundreds sickened by in vain. Please do your job. Do not let us be back here next year or the year after experiencing the same thing. Companies like PCA and Mr. Parnell who make our food should have rules that they live by. Companies should be inspected more than once every 5 years. Companies should not be allowed to shop around for lab results. Companies like King Nut should not be allowed to slap a label on their product they received from a factory that they know nothing about, never visited nor even ever inspected once. The FDA should also have the right to recall contaminated food themselves and not wait for companies to do so on their own. We can't allow the number of FDA inspectors and inspections to continue to decline.

My father was a good man. He faithfully served his country. The system that was set up to protect all of us here today has failed. My father died because he ate peanut butter.

[The prepared statement of Mr. Tousignant follows:]

Testimony of Lou Tousignant

Clifford Tousignant was a highly decorated Korean War veteran. He received 3 purple hearts and faithfully served his country for over 22 years. He fought in many difficult battles over the years that he was in Korea. The only thing he loved more than his country was his family.

He was a proud father of 6 - Paul, Marshall, Susan, Calvin, Jane and myself. He was a grandfather to 15 children and great grandfather to 14 children. He could often be seen, as in the photos shown, with them crawling all over him. He loved every minute of it and loved being in photos with them as well.

He was a man that was damaged by war and early on it affected his family. But like most things in his life he overcame it and became one of the most generous men many have known. The night of his death I sat and spoke with my brother-in-law here today, Dan Herrick. He shared a story with me. When he and my sister were first married, like many Americans, times were tight. My dad would make up reasons for him to come over and fix things that were never even broken; like a car starter, breaks, etc… He would then give him some money for his efforts as a way to help them get by. He helped out many of us over the years; including his own parents when he joined the army as a teenager. As long as he had a few dollars in his pocket, he was willing to help others as best he could.

The salmonella poison got to him in late December 2008 and he suffered for weeks until he died on January 12, 2009. He had just entered a full care facility in Brainerd, Minnesota a month earlier. He had few goals left in life; except one. He wanted to make to 80 years old he was 78. One year and half too early.

Many of our family members have a difficult time going on with our daily lives. We can no longer pick up the phone and ask him what game he is watching. My nieces and nephews will not longer get to crawl over grandpa when they go home or to visit. I

was speaking with my brother Marshall last week and asked him how this was affecting himself and his wife, Ann. He started to cry and said he fortunate to have spent the last 3 and half years with him every day and there is a big hole in their lives not seeing him. My brother Paul, here with today, called him daily. He now has trouble sleeping at night. Not just because we lost our father, but with the senseless way it happened.

How can we live in the United States of America where a man that literally gave his blood, sweat, and tears for his country and was proud that he had. How can we live in a county that in the end let him down?

What happened to our father, the other 7 families that lost a loved ones, and the nearly 600 people that became ill is not new. Over the years, there have hundreds of similar outbreaks with other heartbreaking stories. Why has this been allowed to happen? For years the number FDA inspections has steadily declined. Two years ago the Peter Pan outbreak affected more than 600 people in 47 states. Two years later here we are again asking for change.

I submit to you ladies and gentleman how can we truly be leaders of the free world if we can't keep our own citizens safe from the food that we eat every day. Do not let the death of my father and the seven others like him be in vane.

Please do your job. Do not let us be back here next year or the year after experiencing the same thing. Companies like PCA who make our food should have rules that they live by. Companies should be inspected more than once every five years. Companies should not be allowed to shop around for lab results. Companies like King Nut should not be allowed to slap a label on a product they received from a factory that they no nothing about, never visited, nor never inspected. The FDA should also have the right to recall contaminated food themselves and not wait for the companies to do so.

My father was a good man. He fought for his country. He died because he ate peanut butter.

Mr. STUPAK. Thank you, Mr. Tousignant.
Mr. Hurley, your testimony, please.

TESTIMONY OF PETER K. HURLEY

Mr. HURLEY. Good morning, Congressmen, Congresswomen and committee members. My name is Peter Hurley. My wife Brandy and I are parents of three children: Lauren, 5, Jacob, 3, and Alyssa, 8 months. I am a police officer in Portland, Oregon, and my wife is a marketing manager.

Our whole family, baby and all, have traveled from Oregon to Washington, D.C., to testify before you regarding the salmonella outbreak that has affected us as well as hundreds, if not more likely, thousands, of fellow Americans.

I want to take a moment to acknowledge the eight families who have lost loved ones. Eight people have died due to PCA's willful negligence. We were just lucky. It could have been very different for us.

We made this journey to appear before you because we felt it important enough for you to hear our story of how the Peanut Corporation of America poisoned our son. We want you to hear how Jacob and a PCA-supplied product are genetically linked in the hopes that you will take action to protect our food supply.

Jacob's story began with him becoming ill with diarrhea and vomiting in early January. He was sallow, lethargic and probably had a fever that we missed. In a few days he began to have blood in his diarrhea. We took him to the pediatrician. A few days later the pediatrician called to let us know that the lab results had come back and that Jacob had salmonella poisoning. At this point we did not know how Jacob got the poisoning, and because of that, we did not know how to protect the rest of the family. All we knew was that five or six people had already died in a new salmonella outbreak. At that time only King Nut peanut butter, a PCA product, was listed as a source, which we did not have. What had we unknowingly given him that had given him salmonella poisoning?

As Jacob's diarrhea continued, my wife was given the oK from our pediatrician's office for Jacob to eat his favorite comfort food, Austin toasty crackers with peanut butter, the very food that we later found was the cause of his poisoning, so here we have a boy who is trying to get over food poisoning and one of the foods that was seen safe even to the people in the pediatric medical community is the exact product that is continuing to poison him.

A week later, Dr. Bill Keene from Oregon's Office of Disease Prevention and Epidemiology came to our house at 5:00 on a Saturday night. As a friend said, this is like having the head of the FBI coming out to take fingerprints. On that Saturday night, Dr. Keene took custody of our supply of Austin toasty crackers with peanut butter manufactured by Kellogg's with a PCA product. One week later, Dr. Keene called us to say that Jacob and the crackers he had taken from our house had an exact DNA subtype match for salmonella. Three out of the six packages of crackers he tested were positive, and that was all that we had left. The issue was no longer what had we done unknowingly but what had PCA done knowingly.

Jacob continued to have diarrhea for 11 days. We had to be extremely vigilant to ensure that there was never any cross-contamination between Jacob and Alyssa, our 7-month-old. If Alyssa had come down with salmonella poisoning, there is a good chance that we would be one of the families who had lost a loved one due to PCA's willful negligence.

I have read the FDA's most recent report. This was not an accident. It sickens me to know that a company and its employees could knowingly allow tainted product to go out the door and into the Nation's food supply. Does no one have a conscience anymore? People would be in utter outrage if they heard of a police officer putting a loaded gun to someone's head, pulling the trigger, and then in the horrific aftermath say it was just that the bullet in the chamber wouldn't fire. We, the United States, are the first world. Have we fallen to second world food status for our food safety? As the woman taking care of our dog while we are here in D.C. said, "Even my dog is not safe. What is this, China?"

Where do we go from here? We need to have a faster 911-oriented medical response for food contamination in order to prevent further innocent victims. We need FDA inspectors out there with the authority to stop production immediately when there is a problem. We need the FDA to have the ability to criminally prosecute quickly and effectively. Oregon has the dubious distinction of suffering the first-ever domestic terrorism in the United States. It was carried out by the Rajneeshees in the 1980s. They sprayed a salad bar in The Dalles, Oregon, with salmonella. If a small group of religious fanatics in Oregon could pull it off, who else could?

None of us should be so naive as to think that Al-Quaeda could not easily taint our food supply. If the very well-funded Al-Quaeda could put it mind to it, I shudder to think of what could happen to this country when people do not know where to turn to find safe, uncontaminated food. The panic, pandemonium and lawlessness would be horrific.

I will leave you with my favorite quote by the 19th century author, poet and philosopher, Johann Wolfgang Goethe: "Few men have imagination enough for reality." On behalf of all Americans, my whole family, Jake and I ask you to please have imagination enough to think of the worst-case scenario and to work to protect against it. Thank you.

[The prepared statement of Mr. Hurley follows:]

February 11, 2009

To:

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

From:

Peter K. Hurley and family
Wilsonville, Oregon

RE:

Salmonella poisoning of Jacob M. Hurley due to his eating contaminated peanut butter crackers from a Peanut Corporation of America processed product.

My name is Peter Hurley. My wife Brandy and I are the parents of three children; Lauren 5 years old, Jacob 3 years old and Alyssa 8 months old. I am a police officer in Portland, Oregon and my wife is a marketing manager for a car dealership.

Our whole family, baby and all, have traveled from Oregon to Washington, D.C. to testify before you regarding the salmonella outbreak that has affected us, as well as hundreds and if not more likely thousands of fellow Americans.

I want to take a moment to acknowledge the eight the families who have lost a loved one. Eight people have died due to PCA's willful negligence. We were just lucky. It could have been very different for us.

We made this journey to appear before you because we felt it important enough for you to hear our story of how the Peanut Corporation of America (PCA) poisoned our son. We want you to hear how Jacob and a PCA supplied product are genetically linked in

hopes that you will take action to protect our food supply; so that Americans do not have to worry about even the simplest of foods killing their loved ones.

Jacob's story began with him becoming ill with diarrhea and vomiting in early January 2009. He appeared to be coming down with the flu. He was sallow, lethargic and probably had a fever that we did not catch. In a few days he began to have blood in his diarrhea. Knowing that blood in the stool is serious and needs immediate attention, we took him to the pediatrician who sent us home with a fecal collection kit. A few days later the pediatrician called to let us know that the lab results had come back and that Jacob had salmonella poisoning! He stated that we should expect a phone call from our county health department.

At this point we did not know how Jacob got the poisoning and because of that we did not know how to protect the rest of the family. All we knew was the Jacob had Salmonella poisoning and that five or six people had all ready died in a new outbreak linked to peanut butter. But, at the time only KING NUT PEANUT BUTTER was listed as a source, which we knew we did not have. We called Jacob's school to see if other children were sick, and none were. At that point we began to feel helpless in not knowing what got him sick. What had we unknowingly given him that gave him salmonella poisoning?

As Jacob's diarrhea continued, my wife was given the OK from our pediatrician's office for Jacob to eat his favorite comfort food, AUSTIN TOASTY CRACKERS WITH PEANUT BUTTER!! The very food that we later found was the cause of his poisoning! So, here we have a boy who is trying to get over food poisoning and one of the foods that would seem safe even, to people in the pediatric medical community, is the exact product that is continuing to poison him.

A week after we received the initial results of salmonella poisoning from the doctor, we spoke with a staff member of the State of Oregon's Office of Disease Prevention and Epidemiology. By this time there was initial information coming out that peanut

products were looking like the link to a nation wide salmonella outbreak. The next day the epidemiologist for the Sate of Oregon, Dr. William Keene, came to our house, himself, at five o'clock on a Saturday night. As a friend said this is like having the head of the FBI coming out to take fingerprints. I have to commend Dr. Keene on his dedication to make such a visit. On that Saturday night Dr. Keene took custody of our supply of AUSTIN TOASTY CRACKERS WITH PEANUT BUTTER, manufactured by KELLOGS, with PCA product in it.

One week later Dr. Keene called us to say that Jacob and the crackers he took from our house had an exact DNA-subtype match for Salmonella Typhimurium. Three out of six packages of crackers tested positive. ***This was the food that even the pediatrician thought safe enough for us to continue to feed him while he was sick!*** The issue was no longer what had we done unknowingly, but what had PCA done knowingly?

Jacob continued to have diarrhea for eleven days. Alyssa, our baby, was seven months old at the time. We had to be extremely vigilant with cleaning to ensure that there was never any cross contamination between Jacob and Alyssa. If Alyssa had come down with salmonella poisoning there is a good chance that we would be one of the families who lost a loved one due to PCA's willful negligence. We know from the FDA's most recent report that it was truly willful negligence.

I am using the word poisoned carefully here. I realize what I am saying. I have read the Food and Drug Administration's (FDA) most recent Form 483 report, dated 01/09/2009-02/05/2009, regarding the plant where the peanut butter product for these crackers came from. This was not an accident. PCA knowingly allowed for tainted product to leave the plant, as well as allow it to stay in the production supply chain. It sickens me to no end that the majority of a company and its employees could knowingly allow tainted product to go out the door and into the nations food supply. Does no one have a conscience? Were people jut hoping that no one would get sick or die? People would be in utter outrage if they heard of a police officer putting a loaded gun to someone's head, pulling the trigger, and in the horrific aftermath say "I was just hoping that the bullet in the

chamber wouldn't fire." NO, NO, NO! Both of these scenarios are utterly unacceptable. One is real and the other is fictitious, but neither should be real in the United States.

Never in my wildest dreams would I have thought I would be sitting before a Congressional subcommittee representing millions of Americans, begging for you to take action against a rouge food production company. But, that is what I am doing today. We, the Hurley family from Wilsonville, Oregon, have been affected by PCA and on behalf of millions of Americans, we need you to take action.

We, the United States, **are** the first world. Have we fallen to second world status for food supply safety? I think if you ask Americans who pay attention to what is happening in the world they would answer "YES" to this question. It has gotten to the point where we have a food safety crisis in America.

As the woman taking care of our dog while we are gone said, *"Even my dog is not safe! What is this, China?!"*

Where do we go from here? Well, being in the law enforcement profession, I see many parallels between food safety monitoring and control to that of criminal law enforcement. We need to have a faster 9-1-1 oriented medical response to food contamination, in order to prevent further innocent victims. You can liken this to an active shooter type scenario. In that situation you have someone who is actively shooting and killing people at random; as in a school or mall. In those incidents, people are begging for the police to go in and stop the killer. Well here you have food bacteria randomly killing innocent people. And just as with a shooter, the faster you stop the spread of the bacteria and or product, the fewer victims there will be.

So what does that mean in the real world? It means having state epidemiologists like Oregon's own Dr. Keene who will come to your house on a weekend night to collect evidence. Just like a police officer would do in a rape case. Criminals and bacteria do

not work a day job. They are attacking us 24/7 and that is why epidemiologists need the resources across the country to do the same kind of work Dr. Keene was able to do.

You also need the cop on the beat approach as well. You need FDA inspectors out there with the authority to stop production immediately when there is a problem. It is like the police officer stopping two people from arguing in public before it turns into a fight, then a brawl and then a riot.

The FDA needs the ability to criminally prosecute quickly and effectively when needed. If someone is convicted of a felony in the criminal justice system, they go to prison and are not allowed to vote. But, if you poison Americans via their food supply what are the consequences? You pay a fine and keep producing? Is this right? Is this what we as Americans want? I can say with certainty it is NOT!

I would like for all of us to think of the worst case scenario here, food borne terrorism. Oregon has the dubious distinction as being the first place for domestic terrorism. It was carried out by the Rajneeshees, in the 1980's. They were a fanatical religiously based criminal group that was in the Oregon high desert. In 1985 they poisoned Wasco County residents at a restaurant salad bar in the town of The Dalles. They sprayed the salad bar with Salmonella. Over one hundred residents fell ill. It would have been much worse if they had only gotten the concentration levels correct. This act of domestic terrorism was carried out successfully almost twenty five years ago by a small group of religious fanatics in rural Oregon. If they could pull it off, who else could?

None of us should be so naive as to think that Al-Qaeda could not easily taint our food supply very effectively. If, the very-well funded Al-Qaeda put its mind to it, I shudder to think of what could happen to this country when people do not know where to turn to find safe, uncontaminated, food. The panic, pandemonium and lawlessness would be horrific.

So, now is the time to take action to protect our food supply before another national out break occurs, whether it is greed or terrorist motivated.

I will leave you with my favorite quote by the 19th Century author, poet and philosopher Johann Wolfgang Goethe:

"*Few men have imagination enough for reality.*"

On behalf of all Americans, my whole family, Jake and I ask you to please have enough imagination to think of the worst case reality and to protect against it.

With this I conclude my testimony to the Congressional Subcommittee on Oversight and Investigations for Energy and Commerce.

Thank you.

Respectfully,
Peter K. Hurley
Wilsonville, OR 97070

Mr. STUPAK. Thank you, and thank you to this panel for not only being here but also sharing your story and your video to put a human face on this latest recall we have. I would like to express my condolences to you, Mr. Almer, and to you, Mr. Tousignant, and Mr. Hurley, we are glad that Jacob is doing better and it is good to have your whole family here. Thank you for being here.

As family members and victims of this outbreak, I am sure that you have asked yourself the same questions I have asked myself: What was this company thinking releasing tainted product to the public. During our investigation, the committee requested and received internal e-mail from PCA relating to the outbreak and past testing for salmonella. I would like to ask you about some of these documents. Mr. Hurley, right in front of you is there book, the document book. Let me ask you this. On October 6, it is tab #43, if you want to open it up there. Tab #43, on October 6, 2008, Stewart Parnell, president of the Peanut Corporation of America, responded to news from Sam Lightsey, the manager of PCA's plant in Blakely, Georgia, as tab #43 says, Mr. Lightsey had informed Mr. Parnell, "We received final lab results from Deibel this morning and we have a positive for salmonella." Mr. Parnell's response was as follows, and again, it is found there in tab #43: "We need to discuss this, the time lapse. Besides the cost, it is costing us huge..." and there are dollar signs "and causing obviously a huge lapse in time from the time we pick up peanuts until the time we can invoice." And in there you see there are five dollar signs. Let me ask each of you, what is your reaction to this company responding to positive salmonella testing with concern about its own financial well-being? Mr. Hurley, do you want to start?

Mr. HURLEY. Not to sound trite or overly confident, but as a police officer, I can unequivocally say that it is criminal.

Mr. STUPAK. Mr. Tousignant?

Mr. TOUSIGNANT. An act that is this egregious, I completely agree with Mr. Hurley. I mean, this is a completely criminal act that in essence he was really playing Russian roulette with children and the elderly when he sent this peanut butter out.

Mr. STUPAK. Mr. Almer, do you care to comment?

Mr. ALMER. When I came here today, I didn't think I could possibly get more outraged than I already am about how this happened, but I have to tell you, it has reached another level after seeing e-mails and comments from Mr. Parnell. No excuses.

Mr. STUPAK. On tab 46, there is another tab in there, another e-mail, and let me just—there are other faxes and e-mails the committee has uncovered but you indicated that it was criminal, Mr. Hurley. Being a former police officer myself, I am identifying with you. The Justice Department is doing their investigation. There are certain things that our committee could and could not bring out at this time, so I want to assure all of you that there still is a criminal investigation going on.

You also mentioned about your dog and the sitter taking care of it saying, "What are we, China?" Well, in 2006 some of those peanuts that were positive came from China, so it is a global problem.

But let me ask you this, #46, tab 46, even after several weeks into this outbreak, Mr. Parnell was asking the FDA whether it could use peanuts from its plants. Here is what they wrote to the

FDA, "Obviously we are not shipping any peanut butter products affected by the recall but desperately at least need to turn the raw peanuts on our floor into money." So we have at least two e-mails here in which Mr. Parnell reacts to the outbreak by worrying about how money it is costing him. Any comments on that? Mr. Hurley.

Mr. HURLEY. Narcissistic, I would say, maybe.

Mr. STUPAK. OK. Mr. Tousignant?

Mr. TOUSIGNANT. I am at a loss, personally. I mean, I just can't see how anyone could run a business and be a member of a community and maybe even belong to a church in that community and be making decisions not only like this but also putting jobs in that community as well in a very, very tight environment like this too.

Mr. STUPAK. Mr. Almer?

Mr. ALMER. I would expect that if you are making food, you would want to eat that food that you are producing, and I don't believe that Mr. Parnell would actually want to eat this product if he is producing food in that manner.

Mr. STUPAK. Well, thank you, and again, let me thank you for coming here and sharing your stories. I know it is difficult, but we need to have the human face because people have to see. They just think we have these hearings but there is a reason for these hearings and that is so people see what happens when frankly a number of people let us down but including our own government. That concludes my 5 minutes for questioning. Mr. Walden for questions, 5 minutes, please.

Mr. WALDEN. Thank you very much, Mr. Chairman. As we have sat here, I have been updated that now in Oregon we have 12 lab-confirmed reports of salmonella, and also as I referenced in my comments, they now have confirmed the dog and the dog biscuits from the household were positive as well, so Mr. Hurley, I believe it was you who said somebody is watching your dog. We now know that it is there as well.

I wonder of Mr. Parnell is in the audience. Is Mr. Parnell in the audience? You know, I would think that the least he could have done was be here to hear your comments and to hear about your loved ones, like a victim impact panel, because that is really what this is today.

Mr. Almer, I will be asking Mr. Parnell, as I mentioned in my opening statements, and I appreciated the comment about Russian roulette because that is really what this is about is, which of these would he eat and his company because they sure put it out there for your mother and your father and, Mr. Hurley, your son, and all the rest of us to consume, and I wonder if he will take the top off. We are going to give him that opportunity.

Mr. Hurley, from your written testimony it seems like you were pleased with the State of Oregon's response to your son's illness. Can you tell me what Oregon did that was helpful to you and may serve as a model for other States? What out of that experience can you share with us?

Mr. HURLEY. At the time when Dr. Keene came to our house, I was unfamiliar with his rank and status and——

Mr. WALDEN. As the state epidemiologist.

Mr. HURLEY. As the state epidemiologist. Exactly. And since then I have learned, as my friend said, it is kind of in terms of rank like

having, you know, the director of the FBI come by to take latent fingerprints. What he did though is unique for the whole country, and that is that Jake is the only person in the whole country where you have a DNA link between the product, the Austin peanut butter crackers, and his lab samples. Sorry for the crassness, but it was lab fecal samples. And it is an exact DNA match so that they know that the peanut butter crackers that he ate that went through his system is what made him sick, and Jake is the only one in the whole country and that is because Dr. Keene came to our house at 5 p.m. on a Saturday night on his own time while running errands because he was concerned enough about where this was going and what was happening that he then took those samples, sent them off to the lab and he said that the lab spent lots of time and lots of hours and money on it to find that link, and with that kind of a link, then they had a batch number and a processing number that they were able to contact Keebler with directly.

Mr. WALDEN. And as far as you know, that wasn't done anywhere else in the country?

Mr. HURLEY. To this date when I—I spoke to him last on Friday, I believe it was, and at that time nobody else had any direct links, and as he said, most States don't have the manpower or money to do that, and also it seems as if most State epidemiologists, they know that people have gotten sick because they get that from the county health records and then they work on the other side looking at the lab results of product out there or voluntary lab results but they don't put the two and two together by looking for product at its location.

Mr. WALDEN. I would say too as my staff was collecting this assortment of products that are on the recall list, we ran into even in some of their homes items that are on that list that frankly they thought had already been thrown out, destroyed, whatever, and sort of beyond this hearing but in real time, people may still have products at home that should be destroyed, and as we were chatting here, just the breadth, the scope of the items that are out there, what would you—Jacob suffered through this. Certainly as apparent, and I, like you, am a parent, but what should we be telling people across the country today about this?

Mr. HURLEY. I don't know what we should be telling them but I do know that one of the tough things in this has been getting all the products off the shelves. I know that locally in Oregon there was a story done where they went to some small local markets where people weren't getting their product directly from a supplier, they were going out and purchasing themselves, a small mini market kind of situation, with lots and lots and lots of products on the shelf, and, you know, how do you get that word out when it is voluntary. There is no system in place to get the word out to all these retailers of all these different products.

Mr. WALDEN. Did you do searches online looking for products once you started down this process? I mean——

Mr. HURLEY. No. You know, we gave up our supply of peanut butter crackers to the doctor and after that, as he said, you know, just don't eat anything with peanuts in it or any peanut products until we know more down the road, and so, you know, we have got

stuff still in our pantry but it is sitting there waiting to kind of see how this develops because I know it will be a little bit longer.

Mr. WALDEN. I guess that is the concern is everything in the pantry, and it is amazing to me how much of what we consume has some peanut or peanut paste or something in it that may well be on this list.

Thank you, Mr. Chairman. Thank you, Mr. Hurley.

Mr. STUPAK. Thank you. I just want to let you know, as of last night, the Republican cloakroom still had the Keebler peanut butter crackers in there. Mr. Shimkus brought it to our attention, and I think we got it out of your cloakroom.

Mr. WALDEN. Yes, they are supplied by the Democrats in a conspiracy.

Mr. STUPAK. Just trying to help.

Ms. Christensen for questions, please.

Ms. CHRISTENSEN. Thank you, Mr. Chairman, and again, thank you and your families for being here this morning and for sharing these painful stories with us.

Do you have any concerns about the speed with which they outbreak was linked to peanut butter by public health officials? We have focused a lot on the company itself but I want to just turn the focus to our response as a government.

Mr. ALMER. I would like to add that my mom at the peanut butter some time in mid-December and the salmonella outbreak was known about in early September, so the time it took to find out the cause could have prevented a lot more of the problems that happened.

Ms. CHRISTENSEN. I just have another question that either of you could answer or all of you. I will preface it by saying that as a physician I used to do drug testing on ships coming into port and so forth, the people that worked there, and I had to ascertain by temperature that this person gave me the sample and I had to be responsible for the chain as it went from the ship to the lab. So I have a lot of concerns about the second lab test, whether the second samples were from the same batch, especially with positive tests going back to 2007. Do you think it is good enough for the company themselves to be the ones collecting, contracting for the testing and reporting the results? Shouldn't that be fixed?

Mr. TOUSIGNANT. Well, I think clearly in this case that is definitely the key. I mean, clearly the company could not be trusted to do it on their own. Now, I know that there are probably a lot of companies that are running an ethical business, but unfortunately, we have to worry about the ones that are not, and we have to have a process in place that allows us to be in charge of that.

Ms. CHRISTENSEN. Thank you. I don't have any other questions for this panel, Mr. Chair.

Mr. STUPAK. Thank you, Ms. Christensen.

Mr. Deal for questions, please, 5 minutes.

Mr. DEAL. Well, I too express my sympathy to all of you for the loss of your family members and certainly the trouble that your young son has undergone. We have heard Mr. Hurley talk about his interaction with his State epidemiologist. Would the other two of you elaborate on any contact you may have had with health au-

thorities? For example, did any of you get contacted by the CDC, et cetera?

Mr. TOUSIGNANT. My brother, actually Marshall, was contacted by the State of Minnesota and we found out, I wan to say about a week after the fact after my father died or maybe a few days after he died that indeed he did have salmonella and they actually found it in his blood.

Mr. ALMER. It was about 2 weeks after my mother died that my sister Ginger received a call from the Minnesota Department of Health if we had brought in any kind of food from the outside, had she eaten chicken, had she eaten peanut butter, and it was my sister who remembered she had served my mother peanut butter toast two times. That really became a huge key to finding out—actually I have heard the Minnesota Department of Health was very instrumental in finding the very source of this outbreak, and we were told by them that my mother's death was key to the whole thing.

Mr. DEAL. Well, I think the reason for this oversight and investigation hearing is to find out how we can best plug the loopholes and close the gap so that hopefully we will not see a repeat of this kind of situation in the future, and we thank you all for taking the time and going to the expense of being here today, and with our assurances that I am sure our chairman and other members of this committee will follow through to try to make sure we can do the best we can from our end to make sure it doesn't repeat itself.

Thank you all for being here. I yield back.

Mr. STUPAK. Ms. Sutton for questions, please.

Ms. SUTTON. Thank you, Mr. Chairman, and thank you all so much for your testimony, for coming here to dispel any notion that your loved ones are acceptable collateral damage or some sort of statistic as opposed to real people with real families who are suffering because of actions that have been taking place.

If I may, I would like to show you some new information that the subcommittee received and get your response to it. I have a statement from Michelle Pronto, and I believe it is at tab 10. Ms. Pronto works for J. Leek Associates, which is one of the private labs PCA used to test salmonella. She manages the microbiology lab there. The subcommittee spoke with Ms. Pronto and she agreed to provide a written statement, which I ask to be placed into the record.

Mr. STUPAK. Without objection.

[The information was unavailable at the time of printing.]

Ms. SUTTON. Ms. Pronto explains in her statement that in October of last year her lab found salmonella in PCA's peanut products. She reported this positive finding to Sam Lightsey, who is the plant manager, as we know, in Georgia, and this is how she described their conversation. She stated, "When I called Mr. Lightsey in early October 2008 to give the serology reports that JLA had obtained from Deibel Lab for the confirmed salmonella, he paused and said uh-oh or something to that effect and then told me he had released the product for shipping. When I asked if he could get it back, he said it was on a truck heading to Utah." Now, you guys saw that earlier, and let me ask you, any of you, is there anything you would like to say in response when you hear this statement

from the plant manager and that he shipped the product without even waiting to get the results of the salmonella test?

Mr. ALMER. I would like to add, I know that trucks can be stopped, doors can be opened, product can be taken out, or the truck can be just turned right around. It costs more money, sure, but it is easy to do.

Ms. SUTTON. Anybody else?

Mr. HURLEY. I would concur. That is absolutely ludicrous.

Ms. SUTTON. And let me share something else that Ms. Pronto had to say. She said, "During a phone conversation in August 2008, Sammy Lightsey of PCA informed me that the Albany, Georgia, JLA lab was reporting higher aerobic plate counts—those are APC results—and higher coliform results than another lab he apparently used." Then she said this: "I received an e-mail on 9/10/08"—September 10 of 2008—"from JLA employee Stephanie Fletcher stating that she was told by QC manager"—quality control manager—"of PCA that PCA was no longer going to send us samples." Finally, she said this: "I called Mr. Lightsey to follow up on the recent discussion regarding the confirmed positive and he confirmed that because of the high coliform results, they were going to send samples to a different lab." So this lab official certainly seems to be saying that when PCA didn't like the positive test results, it just took its business elsewhere.

So what is your opinion, and I could guess but I don't think anyone could say it better than you. What is your opinion of a business that engages in activity like this?

Mr. TOUSIGNANT. I think unfortunately that is an example of why we can't trust self-checking or self-regulation, and I think this is an example of why our food supply is not safe.

Mr. HURLEY. You can't have lab shopping. You can't have lab shopping going on to find your best results.

Mr. ALMER. It is just a complete conflict of interest. They are the ones who do not benefit by the negative results or positive results, whatever they may be. They can't shop around.

Ms. SUTTON. Again, I thank you very much for your testimony and I am so very sorry for your loss.

Mr. STUPAK. Following up that last question, if I may, with your 30 seconds, do you think any lab results from any food producer should automatically be sent not only to the producer of that food but also to the FDA simultaneously? Any objection to that?

Mr. HURLEY. No objection, and I actually would have just been under the assumption that that is how the process already was.

Mr. STUPAK. That is not the way it goes. It is part of our legislation. Thank you.

Mr. Gingrey for questions, please, 5 minutes.

Mr. GINGREY. Mr. Chairman, thank you, and I have already expressed my condolences to the families and I will repeat that now. I know this is a painful experience for all the family members as we can see in your faces as you give your testimony.

I guess the main question that I want to ask you because we will have the two subsequent panels, hopefully the second panel will respond to our questions but it is likely, as I said in my opening statement, that they will not, but of course, the third panel is a very important panel, so I guess my question to each of you is,

what would you want us to ask them? And when I say "them" I am talking about the FDA, I am talking about the CDC, I am talking about USDA, United States Department of Agriculture, and I am talking about the department of agriculture in the respective States, all 50 have one, and the health departments. And so if you could maybe tell me ahead of time what to ask, I will be glad to do that when we have that opportunity.

Mr. ALMER. I would like to respond and ask them why anyone would not want to have mandatory recalls. Why do we leave it up to the companies to decide when they are going to recall their product? That is an important part. I guess that would be my main question.

Mr. TOUSIGNANT. I am not sure that you are asking the question maybe down this line but the question that I have is, why does the FDA not already have this authority? Why do they not have the ability to recall these items themselves? And secondly is a budgetary issue. Why are there inspectors and number of inspections continuing to decline? Who is in charge of the budget? Because if you think about people's main concern, it is safety of food foremost. We have to be able to eat. This is just as important as the economy is right now.

Mr. HURLEY. No comment.

Mr. GINGREY. Well, I thank you gentlemen, and again, I think that we on the committee are very appreciative of you coming and testifying as painful as it is. I don't know if you are aware but on this committee, on both sides of the aisle, we probably have three M.D.'s, we have a registered nurse, we have a clinical psychologist, and we have some experts that have been on the committee for a long time, the chairman and ranking member, in regard to these healthcare issues. So it is something that certainly has got our attention and obviously we plan to do everything we can to try to close that weak link in the chain because, as I said, it is only as strong as the weakest link and obviously there is a problem, and we thank you so much for being here.

Mr. WALDEN. Would the gentleman yield?

Mr. GINGREY. I will be glad to the yield to the ranking member.

Mr. WALDEN. I think it is important to point out that it is already against the Food, Drug and Cosmetic Act law to knowingly ship product that tests positive. That is the amazing thing here. Out of everything we have, it would appear they knew it was positive. If you get a positive hit on a salmonella test, you are supposed to destroy the product. They may test again to figure out in their process where they are having this contamination. That is a different deal. But you are not supposed to ship it out for consumption, and that is what is outrageous here. So that piece is already in the law. Obviously the inspection piece and some of these other things need to be dealt with, but it is just stunning.

I yield back.

Mr. GINGREY. Mr. Chairman, if I have any remaining time, I yield back.

Mr. STUPAK. The chair will use 45 seconds of your remaining time. Even subpoena power, I have been trying to get the FDA to have subpoena power for 12 years. They keep denying us saying

they don't need it, a great example where you need subpoena power.

Ms. DeGette.

Ms. DEGETTE. [Presiding] Thank you. Well, oK, let us talk about subpoena power. Let us talk about the criminal laws. But these companies don't even have to produce their records to the FDA if they have these tests for salmonella, and in the previous peanut contamination hearing we had with ConAgra, what happened was, they had—it wasn't as blatantly criminal as this case, but what happened in that case was, they had water dripping down and they had all kinds of records that showed this, and they had the FDA inspectors come to the factory but the company made this decision not to produce the records because the records showed that there was a problem, and so while it is true that it is criminal activity and while it is also true that the FDA could use subpoena authority, it would be pretty simple for Congress to pass a law, and in fact, I think it is in Mr. Dingell's bill, to say that it is also a requirement that they produce this information when they have a test that shows negative, that they produce it to the FDA and put some criminal penalties in place, and I am sure all of you gentlemen would agree with that too.

I don't really have any questions. I just sit here and I feel sick at heart when I hear you talk about your families, and Mr. Hurley, when I see your little kids, you know, I have two girls myself, so I feel sickened hearing about your parents, and what makes me so sick, as I said in my opening statement is, I have been sitting here for 12 years listening to this. So I guess what I will say is, I want to echo what all of you said. It shouldn't be that hard for the most sophisticated country in the world to put a system in place that requires them to provide the documents when they see a problem, that gives the FDA mandatory recall authority, which by the way would act, I think, to light a fire under these companies if they knew that there was mandatory recall authority and they couldn't mess around. And then as I mentioned in my opening statement, traceability so that what happened in Oregon could happen in all the States where if you had mechanisms in place that were interoperable, then if you found salmonella in a little kid in Oregon, you could rapidly work throughout the United States to figure out the source of that salmonella and to recall all those food products. And if that happened, I don't think we would have lost Mr. Almer's and Mr. Tousignant's parents because we knew about that salmonella several months in advance.

So I will make a commitment to you as someone who has worked on this for years along with Mr. Stupak, Mr. Dingell, Mr. Waxman, our friends on the other side of the aisle. We are going to do this, and I hope we will do it this year because I don't want to be back here in 6 months. Neither do you, Mr. Walden or Mr. Gingrey, any of you guys. We have just sat here too long listening to this and we can fix it. I have got some legislation. We have comprehensive legislation. We need to figure out, should we move this one bill at a time. We could do my mandatory-recall bill on the suspension calendar next week. Mr. Walden would agree. I will bet you Mr. Barton would agree. And we could do comprehensive food safety. We have been working on it for a long time. So I will just make

the commitment to you. We are going to do this and we are going to do this in one your loved ones' memories. I will yield back.

I recognize Mr. Burgess for 5 minutes.

Mr. BURGESS. I thank you. And it does seem like deja vu all over again to quote a great American. Mr. Walden is exactly correct in the way we have dealt with a lot of these things repetitively and all the issues with notification, all the issues with recall, all of the issues with the failure of the kill step to take the bacteria off the exterior of the peanut. Those are all very important. If you have a criminal mind at the back of it running the operation, it is just hard to know how you deal with that asymmetric threat. We know that through multiple hearings, as I referenced in my opening statement, we beat on the FDA until it is a wonder there is anything left of them. They need better systems in place. We need to fund them better. We recognized that through hearing after hearing after hearing last Congress. We haven't even done our appropriations from last year yet. Those are due to come up in an omnibus bill in March so they need more money and we know that. We have been slow to respond. But still, the baseline, if you have got that asymmetric threat of a criminal mind, all of these things are very, very difficult to prevent if you have got someone who is willfully ignoring the rules and not just ignoring the rules, purposely working against you.

Dr. Gingrey is correct. You do have three physicians on this subcommittee. You have got a clinical psychologist and a nurse. After today's hearing, we may need the clinical psychologist as well as the nurse. I am not sure if the doctors are going to do you any good.

But let me just ask you, being a physician myself, I would like to ask each of you the same question generally, and Mr. Deal got to it a little bit, but this can be a difficult diagnosis, even though the clinical symptoms present themselves, and we are talking about salmonella and it seems very obvious to link the clinical symptoms with the ultimate diagnosis, but Mr. Almer, in your situation, was the correct diagnosis, did the doctors have that in order to timely offer treatment or was this something that was established after the fact?

Mr. ALMER. We actually though she had died from pneumonia, and we found out 2 weeks later that that wasn't even on the death certificate, and we were given notice by the department of health of the salmonella positive test. That was our first notice of it.

Mr. BURGESS. And there is some time lag in normal clinical circumstances between submitting a sample and getting a test result back, whether it is positive or negative. So is that in fact what occurred during that time interval or was this something in fact that was discovered completely after the fact?

Mr. ALMER. From what I am told, somebody was doing their due diligence at the facility and they noticed they had some patients with diarrhea and sent the stool samples for testing and my mother's was one of those.

Mr. BURGESS. So there were actually more people in the facility who were affected?

Mr. ALMER. There were actually—my sister lives up in the Brainerd community where three of the people have died. There actually are two others that may also die of salmonella at this time.

Mr. BURGESS. Just for my curiosity, were any diagnoses made in time to offer treatment? Salmonella is treatable. Oftentimes the other underlying conditions can make it impossible but the organism itself is one that we can generally get if we have got the knowledge.

Mr. ALMER. There was some treatment, possible sepsis, blood infection, which is common, I guess, with salmonella, but I don't think any of us knew or the facility knew that my mother had salmonella at that time, so she was already gone before anyone knew.

Mr. BURGESS. So to the best of your knowledge, no one received lab results in a timely fashion that would have allowed treatment to stop the disease?

Mr. ALMER. No, to my knowledge, no.

Mr. BURGESS. Yes, sir, and in your case with your dad?

Mr. TOUSIGNANT. I am sorry?

Mr. BURGESS. I am going to mess up your name anyway but I can't see your name plate. Tousignant?

Mr. TOUSIGNANT. Mr. Tousignant, yes.

Mr. BURGESS. Yes, sir. OK. I am sorry. In your situation, was the diagnosis established before your dad died?

Mr. TOUSIGNANT. To the best of my knowledge, no. I believe it was, like I mentioned earlier, a few days to a week later.

Mr. BURGESS. And again, very, very difficult for the caregivers involved because they are doing their best, and in your dad's situation, a bloodborne infection which obviously would be a good deal more aggressive.

And then Mr. Hurley in your situation, the epidemiologist came to the house, but prior to that level of involvement, did your son's caregivers have an idea, did your son's physicians have an idea, that his symptoms clinically might tip off the diagnosis of salmonella?

Mr. HURLEY. Nothing was mentioned to us in the beginning, and actually the samples were given on a Wednesday. On Friday the pediatric nurse called and said so far things look good, and then it was the next day on Saturday or Sunday that the doctor called from home to let us know.

Mr. BURGESS. And then it was that result that led the epidemiologist to come to your home to collect samples?

Mr. HURLEY. Correct. First it went to the county. A couple days later I got a call from the county health, and then a couple days later got a call from the state epidemiology office, answered some questions over the phone because then things were really starting to move along nationally in terms of PCA, and so then when he found out that even while he was sick that he was eating the peanut butter crackers, he said can I come over in a couple of hours.

Mr. BURGESS. But of course, your son was under active care from a pediatrician or infectious disease specialist during the course of his illness?

Mr. HURLEY. No. I mean, they told us what the illness was. Basically we just treated for—I mean, just made sure he had plenty of fluids and——

Mr. BURGESS. So it was symptomatic treatment?

Mr. HURLEY. Right, symptomatic treatment, but no, he was not in a hospital.

Mr. BURGESS. Well, again, this underscores it. It is a difficult diagnosis in a clinical setting and then obviously made more much difficult by the criminal minds behind this enterprise. So again, just like every other member of the committee, our condolences on your loss and thank you for spending so much time with us this morning.

I yield back, Mr. Chairman.

Mr. STUPAK. Ms. Schakowsky for questions, please.

Ms. SCHAKOWSKY. It is not so much a question, unless you want to respond to it, but I do want to be sure and get on the record, and I am wondering, is Mr. Parnell here yet? He is to be on the next panel, I guess. There is on tab 4 a couple of e-mails that I just can't get over. On June 6, 2008, a PCA employee sent an e-mail to Steward Parnell alerting him that their product may have salmonella. If you look at that, you see it says "lot number put on hold," exclamation points, "I just spoke with Stephanie, with JLA," the private laboratory. "This lot is presumptive salmonella," in caps, and a total of 15 exclamation points in these two sentences alone. Now, to any normal person, this would be a red flag and the alarms would go off and you would realize this is serious. I am sure everyone would agree with that.

So here is the e-mail that Mr. Parnell sent in response. Later in the day he wrote, "I go through this about once a week. I will hold my breath again." So how is anyone to react to the incredible disregard of this urgent e-mail? It is just absolutely beyond me. I don't know if any of you can put this into words, and certainly we would welcome your words on the record. Mr. Tousignant, did you want to——

Mr. TOUSIGNANT. When this first happened, I think for a couple of my brothers and sisters and I, we wanted to believe that this somehow was really just an accident, that something happened with one of the companies, that somehow this got into the food. And as we have gone along in this process of discovery and learning more information as each day goes on, it just baffles me and I know it probably baffles every single one of us up here today and our families and the others in the country, that this is affected, that any one person can make a decision like this so consistently and so blatant.

Ms. SCHAKOWSKY. I also want to say that I understand if you feel angry at us as well because as Congresswoman DeGette said, we have been here before, and again, as others have, I just want to make a commitment that we are definitely going to create the systems, act quickly so that hopefully we put in place the assurances that you are the last panel of people suffering from this that have to come before us. Thank you.

Mr. STUPAK. Thank you, Ms. Schakowsky.

Let me thank this panel again. I think that concludes everybody's questions. So Mr. Hurley, your family asked when we were going to let you go. You are free to go if you want or stay for the rest of this hearing, you can, Mr. Tousignant and Mr. Almer, if you would like to, you can, but thank you for being here and

thank you for putting a face on the tragedy that families are feeling across this country. Thank you very much for your testimony.

Once the clerk clears that table, we will start with our second panel of witnesses. Our second panel of witnesses will come forward. On our second panel, we have Mr. Stewart Parnell, who is president of Peanut Corporation of America, and Mr. Sammy Lightsey, plant manager of that Peanut Corporation of America's Blakely, Georgia, facility.

It is the policy of this subcommittee to take all testimony under oath. Please be advised, gentlemen, that witnesses have the right under the rules of the House to be advised by counsel during their testimony. Do you wish to be represented or advised by counsel, Mr. Lightsey?

Mr. LIGHTSEY. No.

Mr. STUPAK. Mr. Parnell?

Mr. PARNELL. Yes, sir.

Mr. STUPAK. I would ask you to state the name of your counsel who will be advising you. Counsel cannot testify but can advise you, and before you answer a question if you want to consult with them before you answer it, you are allowed to under the rules of the House. So who would your counsel be, sir?

Mr. PARNELL. Bill O'Reilly.

Mr. STUPAK. OK, and Mr. O'Reilly, you are right here then, right? OK. Mr. Lightsey?

Mr. LIGHTSEY. I am sorry. I misunderstood the question.

Mr. STUPAK. Hit your mic, right there, a little button there. Is Mr. O'Reilly going to be your counsel too?

Mr. LIGHTSEY. No, Jim Parkman.

Mr. STUPAK. Jim?

Mr. LIGHTSEY. Parkman.

Mr. STUPAK. Parkman. OK. Mr. Parkman, raise your hand just so we know who you are. OK. Very good. The sample applies to you. If you want before you any questions you want to consult with your counsel, you have a right to do so. So I am going to ask you both to rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. You are now under oath. You will 5 minutes for an opening statement or you may submit a longer statement for inclusion in the hearing record.

TESTIMONY OF STEWART PARNELL, PRESIDENT, PEANUT CORPORATION OF AMERICA; AND SAMMY LIGHTSEY, PLANT MANAGER, PEANUT CORPORATION OF AMERICA

Mr. STUPAK. Mr. Lightsey, do you have an opening statement?

Mr. LIGHTSEY. No, I do not.

Mr. STUPAK. Mr. Parnell?

Mr. PARNELL. No, sir.

Mr. STUPAK. Then we are going to go right to questions, and members have 5 minutes for questions, and I will begin.

Mr. Parnell, I want to ask you about an e-mail you sent to your employees at the Peanut Corporation on January 12, 2009, after public health officials found salmonella in peanut butter from your plant in Georgia. Right in front of you right there is our binder tab.

It is tab #44, if you care to look at it. In particular, I want to ask you about the following statement you made in that e-mail. You said, "We do not believe the salmonella came from our facility. As you probably know, we send hourly PB samples to an independent lab to test for salmonella during production of peanut butter and we have never found any salmonella at all." Mr. Parnell, during its investigation FDA found on 12 separate occasions between June 2007 and September 2008 peanut products produced by PCA and tested by private labs were found to be contaminated with salmonella. On six of these occasions the FDA found that you had already shipped the product and that you conducted no subsequent testing. So your statement that you "never found any salmonella at all" does not appear to be true. So here is my question then, and I remind you, you are under oath: Mr. Parnell, did you or any officials at the Peanut Corporation of America ever place food products into the interstate commerce that you knew to be contaminated with salmonella?

Mr. PARNELL. Mr. Chairman and members of the committee, on the advice of my counsel, I respectfully decline to answer questions based on the protection afforded me under the United States Constitution.

Mr. STUPAK. Mr. Parnell, let me ask you this. In the last panel, and you heard the last panel testify, did you not?

Mr. PARNELL. Mr. Chairman and members of the committee, on the advice of my counsel, I respectfully decline to answer your question based on the protection afforded me under the United States Constitution.

Mr. STUPAK. I just asked you if you heard the other panel.

Mr. PARNELL. Mr. Chairman and members of the committee, on the advice of my counsel, I respectfully decline to answer your question based on the protection afforded me under the United States Constitution.

Mr. STUPAK. OK. Well, let me ask you this question, Mr. Parnell. The earlier panel, we talked a little bit about money and some of the e-mails and statements attributed to you about cost of business, how not moving product was hurting you, hurting your business, and that actually you deal with salmonella, again from the e-mails, once a week. So the food poisoning of people, is that just a cost of doing business for your company?

Mr. PARNELL. Mr. Chairman and members of the committee, on the advice of my counsel, I respectfully decline to answer your question based on the protection afforded me under the United States Constitution.

Mr. STUPAK. Mr. Walden, I believe you had a question you had alluded to earlier. Would you like to ask that question?

Mr. WALDEN. I would, Mr. Chairman.

Mr. Parnell, Mr. Lightsey, let me just cut to the chase then. In this container are products that have your ingredients in them, some of which were on the recall list, some of which are probably contaminated. It seems like from what we read you are willing to send out that peanut base with these ingredients, and I just wonder, would either of you be willing to take the lid off and eat any of these products now like the people on the panel ahead of you, their relatives, their loved ones did?

Mr. PARNELL. Mr. Chairman and members of the committee, on the advice of my counsel, I respectfully decline to answer your question based on the protection afforded me under the United States Constitution.

Mr. WALDEN. Mr. Lightsey?

Mr. LIGHTSEY. At this time on advice of counsel, I exercise my rights under the Fifth Amendment of the Constitution.

Mr. STUPAK. Mr. Parnell, is it your intent to refuse to answer all of our questions today based on your right against self-incrimination afforded to you under the Fifth Amendment of the Constitution?

Mr. PARNELL. Yes.

Mr. STUPAK. Mr. Lightsey, is it your intention to refuse to answer all our questions today based on the right against self-incrimination afforded to you under the Fifth Amendment of the Constitution?

Mr. LIGHTSEY. Yes.

Mr. STUPAK. All right. Then I have no choice but that both of you are dismissed at this time. You are subject to the right of the subcommittee to recall you at a later time and date if necessary.

I would now like to call our third panel of witnesses to come forward. On our third panel we have Dr. Stephen Sundlof, who is the director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration; Mr. Oscar Garrison, who is the assistant commissioner of the Consumer Protection Division at the Georgia Department of Agriculture; Ms. Darlene Cowart, who is the president of J. Leek Associates Incorporated, JLA, and Mr. Charles Deibel, who is president of Deibel Laboratories.

It is the policy of this subcommittee to take all testimony under oath. Please be advised that you have the right under the rules of the House to be advised by counsel during your testimony. Do any of you wish to be advised by counsel during your testimony? Ms. Cowart?

Ms. COWART. Yes, Mr. Chairman, I have counsel present today, and I do wish to be represented.

Mr. STUPAK. Counsel's name is?

Ms. COWART. Mr. Evans Plowden and his associates.

Mr. STUPAK. OK. If you want to consult with them before you answer a question, please do.

Ms. COWART. Thank you.

Mr. STUPAK. Mr. Deibel?

Mr. DEIBEL. Yes, sir, I have counsel present but they are sitting in back of me.

Mr. STUPAK. Just identify their name for the record.

Mr. DEIBEL. Charles Deibel.

Mr. STUPAK. Mr. Deibel, your lawyer's name. You stated your name.

Mr. DEIBEL. Richard Chapman.

Mr. STUPAK. Mr. Garrison, do you wish to have counsel present?

Mr. GARRISON. Yes, sir, I am being represented by Mr. Ted Hester of King and Spaulding at the request of our Georgia Attorney General, Thurbert Baker.

Mr. STUPAK. Very good. Mr. Chappell?

Mr. CHAPPELL. Mr. Chairman, no, sir.

Mr. STUPAK. Dr. Sundlof?

Dr. SUNDLOF. No, sir, Mr. Chairman.

Mr. STUPAK. OK. As I said, it is the policy to take all testimony under oath. I am going to ask you now to rise and raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. Let the record reflect that the witnesses replied in the affirmative. You are now under oath. We will begin with opening statements for 5 minutes. If you wish to submit a longer statement for inclusion in the record, that will be allowed. Dr. Sundlof, let us start with you, please, sir.

TESTIMONY OF STEPHEN SUNDLOF, D.V.M., PH.D., DIRECTOR OF THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY MICHAEL CHAPPELL, ACTING ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION; OSCAR GARRISON, ASSISTANT COMMISSIONER, CONSUMER PROTECTION DIVISION, GEORGIA DEPARTMENT OF AGRICULTURE; DARLENE COWART, PRESIDENT, J. LEEK ASSOCIATES, INC.; AND CHARLES DEIBEL, PRESIDENT, DEIBEL LABORATORIES

TESTIMONY OF STEPHEN SUNDLOF

Dr. SUNDLOF. Thank you, 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, which is part of the Department of Health and Human Services. I am accompanied today by Mr. Michael Chappell, FDA's acting associate commissioner for regulatory affairs. FDA appreciates the opportunity to discuss 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, or PCA.

Let me begin by expressing my personal and the agency's concern for people harmed in this outbreak of foodborne illness. FDA can and will learn from this outbreak what we can do to better assure the safety of our food supply moving forward. And it is important to note that the manufacturers play a critical role in ensuring the safety of the foods that they introduce into commerce. Strong food safety programs begin with a commitment and the strong oversight of the managers and the promotion of strong food safety culture throughout the company.

In the typical traceback process employed by FDA and our partners at the Centers for Disease Control and Prevention, CDC notifies FDA when it identifies the possible foods associated with foodborne illness through its epidemiological investigation. At that point the FDA starts its investigation to identify the source of contamination. In the current case, FDA started its tracing process before CDC notified us of a strong epidemiological link to both help inform the epidemiological study and to shorten the time required to remove potentially contaminated foods from the market. Since early December of 2008, FDA has collaborated with the CDC, U.S. Department of Agriculture and state public health departments to

investigate the multi-State outbreak of human infections due to salmonella typhimurium.

Peanut butter was first identified as a possible source in mid-December, and on January 7 and 8, based on preliminary epidemiological data, the FDA decided to investigate institutional food sources of peanut butter rather than wait for more-conclusive data. On January 7, FDA made its initial contact with the King Nut Company, which distributes peanut butter manufactured by PCA to institutional facilities, food service industries and private label companies. Two days later on January 9, FDA initiated our inspection of the PCA manufacturing plant in Blakely, Georgia. As part of its epidemiological investigation, the Minnesota Department of Health tested an open 5-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 found that peanut butter contained the same strain of salmonella typhimurium. However, because it was an open container which could have been contaminated by someone or something else in the environment, these results did not confirm the Blakely plant as the source.

So FDA expanded the testing of unopened containers of the same brain of peanut butter, and on January 19, the Connecticut Department of Health tested an unopened container of King Nut peanut butter and found that it contained the same strain of salmonella typhimurium associated with the illness 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 Blakely processing plant.

As I noted earlier, FDA had already initiated the inspection of PCA's Blakely plant on January 9. We completed our inspection on January 27. FDA's environmental sampling at the plant found two salmonella strains, neither of which was associated with the outbreak. We are confident, however, that based on the investigations by the States, CDC and FDA that the Blakely plant is the source of contamination related to the salmonella typhimurium outbreak. Further, FDA's review of the testing records revealed 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. Expanded recalls followed on January 28 and on January 28 the firm voluntarily recalled all peanut products processed in its Blakely facility since January 1, 2007, and these included dry and oil-roasted peanuts, granulated peanuts, peanut meal, peanut butter and peanut paste. Many companies that received the peanuts and peanut products manufactured by PCA's Blakely facility have in turn conducted their own voluntary recalls. FDA is continuing to work with the 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 of the products. FDA has established a web page to provide constantly updated information on the contamination and recall. It includes a searchable databases to assist

consumers in quickly identifying recalled products, and we encourage consumers to check this Web site frequently.

FDA is reviewing with Health and Human Services our prior legislative requests to strengthen the agency's ability to protect Americans from foodborne illness to determine whether those requests should be updated in light of our experience with this outbreak. At this time we want to highlight the need for enhanced authorities in several areas. Number one, authority for FDA to issue preventive controls for high-risk foods; two, authority for enhanced access to food records during routine inspections; three, the authority for FDA to require food facilities to renew their registrations every 2 years and for FDA to modify the registration categories. In addition, we note that mandatory recall authority would be a useful tool that in some circumstances could result in faster removal of implicated products from commerce.

In closing, Mr. Chairman, let me assure you that the FDA is working hard to ensure the safety of the food supply in collaboration with our federal, State, local and international food safety partners. 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 and food safety is a priority of 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. It is also premature for FDA to draw conclusions about our preliminary observations or how the 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 follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

STEPHEN F. SUNDLOF, D.V.M., PH.D.

DIRECTOR

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

FEBRUARY 11, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning Mr. Chairman and members of the Subcommittee. 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 (HHS). 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 continue as we speak, our final conclusions and recommendations are necessarily pending the outcome of our investigation.

Let me begin by expressing the Agency's concern for people harmed in this outbreak of foodborne illness. This outbreak highlights a number of shortcomings with our nation's food safety systems, and underscores the need for greater Federal oversight, more effective industry practices, and stronger safeguards for the American people. A good day at the FDA is when avoidable outbreaks do not occur -- and that did not happen here. We can, and will, learn from the outbreak what we can do to better assure the safety of our food supply moving forward. It bears noting that manufacturers play a critical role in ensuring the safety of the foods they introduce into commerce. Strong food safety programs in food manufacturing facilities begin with the commitment and strong oversight of management and the promotion of a strong food safety culture throughout the company.

This testimony will review the facts of this outbreak – as we know those facts today – and FDA's investigation.

TRACEBACK PROCESS

The first step in a foodborne outbreak response is to identify that an outbreak resulting from a food vehicle is occurring. When the Centers for Disease Control and Prevention (CDC) receive information from state and local health departments that identify clusters of illnesses, CDC pursues an epidemiological investigation, which involves working with those state and local agencies to identify the possible food(s) associated with a foodborne illness outbreak. Upon making that identification, 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. Early in 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 trace the food suspected of being the vehicle for transmitting the pathogen back through the supply chain from the retailer, restaurant or institutional setting as far back as the manufacturer or grower, and inspect or investigate 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 help identify shipments of interest and determine 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 present case, FDA began its investigation prior to the establishment of a strong epidemiological link to a particular food, both to inform the epidemiological study and to shorten the time required to remove potentially contaminated foods from the market. Because institutionally-served peanut butter, in five-pound containers, was identified by the state of Minnesota as a potential vehicle, our investigation began with 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 process, the critical first step in our collaborative efforts.

EPIDEMIOLOGICAL INVESTIGATION

In early December 2008, FDA began collaborating 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 caused by *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 investigate institutional food service sources of peanut butter despite the inconclusive epidemiological data.

On January 8, 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 visited 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, although 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 an open container could have been 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 King Nut 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 that was 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 before it left the Blakely processing plant.

PCA sold peanut butter in bulk containers ranging in size from five to 1,700 pounds and peanut paste in sizes ranging from 35-pound containers to tanker trucks. In addition, peanut meal, granulated peanuts, and oil and dry roasted peanuts were sold by PCA in bulk containers of various sizes and, in some instances, in retail-sized containers. Through its investigation, FDA 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 9, CDC is reporting that 600 persons had been infected with the outbreak strain of *Salmonella* Typhimurium from 44 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* Typhimurium outbreak. FDA completed its inspection on January 27. The inspection involved

sampling, documentation collection, and included a heavy focus on information needed to document and support product recall activities.

A document listing observations by FDA's investigators during their inspection of the Blakely plant, known as a List of Inspectional Observations, or FDA Form 483, has been posted on FDA's web site at *www.fda.gov/ora/frequent/default.htm*. This list is not a final Agency determination regarding compliance by the firm. 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. This document was initially issued to the firm on January 27 at the conclusion of the inspection. After a more detailed review of the many records obtained during this inspection, FDA determined that certain information provided by PCA management during the inspection was not consistent with FDA's subsequent analysis of the company's records. Therefore, on February 5, 2009, FDA issued an amended Form 483 to present the variety of testing and shipping circumstances reflected by the firm's records.

FDA's environmental sampling at the plant found two *Salmonella* strains, neither of which were *Salmonella* Typhimurium, the outbreak strain. Presently, CDC is not aware of any illnesses definitely connected to these other *Salmonella* strains. Although these samples did not match the outbreak strain, state sampling and analysis of unopened finished products indicate that PCA products shipped from the Blakely plant were contaminated with the *Salmonella* 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 in which the firm distributed product in commerce that tested positive for *Salmonella*. 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 produced on or after July 1, 2008, due to the risk of *Salmonella* contamination. PCA expanded this recall on January 16 to include all peanut butter produced on or after August 8, 2008, and all peanut paste produced on or after September 26, 2008. This was followed by yet another expansion on January 18, 2009, 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 expanded the recall again to include 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 produced 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. The recalled peanuts and peanut products were used as ingredients in many additional products, exponentially increasing the scope of the recall. To help consumers and others identify affected products, FDA has placed a user-friendly, searchable list of the products being recalled, with corresponding photographs, when available, on its web site at *www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm.* The searchable list currently includes approximately 1,800 entries in 17 categories, representing products that have been recalled by nearly 200 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 thousands 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.

As FDA gathers additional information about these "downstream" 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 also are 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.

RECOMMENDATIONS FOR CONSUMERS

FDA has created 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 28 million times. The web page includes a searchable database, noted earlier, which can be found at *www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm*, to assist consumers in quickly identifying recalled products. In addition to FDA's traditional consumer outreach through press releases and media briefings, we have initiated outreach through so-called "social media" such as Podcasts, Twitter, blogs and MySpace postings.

Consumers are urged to check FDA's web page to determine which products have been recalled and to learn of new recalls as they are announced. Any product that is on the recall list should be disposed of in a manner that will prevent others from consuming it. Consumers also are 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 peanuts or peanut products are advised to consult their health care providers.

Product recalls include some pet food products that contain peanut products made by PCA. In addition to the risk of animals contracting salmonellosis, 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 FDA's web site. The pet food products are also included in the searchable data base of recalled products.

For information on products containing peanuts or peanut products from companies not reporting recalls, consumers may wish to consult the company's web site 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 peanuts or peanut products to inform consumers about whether their products could contain peanuts or peanut products from PCA's Blakely plant. 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 firms on the details of their actions, conducting follow-up audits and inspections, monitoring the progress of firms' actions, working with state and local regulatory authorities, and notifying our foreign regulatory counterparts of affected products that have now been confirmed as having been distributed internationally. Further, 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.

The Agency will continue to review its actions both before and in response to this outbreak to identify lessons learned and areas for improvement. Although we responded to the available epidemiological information and quickly identified PCA's products as the source of the outbreak, we would prefer to prevent contamination from occurring or at minimum to identify it and take action before consumers become ill. It bears repeating that manufacturers play a critical role in ensuring the safety of the foods they introduce into commerce.

The facts of this outbreak, as well as our experience with other outbreaks, highlight the need to enhance FDA's statutory authority to protect consumers from foodborne outbreaks. We are reviewing with HHS, as well as other Federal and state food safety partners, prior requests to strengthen the Agency's ability to protect Americans from foodborne illness to determine whether those requests should be updated in light of our experience with this outbreak. At this time, we want to highlight the previously-identified need for new or enhanced authority in several areas:

(1) Authority for FDA to issue preventive controls for high-risk foods;

(2) Authority for enhanced access to food records during routine inspections to ensure that inspectors have access to all information that bears on product safety; and

(3) Authority for FDA to require food facilities to renew their registrations every two years, and allow FDA to modify the registration categories.

In addition, we note that mandatory recall authority would be a useful tool that in some circumstances could result in faster removal of implicated products from commerce.

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 enhancing 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.

Mr. STUPAK. Thank you.
Mr. Chappell?
Mr. CHAPPELL. I don't have an opening statement.
Mr. STUPAK. OK. Mr. Garrison, opening statement, please, sir, 5 minutes. If you have a longer statement, we will submit it to the record.

TESTIMONY OF OSCAR GARRISON

Mr. GARRISON. Chairmen Waxman, Stupak, Ranking Members Barton and Walden, and distinguished members of the subcommittee, I would like to thank you for the opportunity to offer this testimony today. I am here on behalf of Georgia's Commissioner of Agriculture, Tommy Irvin. I am Oscar Garrison, the assistant commissioner responsible for Georgia Department of Agriculture's Consumer Protection Division. I have been directly involved with food safety at various levels for more than 15 years. I want to express my sympathy to the victims of the salmonella outbreak that were here today and also to the victims of foodborne illness in this country.

The Georgia Department of Agriculture takes its commitment to food safety very seriously. We are more concerned about food safety and food being sold and processed in Georgia than anyone. To more effectively carry out our mission, the Department is working with our State legislature on an amendment to the Georgia Food Act that would require regular testing by the food manufacturers in Georgia. This legislation would require processing plants to promptly report to the Department the presence of any suspected contamination that would render food injurious to health or otherwise unfit for consumption. We encourage this committee to consider federal legislation that would require similar testing and reporting nationwide.

We would like to have additional resources that would permit us to perform more inspections more frequently and comprehensively along with product testing, but with tightening budgets, FDA, Georgia and other States are stretching their resources about as effectively as we are able to. The Department has requested and our governor has recommended $24 million to help fund a new laboratory to be located in south Georgia that would increase the product testing that our Department is currently capable of performing. Currently, we can test about 4,500 food samples per year in our State laboratories. The Georgia Department of Agriculture is required through the Georgia Food Act to license and inspect food sales establishments and processing plants. We inspect approximately 16,000 facilities ranging from processing plants to food storage warehouses to retail grocery stores. These inspections are conducted by a field force of approximately 60 inspectors.

For many years the Department of Agriculture, like agencies in other States, has had a contractual relationship with the Food and Drug Administration that requires us to conduct inspections at various food-processing plants in Georgia that ship products into interstate commerce. Including the two inspections we conducted for FDA, our Department conducted a total of nine inspections at the plant between 2006 and 2008. During these inspections, our inspec-

tors did not see any conditions that would raise a red flag indicating an imminent health hazard.

An inspection is simply a snapshot in time. An inspector can only see what is there at that particular time that they are conducting the inspection. The Department utilizes all the resources available to us to verify that food processors are operating responsibly. However, it is important to recognize that if processors do not act responsibly and most certainly if they engage in criminal activity designed to avoid detection, the most rigorous and regular inspections would not readily detect a problem. We do not have all the facts, but once the Peanut Corporation of America had test results disclosing the presence of salmonella, it was unconscionable for that company to ship the product, fail to recall the product or fail to notify us or FDA.

In closing, let me thank you for joining with us in an effort to improve the safety of this country's food supply. This tragic situation must serve as a wakeup call leading to reforms in the United States food safety network and through additional funding that will permit food safety agencies at the federal, State and local levels to more effectively perform their jobs. Thank you.

[The prepared statement of Mr. Garrison follows:]

Testimony of

Oscar S. Garrison

Assistant Commissioner

Consumer Protection Division

Georgia Department of Agriculture

before the

House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

February 11, 2009

Washington, DC

Chairmen Waxman and Stupak, Ranking Members Barton and Walden, and Distinguished Members of the Subcommittee, I would like to thank you for the opportunity to offer this testimony today. I am here at the request of Georgia's Commissioner of Agriculture, Tommy Irvin.

I am Oscar Garrison, Assistant Commissioner responsible for the Georgia Department of Agriculture's Consumer Protection Division. I have been directly involved with food safety at various levels for more than 15 years. I started as an inspector, was promoted to senior operations analyst, served as primary emergency coordinator for the Department, and was appointed Assistant Commissioner in January, 2007.

The Georgia Department of Agriculture takes its commitment to food safety very seriously. We are more concerned about the safety of food being processed in Georgia than anyone. To more effectively carry out our mission, the Department is working with our state legislature on an amendment to the Georgia Food Act that would require regular testing by food processing plants in Georgia. The legislation would require processing plants to promptly report to the Department the presence of any suspected contamination that would render food injurious to health or otherwise unfit for consumption. We encourage this committee to consider federal legislation that would require similar testing and reporting nationwide. A copy of the latest draft of the Georgia legislation is attached.

We would like to have additional resources that would permit us to perform inspections more frequently and comprehensively, along with more product testing, but with tightened budgets, FDA, Georgia and other states are stretching their resources about as effectively as they are able.

The Department has requested, and our Governor has recommended, $24 million to help fund a laboratory to be located in south Georgia that would increase the product testing that our Department is capable of performing. Currently we are able to conduct about 4,500 tests on products per year. Additionally, the Department has a request pending with the state that would enable us to fill five more inspector positions.

The Georgia Department of Agriculture is required through the Georgia Food Act to license and inspect food sales establishments and processing plants. We inspect approximately 16,000 facilities ranging from processing plants to food storage warehouses to retail grocery stores. These inspections currently are conducted by 60 field inspectors.

For many years, the Georgia Department of Agriculture, like similar agencies in other states, has had a contractual relationship with the Food and Drug Administration that requires us to conduct inspections at various food processing facilities in Georgia that ship products in interstate commerce. We will conduct 175 inspections for FDA under our current contract. We conducted inspections for the FDA at the Peanut Corporation of America's ("PCA") plant in Blakely, Georgia, in 2007 and 2008.

Including the inspections we conducted for the FDA, our Department conducted a total of nine inspections at the plant between 2006 and 2008. During these inspections, our inspectors did not see any condition that would raise a red flag indicating an imminent health hazard. An inspection is a "snapshot in time." An inspector can only see what is there at that time. Reports from plant workers of problems with a leaking roof, or birds getting into the facility were never witnessed by our inspectors nor reported by PCA staff or anyone else to our inspectors or to our main office at any time.

In 2007 and 2008, our Department pulled and tested 35 product samples from the five Georgia facilities that produce peanut butter. All were negative for Salmonella. The last sample pulled from PCA's Blakely plant was in August 2007 and was negative.

The Department uses all the resources available to us to verify that food processors are operating responsibly. However, it is important to recognize that if processors do not act responsibly, and most certainly if they engage in criminal activity designed to avoid detection, the most rigorous and regular inspections would not readily detect a problem. We do not have all the facts, but once PCA had test results disclosing the presence of Salmonella, it was unconscionable for the company to ship the product, fail to recall the product, or fail to notify us, FDA and public health officials.

In closing, let me thank you for joining with us in an effort to improve the safety of the country's food supply. This tragic situation must serve as a wake-up call leading to reforms in the U.S. food safety network, and to additional funding that will permit food safety agencies at the federal, state and local levels to more effectively perform their jobs.

LC 25 5454S

_____ offers the following substitute to SB 80:

A BILL TO BE ENTITLED
AN ACT

To amend Article 2 of Chapter 2 of Title 26 of the Official Code of Georgia Annotated, relating to adulteration and misbranding of food, so as to change certain provisions relating to prohibited acts; to provide requirements for testing of samples or specimens of foods by food processing plants for the presence of poisonous or deleterious substances or other contaminants rendering such foods injurious to health or otherwise unfit for consumption; to provide for rules and regulations; to change certain provisions relating to right of entry in food establishments and transport vehicles and examination of samples obtained; to provide for inspection of records; to provide for related matters; to provide an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Article 2 of Chapter 2 of Title 26 of the Official Code of Georgia Annotated, relating to adulteration and misbranding of food, is amended in Code Section 26-2-22, relating to prohibited acts, by adding a new paragraph to read as follows:

"(5.1) The failure to comply with testing, reporting, or record-keeping requirements provided by or pursuant to Code Section 26-2-27.1;"

SECTION 2.

Said article is further amended by adding a new Code section to read as follows:

"26-2-27.1.

(a)(1) In order to protect the public health, safety, and welfare and ensure compliance with this article, the Commissioner shall by rule or regulation establish requirements for regular testing of samples or specimens of foods by food processing plants for the presence of poisonous or deleterious substances or other contaminants rendering such foods injurious to health or otherwise unfit for consumption. Such rules or regulations shall identify the specific classes or types of food processing plants, foods, and poisonous

or deleterious substances or other contaminants that shall be subject to such testing requirements and the frequency with which such tests shall be performed by food processing plants, provided that any required test shall be performed not less than annually by a plant that is subject to such testing requirement.

(2) In addition to any regular tests required pursuant to paragraph (1) of this subsection, the Commissioner may order any food processing plant to have samples or specimens of its foods tested for the presence of any poisonous or deleterious substances or other contaminants whenever in his or her determination there are reasonable grounds to suspect that such foods may be injurious to health or otherwise unfit for consumption.

(3) If a food processing plant has reasonable grounds to suspect the presence of any poisonous or deleterious substance or other contaminant rendering any of its foods injurious to health or otherwise unfit for consumption, such plant shall report the same to the department not later than the next business day after becoming aware of such grounds for suspicion.

(b) Any test required pursuant to this Code section shall be performed by qualified personnel at a laboratory approved by the department.

(c) A food processing plant shall be responsible for the cost of any testing required pursuant to this Code section.

(d) If as a result of testing required pursuant to this Code section the presence of a poisonous or deleterious substance or other contaminant rendering a food injurious to health or otherwise unfit for consumption is detected, such result shall be reported by the food processing plant to the department not later than the next business day after the receipt of such result from the laboratory.

(e) Records of the results of any tests required pursuant to this Code section shall be kept by a food processing plant and made available to the department for inspection for a period of not less than two years from the date the results were reported by the laboratory.

(f) This Code section shall not apply to any food processing plant operating under a federal grant of inspection from the United States Department of Agriculture Food Safety and Inspection Service."

SECTION 3.

Said article is further amended by revising Code Section 26-2-36, relating to right of entry in food establishments and transport vehicles and examination of samples obtained, as follows:

"26-2-36.

(a) The Commissioner or his duly authorized agent shall have free access at all reasonable hours to any factory, warehouse, or establishment in which food is manufactured,

processed, packed, or held for introduction into commerce and any vehicle being used to transport or hold such foods to commerce for the purposes:

(1) Of inspecting such factory, warehouse, establishment, or vehicle, and any records of testing of samples or specimens of foods for the presence of poisonous or deleterious substances or other contaminants and the results thereof as may be required pursuant to Code Section 26-2-27.1, to determine if any of the provisions of this article are being violated; and

(2) Of securing samples or specimens of any food, after paying or offering to pay for such sample.

(b) It shall be the duty of the Commissioner to make or cause to be made examinations of samples secured under subsection (a) of this Code section to determine whether or not this article is being violated."

SECTION 4.

This Act shall become effective upon its approval by the Governor or upon its becoming law without such approval.

SECTION 5.

All laws and parts of laws in conflict with this Act are repealed.

Mr. STUPAK. Thank you, Mr. Garrison.

Ms. Cowart, your opening statement, please, for 5 minutes. If you have a longer statement, we will insert it in the record.

Ms. COWART. Thank you.

Mr. STUPAK. Thank you.

TESTIMONY OF DARLENE COWART

Ms. COWART. Mr. Chairman, my name is Darlene Cowart, and you have my biographical information, I believe, in the record. My education has been in biology and food science, and I have worked in the agricultural commodity and food-related quality control area since completing my education. I am currently president of JLA USA. Our company is one of several under the umbrella of JLA Global, which has facilities in the United States and abroad. JLA USA has testing facilities in seven locations in the United States. While the majority of our work is related to the peanut industry, we also provide services and testing to the almond industry and to some degree other food businesses. JLA USA maintains microbiology laboratories in Albany, Georgia, and Edenton, North Carolina. We provide a broad range of testing services to the agricultural commodity and food business. I understand the committee's concerns today relate to the recent salmonella outbreak and therefore involve our microbiology testing.

Mr. Chairman, when we test for salmonella, we receive from the customer samples of the product to be tested together with the notification of the test that the customer wants us to perform. Specifically, we receive a request for analysis which details the battery of tests desired by the customer and includes the customer's description of the product to be tested, and I believe you have copies of these also in the record. I have also furnished the committee staff a detailed description of the method we use to test for salmonella, and I will simply summarize that here.

First we pull a representative sample from the customer's containers to get a composite sample of 375 grams. That composite sample is then put into a sterile bag with other substances and incubated. We remove some of the mixture into the test tubes and for other procedures and eventually we put the resulting substance into what is called a VIDAS instrument. This machine's computer will automatically give us the result either positive or negative for salmonella. If the result is not negative from the instrument, the negative certificate of analysis is sent to the customer. If the result is positive, it is what we call in our laboratory a presumptive positive, which must be confirmed, because at this point several organisms can look like salmonella but are not. However, since the test necessary to confirm the presumptive positive can take up to 5 days, we notify the customer of the presumptive positive by e-mail and a telephone call. The confirmation process is quite technical and is also described in the paper that we furnished the committee staff. If after the confirmation we find that salmonella is ruled out, we prepare a negative certificate of analysis for immediate release to the customer. If we do confirm that the presumptive positive is salmonella, then we prepare and issue a positive certificate of analysis and again we notify the customer via a telephone call and an

e-mail alert. Mr. Chairman, all these procedures confirm to the appropriate FDA and accepted laboratory standards.

From January 1, 2007, through September of 2008, we tested approximately 1,000 samples of product from Peanut Corporation of America. Of these in 2007, six samples were confirmed positive for salmonella, and all the rest were negative. In 2008 we issued a total of four confirmed salmonella positive certificate of analysis. I wish to emphasize, Mr. Chairman, that we at JLA do not take the samples from the product nor do we have knowledge of the sampling procedure used by PCA for the samples we receive. With respect to the PCA samples on each occasion that JLA received samples, the product samples would have been sent by mail to a JLA laboratory together with this request for analysis. The information provided on the request for analysis is the only information about the sample that JLA receives. Following a confirmed salmonella positive issued to PCA in August of 2008, PCA discontinued sending product samples to JLA with one exception. We did receive a few test samples under the name PP Sales, and it is my understanding that this name is an internal designation within PCA and possibly refers to a different product line. JLA did test and obtain a confirmed salmonella positive on a PP Sales sample sent to JLA in late September 2008. A positive COA was issued to PCA in early October 2008. In every instance when we found presumptive positives or confirmed positives, we reported the results to PCA by e-mail and telephone as I described earlier.

Salmonella can occur in raw agricultural commodities and the accepted procedure for killing salmonella in raw agricultural products is to heat the product to a necessary temperature for the appropriate period of time, and that procedure is commonly referred to as the kill step. It is possible for salmonella to be reintroduced into a product after the kill step. This can occur if the product comes in contact with contaminated raw ingredients, equipment or personnel. Therefore, it is extremely important that all food manufacturing facilities maintain proper procedures and processes to ensure that recontamination does not occur. Salmonella in processed foods is preventable and the application of an appropriate kill step combined with good manufacturing processes that eliminate the possibility of recontamination should result in a salmonella-free product. Microbiological testing for salmonella and other pathogens is an important evaluative tool that manufacturers can and should employ to ensure that their manufacturing processes are safe.

Mr. Chairman, we are cooperating fully with the committee and your staff and JLA pledges to continue working with the committee to make certain the food supply is safe for all consumers. Thank you, Mr. Chairman.

[The prepared statement of Ms. Cowart follows:]

STATEMENT OF

DARLENE M. COWART, (Ph.D.)

PRESIDENT

JLA, USA

BEFORE THE

SUB-COMMITTEE ON OVERSIGHT AND INVESTIGATION

OF THE

UNITED STATES HOUSE OF REPRESENTATIVES

ENERGY AND COMMERCE COMMITTEE

FEBRUARY 11, 2009

STATEMENT FOR DARLENE COWART

Mr. Chairman my name is Darlene Cowart; you have my biographical information in the record. My education has been in biology and food science. I have worked in the agricultural commodity and food related quality control area since completing my education. I am currently President of JLA, USA. Our company is one of several under the umbrella of JLA Global which has facilities in the U.S. and overseas. JLA, USA has testing facilities in seven locations in the United States. While the majority of our work is related to the peanut industry we also provide services and testing to the almond industry and to some degree other food businesses. JLA, USA maintains microbiology laboratories in Albany, Georgia and Edenton, North Carolina.

We provide a broad range of testing services to the agricultural commodity and food business.

I understand the committee's concerns today relate to the recent salmonella outbreak and therefore involve our microbiology testing.

MICROBIOLOGY TESTING PROCEEDURES

Mr. Chairman when we test for salmonella we receive from the customer samples of the product to be tested together with a notification of the tests the customers wants us to perform. Specifically, we receive a "Request for Analysis," which details the battery of tests desired by the customer and includes the customer's description of the product to be tested. You have copies of these documents in the record.

I have also furnished the committee staff a detailed description of the method we use to test for Salmonella. I will simply summarize that method here.

First we pull a representative sample from the customer's containers to get a 375 gram composite sample. We put that composite sample with other substances

into a sterile bag and incubate the mixture. We move some of the mixture into test tubes for other procedures and we put the remaining mixture into what is called a VIDAS machine. The machine's computer automatically gives the result—either positive or negative for Salmonella.

If the result is negative then we issue a negative certificate of analysis (COA) which is sent to the customer.

If the result is positive, we call that a presumptive positive which must be confirmed because, at this point several organisms can look like Salmonella but are not. However, since the tests necessary to confirm the presumptive positive can take five (5) days, we notify the customer of the presumptive positive by email and telephone call.

The confirmation process is quite technical and is described in the paper we furnished the committee staff.

If, after the confirmation process, we find that Salmonella is ruled out we prepare a negative COA for immediate release to the customer. If we do confirm the presumptive positive to be Salmonella then we prepare and issue a positive COA and again notify the customer via telephone call and email.

Mr. Chairman all these procedures conform to appropriate FDA and accepted laboratory standards.

PEANUT CORPORATION OF AMERICA SAMPLES

From January 1, 2007 through September of 2008 we tested approximately 1,000 samples of product for PCA. Of these in 2007 six (6) samples were confirmed positive for salmonella and all the rest were negative. In 2008 we issued a total of four (4) confirmed salmonella positive COA's.

I wish to emphasize, Mr. Chairman, that we at JLA do not take the samples from the product nor do we have knowledge of the sampling procedure used by PCA for the samples we receive

With respect to PCA samples, on each occasion that JLA received samples, the product samples would have been sent by mail to a JLA laboratory together with a Request for Analysis. The information provided on the Request for Analysis is the only information about the sample that JLA receives.

Following a confirmed salmonella positive issued to PCA in late August 2008, PCA discontinued sending product samples to JLA with one exception. JLA did receive and test a few samples sent under the name "PP Sales". It is my understanding that this name is an internal designation within PCA and refers to a different product line. JLA did test and obtain a confirmed salmonella positive on

a PP Sales sample sent to JLA in late September 2008. A positive COA was issued to PCA in early October 2008.

In every instance when we found presumptive positives or confirmed positives we reported the results to PCA by email and telephone as I described earlier.

SALMONELLA GENERALLY

Salmonella can occur in raw agricultural commodities. The accepted procedure for killing salmonella in raw agricultural products is to heat the product to the necessary temperature for the appropriate period of time. That procedure is commonly referred to as a "kill step".

It is possible for Salmonella to be reintroduced into a product after the kill step. This can occur if the product comes into contact with contaminated raw ingredients, equipment or personnel. Therefore, it is extremely important that all

food manufacturing facilities maintain appropriate procedures and processes to assure that recontamination does not occur.

Salmonella in processed food is preventable. The application of an appropriate kill step combined with manufacturing processes that eliminate the possibility of recontamination should result in a salmonella free product. Microbiological testing for salmonella, and other pathogens, is an important evaluative tool that manufacturers can, and should, employ to ensure that their manufacturing processes are safe.

Mr. Chairman we are cooperating fully with the committee and your staff. JLA pledges to continue working with the committee to make certain the food supply is safe for all consumers.

Thank you Mr. Chairman.

Mr. STUPAK. Thank you.
Mr. Deibel, your opening statement, please.

TESTIMONY OF CHARLES DEIBEL

Mr. DEIBEL. Good morning, Chairman Stupak and members of the subcommittee. I would like to thank you for giving me this opportunity to speak with you today. My name is Charles Deibel and I am the president of Deibel Laboratories, a firm that specializes in microtesting food and personal care products and food safety consulting. We have 10 labs in North America with our headquarters in Illinois. For more than 40 years Deibel Labs has provided scientific consulting services to food manufacturers around the country. My father, who remains active in the company today, started Deibel Labs when he was the dean of the University of Wisconsin's bacteriology program in the late 1960s. He is widely recognized as one of the most knowledgeable scientists in the food industry, pioneering test methods still in use today and helping to shape food safety systems in America. In addition to microtesting food products and their ingredients, we work with many manufacturers to help evaluate their existing food safety programs, conduct risk assessments, perform plant audits and offer training in food safety procedures.

I would like to give you a brief summary of Deibel Lab's dealings with Peanut Corporation of America, or PCA. My company did not provide day-to-day testing services for PCA as we did for many of our clients. Instead, during 2007 and 2008, PCA's Plainview, Texas, and Blakely, Georgia, facilities sporadically submitted samples containing peanuts to Deibel Labs to test. We have voluntarily cooperated with the Centers for Disease Control, the Food and Drug Administration and this subcommittee to provide detailed records of the tests we performed for PCA's facilities including samples from PCA's Blakely facility that tested positive for salmonella in late September 2008 and our records of the immediate communications of those results to PCA's Blakely facility personnel. We also provided records detailing the requests that personnel at the Blakely facility made to us to retest existing samples and the negative results of those tests.

Mr. Chairman, may I briefly supplement the written statement that is in the record?

Mr. STUPAK. Without objection, yes.

Mr. DEIBEL. As you know, the story about PCA's actions becomes clearer almost by the hour. I have learned more in reading the FDA's Web site publications, the results of the investigation recorded, readings in newspapers and in sitting today. I am horrified in seeing the projections of the very damning e-mails in the screens to our left and right.

In late January the FDA and CDC requested that our labs provide them with cultures of ingredients we tested, and based on provisions of the 2002 Bioterrorism Act we voluntarily submitted this work. In late January counsel for this committee came to us as part of the subcommittee's investigation. We voluntarily and promptly provided staff counsel with all relevant documents and access to witnesses and myself within minutes of any request. On February 5, 2009, we first saw and learned of the willful and gross

negligence in sanitary manufacturing and Good Manufacturing Practices contained in FDA's amended investigation report. At about that same time we received samples from the PCA Texas facility and found them to be positive for salmonella. We promptly provided that information to your committee and FDA.

It is not unusual for Deibel Labs or for other food testing laboratories to find that samples clients submit do test positive for salmonella and other pathogens. What is virtually unheard of is for an entity to disregard those results and place potentially contaminated products into the stream of commerce. I commend the subcommittee for examining what can be done to prevent an incident like this from happening again.

As discussions progress on how best to reform our national food safety program, I urge you to look at the entire model used today. Our current food safety system relies heavily on inspections conducted by the FDA and the State agencies with which it contracts. This is a reactive response rather than the comprehensive, systemic process needed to safeguard our food. The FDA should focus on quality control systems that minimize the potential for contamination to occur in the first place and develop mitigating strategies for correcting a potential issue before it impacts food safety.

The FDA has a great deal of knowledge and understanding of how manufacturers can improve our food safety practices. Our Nation's small and medium-sized companies in particular could greatly benefit from guidance documents from FDA yet their job is to inspect, not to provide guidance and so they don't. Yet the USDA routinely issues guidance documents to the food processors under its jurisdiction. FDA staff are reluctant to point manufacturers to the information and resources they need or provide direct guidance on how an observation can be corrected. As a result, opportunities to improve food production practices are missed. Testing, much like inspection, is only one piece of an overall food safety policy. It is the last chance to catch a problem.

The larger piece, however, is on the front end, quality control systems that minimize the potential for the contamination to occur in the first place. Every year millions of pounds of food products end up in landfills because of positive test results for harmful organisms. The problem here is not in finding a positive test result. The issue we are discussing here is a firm that found a positive, tried to contest the compliancy and released the product anyway. The attention to this issue of food safety is important. It is an opportunity to build stronger bridges between FDA and the food manufacturers. By taking a preventative, systemic approach, we can implement reforms that will go a long way towards ensuring that consumers have access to safe and wholesome foods. Thank you.

[The prepared statement of Mr. Deibel follows:]

Statement of Charles T. Deibel
President, Deibel Laboratories, Inc.

Before the Oversight and Investigations Subcommittee
House Energy and Commerce Committee
United States House of Representatives

February 11, 2009

Statement of Charles T. Deibel
President, Deibel Laboratories, Inc.
Before the Oversight and Investigations Subcommittee
House Energy and Commerce Committee
United States House of Representatives
February 11, 2009

Good morning Chairman Stupak and members of the Subcommittee. I would like to thank you for giving me the opportunity to speak to you today. My name is Charles Deibel and I am president of Deibel Laboratories, Inc., a firm that specializes in micro-testing food and personal care products and food safety consulting.

Background of Deibel Laboratories, Inc.

We have ten laboratories in North America, with headquarters in Illinois. For more than forty years, Deibel Labs has provided scientific consulting services to food manufacturers around the country. My father, who remains active in the company today, started the Deibel Labs when he was dean of the University of Wisconsin's bacteriology program in the late 1960's. He is widely recognized as one of the most knowledgeable scientists in the food industry, pioneering testing methods still in use today and helping to shape many food safety systems.

Deibel Labs is a member of numerous industry and professional organizations, including the International Association for Food Protection. Deibel Labs' professionals also are members of such organizations, including the Institute of Food Technologists, the International Association of Food Processors, the National Restaurant Association, and the National Confectionary Association. Many of our professionals are also certified as GMA-Safe and NFPA-Auditors and conduct training in numerous food safety programs.

In addition to micro-testing food products and their ingredients, we work with many manufacturers to help evaluate their existing food safety systems, conduct risk assessments, perform plant audits, and offer training in food safety procedures.

Dealings with Peanut Corporation of America and Cooperation With the Ongoing Investigations of the Peanut-Related Salmonella Outbreak

I want to give you a brief summary of Deibel Labs' dealings with Peanut Corporation of America or "PCA." My company did not provide day-to-day testing services for PCA as we do for many of our clients. Most relevant here, during 2007 and 2008, PCA's Plainview, Texas and Blakely, Georgia facilities sporadically submitted samples containing peanuts to Deibel Labs to test.

We have voluntarily cooperated with the Centers for Disease Control ("CDC"), the Food and Drug Administration ("FDA") and this Subcommittee to provide detailed records of the exact nature and timing of the tests that we performed for PCA's facilities, including samples from PCA's Blakely facility that tested "positive" for Salmonella in late September 2008 and the records of our immediate communications of those results to PCA's Blakely facility personnel. We also provided records detailing the requests that personnel at the Blakely facility made to us to re-test existing samples and the "negative" results of those tests.

It is not unusual for Deibel Labs or other food testing laboratories to find that samples clients submit do test positive for Salmonella and other pathogens, nor is it unusual that clients request that samples be re-tested. What is virtually unheard of is for an entity to disregard those results and place potentially contaminated products into the stream of commerce.

Considerations Impacting the National Food Safety System

I commend this Subcommittee for examining what can be done to prevent an incident like this from occurring again. As discussions progress on how to best to reform our national food safety system, I urge you to look at the entire model used today.

Our nation's current food safety system relies heavily on inspections conducted by the FDA and the state agencies with which it contracts. This is a reactive response, rather than the comprehensive, systemic process needed to safeguard our food. We believe that the FDA should focus on quality-control systems that minimize the potential for contamination to occur in the first place and develop mitigating strategies that correct a potential issue before it impacts food safety.

The FDA has a great deal of knowledge and understanding of how manufacturers can improve food safety practices. Our nation's small and medium sized companies, in particular, could greatly benefit from guidance documents from FDA. Yet, the FDA's job is to inspect, not to provide guidance, and so they do not do so. Yet, the United States Department of Agriculture ("USDA") routinely issues guidance documents to the food processors under its jurisdiction. FDA staff is reluctant to point manufacturers to the information and resources they need, or provide direct guidance on how an observation can be corrected. As a result, opportunities to improve food production practices are missed.

Testing, like inspection, is only one piece of an overall food safety policy. It is the last chance to catch a problem. The larger piece is on the front end–quality-control systems that minimize the potential for contamination to occur in the first place.

Every year, millions of pounds of food products end up in landfills because of positive tests for harmful organisms. The problem is not in a finding a positive result for such organisms from a test of a sample of its product—the issue we are discussing here is that a firm having commissioned testing of its product that found a positive, apparently attempted to test that same product into compliancy, and then released the product to the public anyway.

This attention to the issue of food safety is an opportunity to build stronger bridges between the FDA and food manufacturers. By taking a preventative, systemic approach, we can implement reforms that will go a long way towards ensuring that all consumers have access to a safe and wholesome food supply.

Thank You.

Mr. STUPAK. Thank you. That concludes the opening statements. I ask unanimous consent that Chairman Dingell, his full statement be made part of the record. Without objection.

[The prepared statement of Mr. Dingell follows:]

Statement of
Representative John D. Dingell
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing on "The Salmonella Outbreak: The Continued Failure to Protect the Food Supply"

February 11, 2009

Thank you, Mr. Chairman, for holding this hearing on the continuing inability of state and federal regulators to ensure the safety of our Nation's food supply. Let me begin by expressing my deepest gratitude to the relatives of the victims of this latest *salmonella* outbreak for appearing before the Subcommittee today. I hope that those witnesses, who have lost loved ones as a result of this catastrophe, will accept my condolences. To the representatives of Peanut Corporation of America, the FDA, the Georgia Department of Agriculture, Kellogg's, and the testing laboratories implicated in this crisis: be forewarned that you must answer difficult questions concerning your culpability in this matter, including how it might have been avoided altogether. You bear a tremendous responsibility to protect the public health and must be made to answer for any dereliction of this duty.

During the 110th Congress, this Subcommittee conducted nine hearings about the myriad faults in the regulatory system designed to protect Americans from dangerous foods and drugs. These hearings established that scarce resources available to the FDA, as well as state and local health departments, have hampered those agencies' abilities to prevent contamination of the Nation's food supply. These hearings also revealed a lack of coordination between federal, state, and local agencies, and emphasized the inadequacy of key provisions in the Bioterrorism Act of 2002 meant to ensure the rapid traceability of food. The latest *salmonella* crisis is further evidence of the rather patent disrepair of the regulatory mechanisms in place to safeguard the public health.

As we will learn from witnesses today, processed peanut products from Peanut Corporation of America plant have sickened over 600 people in 44 states and Canada to date. These products come from PCA's Blakely, Georgia, plant, which was cited as early as 2006 for numerous and repeated health violations by the Georgia Department of Agriculture. In brief, the *salmonella* outbreak caused by PCA's products finds its source in deplorable processing conditions left uncorrected by regular inspection, poor communication and cooperation between state and federal regulators, the practice of lab-shopping by PCA, and the fact that the private laboratories contracted by PCA to test its products were not required by law to forward the results of these tests to FDA or the Georgia Department of Agriculture.

This great confluence of corporate irresponsibility and regulatory negligence provides yet another reason to overhaul the Food and Drug Administration. Mr. Chairman, you, Chairman Pallone, and I have introduced legislation that would guarantee

a reliable stream of resources through registration fees on food manufacturers to support increased inspections of foreign and domestic processing plants by FDA. This legislation would also improve the FDA's trace-back capacity for foods, as well as authorize the Secretary to require manufacturers to report certain test results from certified labs. Finally, our bill would enable FDA to issue mandatory recalls of tainted foods. Given the profusion of new food processing plants and the increased interdependence of the global economy, these expanded authorities are necessary to ensure the public health. I would implore all of my colleagues here today to support H.R. 759, the "Food and Drug Administration Globalization Act of 2009." This sensible, eminently necessary legislation will improve the FDA's ability to protect American consumers, indeed from farm to fork.

Thank you, and I yield back to the balance of my time.

Mr. STUPAK. I will also note for the record that Mr. Inslee was here. I guess he is going to be back, and as a member of the full committee would be allowed to ask questions of this panel.

And we have three different parts of this panel, if you will. We will probably go more than one round of questions so we will try to go 5 minutes and we will come back if we have to.

Ms. Cowart, let me ask you a couple questions if I may. On tab 38 is the first tab I sort of see in here in the binder. It is a November 2, 2006, letter to Mr. Parnell of PCA, Peanut Corporation of America. In 2006 were you consulting with them as to their plant and salmonella? In looking at this, it looks like you were acting more as a consultant as opposed to lab testing, right?

Ms. COWART. At this point I received a phone call, our JLA received a phone call, and they had a problem or they reported a problem with some salmonella in some peanut granules and they needed someone to do a walk-through of the facility, and so by proximity, based in Albany, Georgia, and I have that background, I did go through and do a walk-through and tried to help them understand where the salmonella was coming from on that particular issue.

Mr. STUPAK. So in 2006 JLA was not testing, you sort of did a walk-through to try to figure out where the salmonella was coming from?

Ms. COWART. Right. I didn't pull any samples at that point. Our company has a microbiology department that does testing, and then there is another piece that will help, as you just——

Mr. STUPAK. Sure. And in this tab 38, in this letter, you sort of indicated three sources, right? It could have come from the organic Chinese peanuts?

Ms. COWART. That was what they told me when I arrived there, that that was the source of the granules.

Mr. STUPAK. OK. Or I think you identified it come have come from production because there was some question about not cooking it long enough, high enough temperatures to kill the salmonella, right?

Ms. COWART. What I asked for was the documents for the time and temperature of the roaster, and that could not be provided at the time.

Mr. STUPAK. And then of course there was also in the packaging because they were using water in the packaging area and we all know water is a great source of salmonella, especially in peanut butter, as we know from the 2007 ConAgra outbreak.

Ms. COWART. Yes, sir, and also if you will note in the letter, it also takes about packaging roasted product in a raw zone.

Mr. STUPAK. Correct. OK. So we had three possibilities there identified in your letter there. Let me go next to Exhibit 40, just two back. That is dated February 4, 2008. Now, at this point in time, because you are talking about a kill study and you are making suggestions as to a kill study, is that correct?

Ms. COWART. Yes, sir, I believe they contacted our Edenton, North Carolina, facility to help them understand a kill step study for their roaster, and we were trying to understand how to go about doing that. That is not something that we had ever done before as

a laboratory and so this was a new process for us and so we were trying to understand how to do that.

Mr. STUPAK. OK. So between 2006 and 2008, is it fair you consulted, JLA was a consultant then to the Peanut Corporation of America?

Ms. COWART. No, sir, we were not. These were—this was a moment in time in 2006, and I didn't have any follow-up with them after that.

Mr. STUPAK. OK. So 2006, and you didn't have any follow-up with them until 2008, until this possible kill study, right?

Ms. COWART. Correct. They contacted us, and that is how it usually worked with PCA from JLA's perspective. We are an independent testing laboratory and we do microbiology testing. If they have a question, we will try to answer their question.

Mr. STUPAK. So between 2006 and then again in 2008, in 2006 you had salmonella. Did you have any indication in 2008 at the time this memo was written, which is February 4, that they had other occurrences of salmonella at the Blakely plant?

Ms. COWART. No, sir, I was not aware of them, no, sir.

Mr. STUPAK. OK. You indicate in here that, again the same document, February 4, on Monday you are using oven at three different temperatures, you are going to use these spore strips, which was something different. What is the cost of those spore strips?

Ms. COWART. I am sorry. Could you repeat that question?

Mr. STUPAK. Sure. The third paragraph from the bottom, it says, "Monday I am starting a lab study using oven at three temperatures, 295, 300, 310 with duplicate BI spore strips exposed to the heat for varying times," and you listed times. To do that, these spore strips, which is to help kill the salmonella spores, correct, if there is any in there, if you heat it up?

Ms. COWART. Yes, sir, this is a lab study and so these spore strips, what they were trying to do is not to introduce a pathogen but a surrogate, yes, sir.

Mr. STUPAK. What would it cost to put these spore strips in with your production?

Ms. COWART. I am not sure I know. I don't know that answer.

Mr. STUPAK. Let me ask you this. You support then, it has been suggested throughout today, that labs, food processors should be registered, should be certified, the people doing the testing, and that the results should be filed with the FDA on every test?

Ms. COWART. Yes, sir, I think we agree with that. I mean, having heard what we have heard this week and in the papers, I think it is the right thing to do. I think we would want to be a part of the solution, absolutely, yes, sir.

Mr. STUPAK. Mr. Deibel, how about yourself? Do you think labs that do testing, labs should be certified by the FDA, that people doing the testing should be registered or make sure they have proper qualifications, and that the results of every test whether it is positive or negative be electronically submitted to the FDA?

Mr. DEIBEL. In regards to laboratory accreditations, I mean certainly laboratories should be using the published methods. They should be using good practices in regards to laboratory. We call them GLPs, good laboratory practices. In regards to having a lab-

oratory, mandating that the laboratory would submit those test results to government, I don't believe that would be a good practice.

Mr. STUPAK. How do you prevent lab shopping then, as has been alleged in this case?

Mr. DEIBEL. That I don't know. The overriding concern of this, and I am a consumer, my laboratory does a lot of testing for food safety, we want to have safe food. The entire industry at large, if you look at all the foods that we consume on a daily basis, and I am not just talking the foods that we make but the ingredient companies that manufacture ingredients for those, you know, finished product manufacturers, it is an enormous industry, and on a day-to-day basis most of us eat safe foods and we don't have an illness, and I think based on the huge amount of food companies that are out there, generally, you know, there isn't—my concern, I guess, in reporting those positive results is that you would actually encourage those businesses to test less. There are different types of tests that are done all along the manufacturing process. A raw ingredient before you use it, you do process validation work. You test your environment. We want to encourage that. We want to encourage companies to find problems if they exist, and again, my overriding concern——

Mr. STUPAK. Then how do we ever know then if a company is having positive test results if they are not reporting it to anybody but themselves?

Mr. DEIBEL. Every year millions of pounds of products feed landfills so companies find a positive result, destroy product, do not ship it——

Mr. STUPAK. In theory. In theory they do that, right? Because obviously here they didn't do it.

Mr. DEIBEL. Correct. I guess a food company, it is a business, and they are not in business to manufacture a product that will get somebody sick and they are at their best when they can make safe, wholesome products that a consumer will buy, enjoy and buy again. If a company manufactures a product where somebody eats it, falls ill, they are likely not to be in business.

Mr. STUPAK. So it is just a cost of doing business then when people get sick?

Mr. DEIBEL. Most food companies do spend, I would say in my experience, a lot of money and a lot of their efforts, their resources in making safe and wholesome foods, and we would want to have them be able to have the right to test as much as they can, find the problem——

Mr. STUPAK. Right, but this is our ninth hearing in 2 years. If we don't get on this thing, if we don't require some kind of reporting, how are we ever going to end this? I mean, we can't be doing this every—let us see, nine times in 2 years, every, what, 2 months, a new outbreak?

Mr. DEIBEL. Testing though is just one aspect of the overall food safety program.

Mr. STUPAK. I agree.

Mr. DEIBEL. And we really need to be focusing more on preventative strategies because even in testing, I mean, we see this with PCA. Even when several labs were involved testing, you always didn't find it, even though we knew it was there.

Mr. STUPAK. Because no one was reporting it.

Mr. DEIBEL. It became known that it was——

Mr. STUPAK. Because nobody was reporting it. I agree with you, we should be proactive as opposed to reactive. Right now we are reactive. If we had reporting, mandatory, maybe we could be proactive.

With that, I will turn to Mr. Walden for questions.

Mr. WALDEN. Thank you, Mr. Chairman.

I guess that a question I want to go to the FDA on. Wouldn't you benefit from knowing the lab results?

Dr. SUNDLOF. Thank you, Congressman, yes. FDA like any other enforcement organization wants all the information we can get.

Mr. WALDEN. And you don't get those lab results today, correct?

Dr. SUNDLOF. That is correct.

Mr. WALDEN. And would you be overwhelmed with the number of lab results you would get?

Dr. SUNDLOF. It is hard to say, I mean, but certainly having that information available would be very helpful.

Mr. WALDEN. Only if it is in a form that could be readily accessed and utilized. It seems to me like there ought to be in the modern era of computers a way where those lab results could go in and then flag if there is a facility that repeatedly tests positive for salmonella. It would help you identify where you need to go inspect, wouldn't it?

Dr. SUNDLOF. I believe that is right.

Mr. WALDEN. Now, let me go back to Mr. Deibel. I am troubled with this notion that those lab results shouldn't be shared with the FDA or the Georgia Department of Agriculture or whomever, and I don't disagree that I think they should be inspected. I think they should seek out, I think as a small businessperson I had nothing to do with food, but it seems to me in their best self-interest to make sure their product line works and is sanitary. In theory, most don't want to make somebody sick. So what is the harm in sharing those positive results with the regulators so that they are on notice there may be a problem here?

Mr. DEIBEL. From a laboratory level, we always don't understand what types of samples are coming into our laboratories.

Mr. WALDEN. Right.

Mr. DEIBEL. So it could be part of environmental monitoring where product fell on the floor and they want to test that. It could be——

Mr. WALDEN. OK, but couldn't we——

Mr. DEIBEL. —processed samples. They could be doing a new R&D project.

Mr. WALDEN. Right, but——

Mr. DEIBEL. We just don't know.

Mr. WALDEN. OK, but how hard would it be to have a row of boxes that says this is an R&D sample test, this is an off-the-floor sample, this is something that is going into the Austin crackers that some 3-year-old is going to eat? Is that that hard?

Mr. DEIBEL. That wouldn't be hard, however, I don't know that that would happen.

Mr. WALDEN. All right. So if the private lab doesn't collect the samples, how can you ensure the integrity of those samples? Can you, Ms. Cowart? They just send you whatever, right?

Ms. COWART. Correct. What happens with our company is, we receive samples into our laboratory with a request for analysis and we do the analysis that was written on the request form. We do not know where the samples came from. We don't know the history of them. And so our obligation as an independent laboratory is to run the test and to notify them with the accuracy and speed that we can to get them to them.

Mr. WALDEN. And it sounds like you have a very thorough process to do that, which I commend you for, both e-mail and a voice process.

Ms. COWART. Thank you.

Mr. WALDEN. So let me go back to this notification. We learned yesterday or sometime this week that there is this mystery peanut-processing plant in Texas that apparently has never been reviewed by the FDA, no regulators have been in there. Is that correct?

Dr. SUNDLOF. No, sir. The FDA was in there in 2001 inspecting but at that time they were not producing peanut butter or peanut paste.

Mr. WALDEN. Have you been back since they have been producing peanut butter or paste?

Dr. SUNDLOF. Yes. I am sorry. Which plant are we talking about?

Mr. WALDEN. The one in Texas.

Dr. SUNDLOF. Oh, the one in Texas. I am sorry. Let me retract that. No, we had not been in there.

Mr. WALDEN. Were you aware it even existed?

Dr. SUNDLOF. We were.

Mr. WALDEN. You were aware? Some of the news accounts indicate nobody knew this thing was going on, it wasn't registered, wasn't inspected. Do you know if it had been inspected?

Dr. SUNDLOF. I don't believe it had been inspected.

Mr. WALDEN. So Mr. Deibel, if I understood you correctly, your company was actually doing tests from peanut product from that plant and discovered there was salmonella in some of that plant's product. Is that accurate?

Mr. DEIBEL. The Texas facility?

Mr. WALDEN. Yes, sir.

Mr. DEIBEL. That is correct.

Mr. WALDEN. So if you had had to report that to the FDA, then the FDA would have known there was salmonella in a plant they had never inspected?

Mr. DEIBEL. We did report that.

Mr. WALDEN. To the FDA?

Mr. DEIBEL. We reported this to the subcommittee. I am unsure if we reported it to——

Mr. WALDEN. Wait a minute. When did you do the salmonella test?

Mr. DEIBEL. The result just came off this last Sunday.

Mr. WALDEN. OK. So you just found out about this?

Mr. DEIBEL. Yes.

Mr. WALDEN. But you didn't report that—I mean, you knew we were doing an investigation so you shared it with us in that con-

text. You wouldn't normally have sent us just sort of randomly test results, right? Of course not. But had you reported test results to anybody before?

Mr. DEIBEL. We report test results to our clients but there is no mechanism currently in place to——

Mr. WALDEN. Right. And that is what we in the other context of the full are going to debate is, what is the mechanism that should be there. I mean, I am not an advocate of just sending enormous amounts of data to another government agency that will put it in boxes, it will go in a warehouse that will probably leak and we can produce peanuts there too. But, you know, it doesn't make sense so it has got to be something that is usable. And so had you done tests prior to the ones this week on that plant in Texas?

Mr. DEIBEL. We have been doing results for them for a number of years.

Mr. WALDEN. A number of years, and had you spotted salmonella in any of those tests?

Mr. DEIBEL. No, everything was negative up to the point of the results on Sunday.

Mr. WALDEN. Dr. Cowart, did your firm do any tests on that plant in Texas?

Ms. COWART. On the Texas facility, no, sir, we did no microbiology testing.

Mr. WALDEN. And why do you think—I find it curious that your firm consistently found salmonella, you said six times in 2007 and four in 2008?

Ms. COWART. That is correct.

Mr. WALDEN. And then it sounds like PCA decided we are going to go somewhere else. Is that your read of it?

Ms. COWART. After reviewing the documents and talking with our associates back at the laboratory, it appears that way, yes, sir.

Mr. WALDEN. And then they sort of sent you one under the name of an internal operation just to, I guess, have you do that test.

Ms. COWART. That is right, and again, not knowing the history of the samples, we just took the sample——

Mr. WALDEN. You do the test.

Ms. COWART. —and we did the test. That is correct, yes, sir.

Mr. WALDEN. Did you know whether or not PCA went to any other labs?

Ms. COWART. We were aware of, they were asking us about a high coliform count and an aerobic plate count and so in an effort to answer their question, we did ask them if they could send us the results of the aerobic plate count and the coliform count just to compare, because we obviously go into a diagnostic mode also.

Mr. WALDEN. Sure.

Ms. COWART. And so we did know that they had used another lab for that, yes.

Mr. WALDEN. And then do you like check the calibration of your equipment and all of that to just see?

Ms. COWART. Yes, sir, we do, and we also run quarterly proficiency sample tests so that we can be able to check against an unknown sample that would come in from a proficiency organization.

Mr. WALDEN. All right. And Mr. Deibel, do you have any idea why your data would be different than JLA's data?

Mr. DEIBEL. Just based on——

Mr. WALDEN. How does that all work?

Mr. DEIBEL. We are dealing with a dry commodity good, and as had been mentioned before, you know, water does play a role in these organisms, and so the results are not always going to be consistent within that sample and so you will get some degree of variability in those test results.

Mr. WALDEN. I want to thank the witnesses for your testimony and for answering our questions. It is helpful in our efforts.

Thank you, Mr. Chairman, for your indulgence.

Mr. STUPAK. Thank you.

Mr. Braley for questions, please.

Mr. BRALEY. Thank you.

Dr. Sundlof, as I understand it, the FDA did not conduct inspections of the PCA plant in Blakely, Georgia, from 2001 until January of 2009. Is that correct?

Dr. SUNDLOF. That is correct. Now, we did again inspect in 2001 and at that time they were not producing peanut butter or peanut paste. In I think it was 2007, the State of Georgia inspected under contract from FDA, so in essence, that was an FDA inspection in 2007 and one in 2008.

Mr. BRALEY. Well, after the recent salmonella outbreak was traced to peanut products in January of 2009, FDA conducted a detailed inspection of the PCA facility and issued an inspection report called a 483 report, and in that report you listed 12 occasions in 2007 and 2008 when private labs informed PCA that its products tested positive for salmonella. I want to ask you about one of those. According to the 483 report, in June of 2008 the company received a private lab test that was positive for salmonella, and according to your report, the lot was manufactured on June 9 and the sample that tested positive was provided to the private lab on June 10. Is that correct?

Dr. SUNDLOF. I believe that is correct.

Mr. BRALEY. Dr. Sundlof, wasn't June 10 the same day the Georgia Department of Agriculture inspected the facility on your behalf?

Dr. SUNDLOF. I would have to check my records.

Mr. BRALEY. Well, if that is the case and that is what the records show, the day after the company produced peanut products with salmonella, your inspectors were inside this facility but they didn't detect salmonella because you didn't direct them to test for it. Isn't that true?

Dr. SUNDLOF. That is true.

Mr. BRALEY. And you had the legal authority to order those tests, didn't you?

Dr. SUNDLOF. Yes.

Mr. BRALEY. So why didn't you order salmonella testing that day?

Dr. SUNDLOF. Well, first of all, we did not know of the test results at the time. We did not know those until January. Secondly, our policy had been that on routine inspections, and this is not forcause inspections, in other words, where we don't suspect that there is a problem in the plant, we have not asked our inspectors in general whether it is the FDA inspectors of the inspectors under

contract to collect samples or obtain environmental samples. We are changing that now as a result of this.

Mr. BRALEY. Well, does your office and do your inspectors apply a heightened degree of suspicion when there are other things going on in the food production business that might alert you to potential problems?

Dr. SUNDLOF. Yes, we do. I mean, we take the entirety of all of the findings into account to determine whether or not it raises us to the next level where we would issue an inspection report of action, that there would be required actions to be taken by the company. In this case, I think all of the inspections that were conducted indicated that there were some infractions, that they didn't immediately pose what appeared to be a risk to the safety of the food supply and that the company was correcting those deviations either while the inspector was in the plant or gave assurances that those would be corrected.

Mr. BRALEY. Well, the reason I ask you that very specific question about a heightened index of suspicion is because in April of 2007 this subcommittee held a hearing on a salmonella outbreak at the ConAgra peanut butter plant in Sylvester, Georgia, which is only 75 miles from the PCA plant, and that outbreak resulted in over 400 illnesses in 44 States. Wasn't that cause enough for FDA to order testing for salmonella at the PCA plant?

Dr. SUNDLOF. After that outbreak of Peter Pan, we went back and did a lot of education for the peanut industry. There was a seminar that was given in Atlanta in which the entire peanut industry was invited. We had FDA people there. They had other people talking about the kinds of measures that should be put in place in order to prevent this from happening in the future. We looked back at our records and determined that four people from PCA were registered to attend that particular symposium.

Mr. BRALEY. So then you would agree with me that in this geographic area, in your State, there was certainly a heightened degree of suspicion about the potential for salmonella outbreak at the time these inspections were performed?

Dr. SUNDLOF. Yes.

Mr. BRALEY. And are there any written standards that apply to determine when there is for cause to test for salmonella?

Dr. SUNDLOF. I don't believe there is any written ones. I would ask Mike Chappell if he can comment on that.

Mr. CHAPPELL. Well, after the ConAgra series, we did indeed provide some additional guidance to our field staff, and as Dr. Sundlof just mentioned, the realization is that we probably need to depend more on environmental sampling than we have in the past, not just the for cause, which means the conditions in the plant suggest there are serious problems.

Mr. BRALEY. Mr. Chairman, it seems to me that private labs detected salmonella at the PCA facility but since they only reported it to PCA, the public never found out about it and that is a difference that we can't afford to have in our food safety system, and I yield back.

Mr. STUPAK. I thank you, Mr. Braley.

Mr. Deal for questions, please.

Mr. DEAL. Thank you, Mr. Chairman. My line of inquiry is in two areas. First of all, what are manufacturers required to do, and secondly, what are State and federal authorities allowed to do. Now, in that regard, I would ask first of all, has peanut butter been classified by FDA as a high-risk product?

Dr. SUNDLOF. I don't believe it has. That may change in the near future.

Mr. DEAL. Do you think that would be an appropriate classification?

Dr. SUNDLOF. I believe so.

Mr. DEAL. If it is so classified, what would change with regard to what the manufacturer must do and what the FDA and State authorities can do?

Dr. SUNDLOF. Well, certainly considering it high risk, we would change the way that we inspect, and I think we just addressed that, that in the future we are in the process of writing all of our guidance to our inspectors that they will be taking samples of the product and the environment in the future and that will go a long way I think to detecting these problems earlier, but there is no—in terms of what is required under Good Manufacturing Practice standards, they are written rather broadly and they are written more for all foods than specific products, and as such they are not very prescriptive. You know, what will probably result from this is some stronger guidance that will be more specific about peanut butter as it pertains to the kind of manufacturing controls that need to be put in place and the kinds of inspections that we will do.

Mr. DEAL. Can anything that FDA does by way of classification or otherwise require a peanut butter manufacturer to do product sampling with a specified period of regularity?

Dr. SUNDLOF. Currently, the Good Manufacturing Practice standards are not written that way.

Mr. DEAL. Do you think maybe they should be?

Dr. SUNDLOF. Well, in my testimony I talked about putting more preventive controls, mandatory preventive controls in place in certain food facilities, and what we are talking about here, the term is the Hazard Analysis Critical Control Point, type of quality systems in which all of those kinds of things would be documented for any food process that falls under that kind of preventive control.

Mr. DEAL. In the absence of requiring things like sampling and testing of those samples, then sampling and testing is a voluntary action on the part of the manufacturer. Is that correct?

Dr. SUNDLOF. Currently, that is correct.

Mr. DEAL. And the concern that some people have of requiring disclosure of those voluntary samples of disclosure of the results is that as long as it is voluntary, all that may very well do is to have less testing rather than more testing. Do you share that concern?

Dr. SUNDLOF. Yes.

Mr. DEAL. I am sorry I don't have time for you to elaborate much on it. If you have that concern then, is that one of the things that your recommendations to Congress has included? Is that one of your recommendations?

Dr. SUNDLOF. We will be working—we are more than happy to work with the Administration and the Congress to craft any new

legislation authorities that we need. I mean, I think the concern with us is that we need to make sure that it doesn't discourage additional testing. In other words, if it is required, will companies actually do less testing because they know that the FDA will have access to those records. So it needs to be very carefully thought through how that process works.

Mr. DEAL. Now, one of the problems I understand existed was that you could not access internal records and only had to go under the bioterrorism statutory authority in order to be able to get those internal records. Have you recommended or would you recommend that that be changed in terms of what the FDA or State authorities acting under your jurisdiction have the right to access internal records? Should they have that right?

Dr. SUNDLOF. Yes. That is the other—again, we are working with the Administration on that but certainly if we had greater authority to access those kinds of records outside of the threshold that is required under the Bioterrorism Act to access those records, we would get a lot more information in a timely manner.

Mr. DEAL. Mr. Garrison, I know that you act in conjunction with your contract authority with FDA to do inspections on their behalf that you are contracted to perform. Is that correct?

Mr. GARRISON. That is correct.

Mr. DEAL. And you have outlined the fact that money is a shortage factor and the number of inspectors are in short supply to do all that you undertake to do at the State level as well as in your contract capacity. Is that right?

Mr. GARRISON. Yes, sir. Currently, we receive funding of about $123,000 through our FDA contract. The State funding for our food protection program is some $6 million.

Mr. DEAL. I would ask this of both you, Mr. Garrison, and you, Dr. Sundlof, and that is, especially in the area of the FDA, we have seen that one of the ways to augment and get better results is through a user-fee program in which the producer has an incentive to have the testing done and in effect pays for that extra cost. We see it in other areas under FDA's jurisdiction. Have you considered a user fee to fund the cost for additional inspections at the federal level and/or the State level?

Dr. SUNDLOF. Thank you. We are responding to legislation proposed, the Food Globalization Act, in which user fees are part of that, and we will be submitting formal responses and technical assistance on that bill.

Mr. DEAL. At the State level, Mr. Garrison, are user fees contemplated?

Mr. GARRISON. I would have to say that would be a pay grade above myself. That would be something that Commissioner Irvin and the State legislature and the governor would have to take up.

Mr. DEAL. It is not in the current proposed legislation then?

Mr. GARRISON. Not that I am aware of, no, sir.

Mr. DEAL. Thank you for the extra time.

Mr. STUPAK. Ms. Christensen for questions. Oh, I am sorry, excuse me, Mr. Dingell for questions, please.

Mr. DINGELL. Well, Mr. Chairman, first I want to commend you. This is a continuation of the excellent hearings which you had in the last Congress, and I want to commend you for your vigor and

your energy and your enthusiasm and for the success of your efforts. You are going to make possible major reform here and I want to commend you for that.

These questions are all to Dr. Sundlof. Please, Doctor, answer yes or no because we have relatively little time in which to do this. Food processors should be made to notify the FDA when they begin producing products that have not previously been registered. Do you agree, Doctor, yes or no?

Dr. SUNDLOF. I am sorry. Could you repeat the question?

Mr. DINGELL. Please pay attention because we do have limited time here. Food processors should have to notify FDA when they begin producing products that they had not previously registered. Do you agree?

Dr. SUNDLOF. Yes.

Mr. DINGELL. In light of the current crisis with regard to Food and Drug and producers, should foreign and domestic food facilities be required to have safety plans in place to identify and to mitigate hazards?

Dr. SUNDLOF. In some cases, yes.

Mr. DINGELL. Now, what should these plans, rather should these plans be subject to review by FDA inspectors?

Dr. SUNDLOF. Yes.

Mr. DINGELL. Would increase in inspections by FDA have potentially prevented the salmonella outbreak?

Dr. SUNDLOF. It is potentially possible, yes.

Mr. DINGELL. In other words, more frequent and more thorough inspections by Food and Drug would have done so. Is that right?

Dr. SUNDLOF. Yes.

Mr. DINGELL. Now, if FDA had better traceback capabilities, would that have helped prevent this salmonella outbreak?

Dr. SUNDLOF. It would have helped us recall product quicker.

Mr. DINGELL. Now, should testing done on food products be subject to certain safety requirements and be performed only by a laboratory accredited by FDA?

Dr. SUNDLOF. I have no opinion on that at this time.

Mr. DINGELL. You will note that you had a number of laboratories which performed tests that either didn't reveal the presence of salmonella or that were not reported to FDA. If FDA had had reliable reports from reliable laboratories, would it not have been better able to protect the public?

Dr. SUNDLOF. Yes. I want to just say about salmonella testing, you can test the same product several times and not find the salmonella and it can be still in there. We suspect that these were all good laboratories and that the failure to confirm a positive was not the laboratory's fault but the sampling.

Mr. DINGELL. I am driven to the unfortunate conclusion that if that statement is true, Food and Drug probably could have done without laboratory inspections at all because apparently the laboratory inspections either didn't get communicated to FDA or they didn't reveal the presence of salmonella, and how does Food and Drug do its job without proper assistance in identifying the presence of pathogens like salmonella?

Dr. SUNDLOF. We rely heavily on States and private laboratories and others to help us in our mission.

Mr. DINGELL. It sounds like you are saying trust everybody. I would add to that my dad's abjuration that you should always cut the cards. Now, in light of the salmonella outbreak caused by PCA's products, could this crisis have been mitigated if testing laboratories were required to send their testing results to FDA?

Dr. SUNDLOF. It would have alerted us a lot sooner, yes.

Mr. DINGELL. I am sorry?

Dr. SUNDLOF. It would have alerted us sooner than that there was a problem.

Mr. DINGELL. So you need both qualified and competent laboratories and you need to have them registered and you need to have them send their results to Food and Drug so that you know what is going on, right?

Dr. SUNDLOF. Again, we appreciate all the information that we can get.

Mr. DINGELL. OK. Should FDA have authority to issue mandatory recalls of tainted foods?

Dr. SUNDLOF. We are more than happy to discuss that. It depends, I believe, on how the law is written and what——

Mr. DINGELL. You do not have that authority now.

Dr. SUNDLOF. We do not.

Mr. DINGELL. And you need it if you are to do your job effectively, do you not?

Dr. SUNDLOF. It would be helpful, yes.

Mr. DINGELL. More than helpful, it is necessary. Isn't that so?

Dr. SUNDLOF. I can tell you that almost in every case when we ask companies to recall product, they do it voluntarily.

Mr. DINGELL. Now, Food and Drug was not able to visit or inspect the Peanut Corporation of America for about 8 years. Is that right? And then they turned the matter over to Georgia, which in 2 years is supposed to have visited PCA but they didn't find a thing. What caused the failure of FDA to be able to inspect the people who were subject to their jurisdiction? I am told that the Department of Agriculture can investigate and can visit and inspect dog food producers oftener than Food and Drug can inspect food producers. Do you need more resources at Food and Drug to carry out proper inspections or not?

Dr. SUNDLOF. We would like to do more inspections, yes.

Mr. DINGELL. Well, you are not doing the inspections that need to be done so you are not able to protect the people. PCA tells us clearly that the consumers were not protected because tainted and unsafe salmonella-infected peanut products and peanut butter got on the market, and with more resources you could have done a better job of protecting the public. Is that not so?

Dr. SUNDLOF. It is not clear in this case.

Mr. DINGELL. It is not clear?

Dr. SUNDLOF. It is not clear——

Mr. DINGELL. In 8 years you couldn't investigate them. That is clear to me. Then Georgia investigated them and they couldn't do a good job. So that tells me that Food and Drug does not have either the resources—you are caught in a cleft stick here. Either you don't have the resources or you are incompetent to do the job you are supposed to do. Which conclusion am I to arrive at?

Dr. SUNDLOF. I would hope the former.

Mr. DINGELL. That you don't have the resources? I am content to believe that you are incompetent but I have tried to defend you against that and point out that you need resources. What I get from you, however, is, a modified reluctance to have more resources, and I am distressed because I think that the only way Food and Drug is going to amount to a hill of beans is to have the resources that it needs and to have the statute that it needs and to have the leadership that it needs. I find the leadership lacking, I find the resources lacking, and you are driving me to the conclusion that perhaps maybe Food and Drug is not as diligent as it should be because it might have the resources. Now, what is your response to that?

Dr. SUNDLOF. Well, obviously we need to be inspecting more frequently. In this particular case, we should have been taking environmental samples. That would have led us to find problems earlier. We should have been more directed to the State of Georgia in directing them to take environmental samples. Had they done that, we might have detected this sooner.

Mr. DINGELL. Mr. Chairman, my time has expired. You have been very gracious. I thank you.

Mr. STUPAK. Well, thank you, Mr. Dingell, and on behalf of all the members, when they were doing the tribute on the floor on your resolution, we all would have liked to have been there but we were doing as you have taught us to do, oversight, so forgive us for not being there when they did the House resolution in tribute to your longevity on the floor. I know some of us after hours tonight will be paying tribute to your length of service, but more than that, the quality of service you provided to the American people.

Mr. Gingrey for questions, please.

Mr. GINGREY. Mr. Chairman, thank you, and following up on the chairman emeritus's line of questioning, let me address my first question to Dr. Sundlof of the FDA. You know, I think as I read your testimony that FDA actually went into Blakely, Georgia, to inspect this PCA plant on January 9, 2009, and this was based on the information that had been obtained by Minnesota Department of Public Health that clearly there was salmonella in an open container of this peanut butter product, and yet you go there and you find pretty quickly in going through the records of the company that some of the lab reports that were submitted by these two labs, these private labs, which by the way I don't feel are necessarily responsible for not notifying the FDA. I mean, their job is basically a contract with the company. It is just like if a physician does a blood sample on someone and sends it to a lab and it is a low hemoglobin, as an example. Well, the laboratory is going to report back to the doctor and maybe even flag that, particularly if it is a dangerously low number, but that is where their responsibility ends. I mean, they cannot run down every patient and interfere with a doctor-patient relationship. So it may be that that is something that we should change, and I will get to that question in just a minute. But my question to you is, FDA went in and knew on January 9 beyond a reasonable doubt that this was the source of the contamination and yet waited another 10 days or so to get some unopened can of peanut butter from somewhere in Connecticut to absolutely, unequivocally prove it. Couldn't you have

had the ability to say to the company, cease and desist until we can prove this? If we disprove it, then, you know, you continue operations and maybe the Federal Government, the FDA mitigates any financial loss but when you just continue to get to the nth degree for another 10 days, I don't now how many more hundreds of people got sick or maybe even additional deaths because of that delay. Why couldn't you have issued a cease-and-desist order at that time?

Dr. SUNDLOF. I believe we went in on the 9th. I believe that was a Friday. The company recalled on the following Monday. So we did move very quickly.

Mr. GINGREY. Well, the company recalled a certain product that was produced and then it was later that they recalled it and then finally they had another recall that went all the way back to January 2007, but that probably should have been done immediately.

Dr. SUNDLOF. We can only work with the information that we have at the time. At that time we only knew of the products, the King Nut products as being the source. We moved quickly. They quit producing on that date and quit marketing on that date, on the 9th of January, and started recall of the products that we knew were affected by the following Monday.

Mr. GINGREY. Let me move on to Mr. Garrison with the Georgia Department of Agriculture. Do you feel like the Department under contract with the FDA had sufficient training? Were there any manuals in regard to the inspectors that work with the Department of Agriculture? Did you have enough training and guidance to properly inspect?

Mr. GARRISON. Training is always a continual issue when you are looking at the evolving food continuum that we see. There have been a lot of advances in food processing, a lot of new programs brought online, as Dr. Sundlof stated, Hazard Analysis Critical Control Point. Those inspections are now required in seafood processors and in juice processors. So where there is specific training required of an operator of a facility, then our inspectors are also provided with that training. We have taken the Good Manufacturing Practices from FDA. Those are adopted in the State regulations and those are also in our performance manual that——

Mr. GINGREY. And Mr. Garrison, did the Department abide by the terms of the contract in regard to the frequency of inspections?

Mr. GARRISON. Yes, sir. The terms of the contract only lays out one inspection in the assigned facilities during a calendar year unless there is an indication by FDA that a follow-up would be necessary based on documentation.

Mr. GINGREY. Let me real quickly ask our lab folks, if you will bear with me, Mr. Chairman. If you were required to submit a copy of your report, certainly a positive report, let us say, to the FDA, how much more expense or burden would that be for the laboratories? How much more would you have to charge the food processor that contracted with you to do the lab testing if you were required to submit a duplicate copy to the FDA?

Ms. COWART. Mr. Gingrey, I can speak specifically for our company. All of our documents are e-mailable in a new system that we have put in place since August of 2007 so it would be very simple to e-mail to whoever in FDA would be the appropriate person.

Mr. GINGREY. Mr. Deibel, would you agree with that?

Mr. DEIBEL. Yes. We have a system where we can plug in on each client each client contact that would want a report. The system, once we go through our checks and balances to ensure that the result is accurate and authorized, once that is authorized, it is automatically either e-mailed or faxed to whomever.

Mr. GINGREY. So easily done, not expensive and nothing you would object to if we decide that that should be done in the future?

Mr. DEIBEL. If that was something that this body decided, it would not be a problem.

Mr. GINGREY. Mr. Chairman, I will yield back. I know my time has expired.

Mr. STUPAK. Ms. Christensen for questions, please.

Ms. CHRISTENSEN. Thank you, Mr. Chairman.

I would like to direct my first question to Dr. Sundlof also. I had a chance to look through some of the Senate testimony and the director of food safety for the Center for Science and Public Interest had what I am going to read to you in her testimony. She says that in April of 2008, Canada rejected a shipment of peanuts from PCA as unfit for food. PCA attempted to clear the peanuts for sale in the United States but FDA rejected its test results and eventually the peanuts were destroyed. During that period—well, wouldn't that have sent a red flag up to FDA and shouldn't that have caused FDA to require more inspections of PCA, given the fact that this is April of 2008? Because the testimony goes on to say that FDA did not follow up with inspection of the plant.

Dr. SUNDLOF. That is not entirely true. The shipment was rejected because it was peanut granules and it was determined that it contained some metal fragments in there. It was returned back to PCA. FDA witnessed its destruction so that it did not move into commerce. At that time we also asked that the State of Georgia do an additional inspection in that facility. That was one of the two that was conducted under FDA contract and they went in there I think in May or June was when they went back in to inspect. I believe they determined what the source of the metal was and the firm took corrective action.

Ms. CHRISTENSEN. And Mr. Garrison, you are familiar with those inspections.

Mr. GARRISON. Yes, ma'am.

Ms. CHRISTENSEN. Was it your testimony that you found no evidence for any contamination in those inspections? Was it a complete inspection or was it just related to the metal?

Mr. GARRISON. What the e-mail that we received from FDA stated was, it was to be a contract inspection and focusing on GMPs, which is what the contract states, and also looking for any metal inclusion that may have occurred and to check out the metal detector. What we reported back to FDA was a couple of metal scrubbers, which we would call a brillo pad, that were inside the facility and also a scraper——

Ms. CHRISTENSEN. But that would not have precipitated any other inspections? Was it focused just on the metal?

Mr. GARRISON. No, ma'am. We actually had done a Good Manufacturing Practice inspection during that time.

Ms. CHRISTENSEN. And there was nothing to suspect that there would be any other contamination in those inspections?

Mr. GARRISON. Like I said, there was no red flags that would indicate an imminent health hazard inside that facility.

Ms. CHRISTENSEN. My understanding, Mr. Garrison, is that between 2007 and 2008, PCA had 12 positive salmonella tests reported to them, and in that time the Department tested 35 product samples from five Georgia facilities. How many of those were from the Blakely plant?

Mr. GARRISON. There were three samples taken from the Blakely plant in believe August of 2007.

Ms. CHRISTENSEN. And their first positive was in June of 2007, but you didn't find any in your three?

Mr. GARRISON. No, ma'am, we did not.

Ms. CHRISTENSEN. Since there has been a salmonella outbreak the year before that was in peanut butter, when this outbreak started to surface, did that not raise concern and should not that have precipitated some increased inspection at peanut butter plants, for either Dr. Sundlof or Mr. Garrison.

Mr. GARRISON. From the State perspective, when the outbreak began we worked closely with our department of Public Health and their epidemiologists were monitoring the CDC calls looking for potential causes and implicated foods and then they would bring those to us. You know, once the peanut butter was brought forward as a potential, then at that point the State along with FDA began looking at potential problems that may be associated with those facilities.

Ms. CHRISTENSEN. But nobody seemed to think back to March of 2007 to say well, this is salmonella, we had a salmonella outbreak a year before where the source was peanut butter?

Mr. GARRISON. From a State perspective, we are constantly shuffling resources. You know, when we can run 45 samples through our laboratory, you know, coming into June we were dealing with imported jalapeno peppers that, you know, actually tainted our tomato industry in Georgia. We had melamine in products coming from China that the State was running tests on in October so, you know, with very limited lab resources, we are constantly moving around what we are testing and what we are looking for from a State standpoint.

Ms. CHRISTENSEN. If I can get just one more question, a quick question, to Mr. Deibel and Ms. Cowart. The fact that there was a negative follow-up test after a positive one, how many negative tests would you consider enough to convince you that the positive test result could be ignored? Can you ignore a positive test just because you get another follow-up?

Mr. DEIBEL. Absolutely not. If you tested 50 samples for a given lot and 49 of those were negative and one was positive, that one positive must trump the 49 negatives. The 49 negatives should never have more precedence over that one positive. You cannot retest away a positive result.

Ms. COWART. And I will agree with that statement wholeheartedly.

Ms. CHRISTENSEN. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you.

Ms. Schakowsky, questions, please.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

Mr. Deibel, on April 28, 2008, your lab confirmed that a PCA sample tested positive for salmonella contamination. Is that correct?

Mr. DEIBEL. I believe so. Yes.

Ms. SCHAKOWSKY. I think you said before, what would you have expected a manufacturer to do with that information?

Mr. DEIBEL. We do a lot of consulting services for our clients and most of what we try to get involved with is more on the front-end quality control procedures, working with clients to have——

Ms. SCHAKOWSKY. What would you have expected that they would do?

Mr. DEIBEL. In the event of a positive occurrence, we would expect that they would shut that line down or stop that production, quarantine that lot, try to figure out how that positive occurred in retesting.

Ms. SCHAKOWSKY. OK, but——

Mr. DEIBEL. But ultimately throw it out.

Ms. SCHAKOWSKY. But actually following that initial positive, PCA sent you additional samples from the same lot and they also went to Dr. Cowart's firm and provided an additional sample, and those tests came back negative for salmonella, right?

Mr. DEIBEL. Correct. That is not unheard of.

Ms. SCHAKOWSKY. Dr. Garrison, what is a company expected to do if there is a positive? And do you also agree that negatives don't erase the positive that has been found?

Mr. GARRISON. The State of Georgia Department of Agriculture would expect that company to immediately destroy the product. If it has been put in commerce, it would expect them to recall that. During our testing procedures, when we get what Ms. Cowart had referred to as a presumptive positive from a facility we regulate, we will notify industry at that point, and in most cases, as a matter of fact, in all cases from that presumptive positive, the processing facility will either hold the product if it hadn't went out or go ahead and issue a recall just based on that presumptive.

Ms. SCHAKOWSKY. OK. Now, between June of 2007 and September of 2008, private lab testing found salmonella on 12 separate occasions. You inspected the plant on June 10, 2008. Did you ask if there had been any laboratory tests?

Mr. GARRISON. There is no evidence on our inspection reports that we asked but that is something that the company does not have to supply to the State. That is the reason——

Ms. SCHAKOWSKY. Do you ask though?

Mr. GARRISON. I can't say in this particular instance if we asked or not.

Ms. SCHAKOWSKY. Is it on your report form to ask?

Mr. GARRISON. No, ma'am, it is not something that is required of——

Ms. SCHAKOWSKY. I know it is not required. I am just wondering if you asked and if the company refused to tell you because they don't have to, would that not indicate that there might be some sort of a problem? I mean, I don't understand. If there has been test after test, I think everybody here agrees that a positive test

should result in a product being taken away. I think we will change that. I hope we will change that so they do have to inform you, but I can't understand why that question wouldn't be asked. Can you explain that to me?

Mr. GARRISON. When companies are not required to give records, we don't even know if tests have been conducted.

Ms. SCHAKOWSKY. Exactly.

Mr. GARRISON. And when you are dealing with the elements that we are dealing with in this case, if we think by simply asking they would tell us that they didn't have the results or that they were all negative, you know, we are dealing with a different element here. We are dealing with something that at this point appears to have intention based in it.

Ms. SCHAKOWSKY. There is at tab 42 an e-mail from Stewart Parnell, the owner of PCA, and in these e-mails with the plant manager, Sam Lightsey, Mr. Parnell inquired about the results of a subsequent test from Deibel. Mr. Lightsey informed Mr. Parnell that the subsequent tests were in spec, meaning they came back negative for salmonella. Although Mr. Parnell knew that this lot previously received a confirmed positive for salmonella, Mr. Parnell instructed this plant manager, "OK, let's turn them loose then." Dr. Sundlof, is this the appropriate response to these two tests, to turn the product loose on American consumers?

Dr. SUNDLOF. No, it is not, and I don't believe that is in any way the industry practice. I think this is a case in which one company has violated what I think all other companies know. It is well known within the peanut manufacturing community that testing, even finding a negative is not conclusive, that you have to take many tests, and that certainly once you find a positive test, that that product cannot be considered to be safe.

Ms. SCHAKOWSKY. When you conduct tests as the FDA, do you ask if any tests have been conducted?

Dr. SUNDLOF. I think we do but I am going to ask Mike Chappell to speak to that.

Mr. CHAPPELL. It certainly depends on the nature of the inspection. If you are asking whether it is a routine requirement for our investigators to ask for whatever testing, that is not our procedure, but we are changing that procedure to require that our investigators do ask what testing is being done and ask to have access to those records.

Ms. SCHAKOWSKY. Well, hopefully, Mr. Chairman, we are going to require that those tests get reported back to the FDA. I just want to say that it is really unbelievable that Mr. Parnell knew that the food that he produced was contaminated. It escaped any inspections by the State. Even though the testing laboratory found that there was a positive, nothing happened, and rather than be responsible, destroying these tainted products, he chose to test the same lot over again until he got the result that he wanted and then released the product to the public. We have a responsibility to change that. Thank you. Thanks for the extra time.

Mr. STUPAK. That concludes all the questions of the members in this round. I am sure we are going to go a second round but we do have two members of the full committee who are not members of the subcommittee but they are allowed to ask questions under

the rules of the subcommittee. So Mr. Barrow, I know you have been here all day. Would you like 5 minutes of questions?

Mr. BARROW. Yes, sir. Thank you, Mr. Chairman.

I am not as good a cross-examiner as my hero, Mr. Dingell here, and I am not as good as Mr. Braley over there so I am going to throw you guys a softball. I want to ask you a wide-open-ended question, but listen to the conditions of it because it might not seem that way, especially you, Dr. Sundlof. If you believe that the integrity of testing cannot be separated from the integrity of sampling, and the sampling and testing are both things that have to have integrity, if you want to preserve the existing regime of voluntary inspections and confidential reporting with the testing community but you feel it is necessary to mandate and superimpose on that a mandatory sampling and testing regime, if you want to make sure that the sampling and testing that is done isn't too rigorous that you put folks out of business but isn't too lax to miss stuff you need to know, in other words, if you want to do everything you reasonably can to make sure first that the manufacturer knows what the manufacturer needs to know when the manufacturer needs to know it and you want to make sure that the regulator knows what the manufacturer knows, whatever it is, when they know it, how do we go about doing that? Dr. Sundlof, you go first, please.

Dr. SUNDLOF. Thank you. One of the things that again we will be asking for more authority, and that is to issue preventive controls in plants. That is, they have to have a quality system in place that specifies where the critical control points are, where contaminants can be introduced——

Mr. BARROW. Is a sampling and testing regime going to be a part of that?

Dr. SUNDLOF. Absolutely.

Mr. BARROW. Is there going to be goals or is it going to be quotas? Is it going to be something we think folks out to look at or is it going to be something folks are going to be required to do? Are you going to have different protocols for different sectors of the food-processing industry?

Dr. SUNDLOF. Manufacturers will have to develop their own HACCP plan which is specific to their particular manufacturing facility.

Mr. BARROW. Are you going to require sampling be done by folks who have an independent stake in their work, folks who don't work for just one person or work within the community but who have a whole bunch of clients who actually stand to lose a lot if they don't do their sampling and their testing in a credible manner?

Dr. SUNDLOF. I mean, I can't speak about how the exact program would work but certainly there has to be these checks and balances in there that can be verified by the FDA.

Mr. BARROW. You will agree with me that folks can't be allowed to sample and test themselves?

Dr. SUNDLOF. I am not completely sure about that.

Mr. BARROW. When I was a boy, I learned at my daddy's knee that no person can be the judge of his own case. Don't you all know that?

Dr. SUNDLOF. There may be ways that we could ensure the integrity even if they sample their own product and test their own product.

Mr. BARROW. I am not saying folks can't be allowed to do that. I am saying we need to have a sampling and a testing regime in place in addition to the powers of mandatory recall that folks have talked about. We need to have a system in place where the manufacturer really doesn't have the option of knowing what they need to know when they need to know it and they don't get to be the only ones who decide to act on that information. The public regulator needs to know what they know and when they know it. Don't you think that is necessary, that that is a goal we need to reach for?

Dr. SUNDLOF. Yes, and that is what we are requesting.

Mr. BARROW. Well, that remains to be seen. Thank you.

Anybody else want to take a stab at any of that with a little time left? How about you, Mr. Deibel? I understand the point you are making but you realize the point I am making, don't you? I am not trying to drive people out of the business knowing more than they need to know but I want to make sure they know what they need to know and that we know what they know when we need to know it.

Mr. DEIBEL. I think there are a lot of opportunities in the subcommittee and in the discussions that we are going to be having to really build stronger bridges between government and industry and agree upon best practices that we can all use. I hope those best practices include preventative approaches rather than reactive approaches——

Mr. BARROW. Well, what I want to do is, I want to take you guys out of the situation of having to rat out a client, an existing regime where folks have the right to come to you and ask as a matter of entering into the contractual relationship with you that you will keep quiet but that puts you in an untenable position. That is unacceptable. I recognize your interests there. Nobody can go forward, no part of the existing system can go forward to start doing the right thing if everybody else is going to continue to be allowed to do the wrong thing. So I want to put in place something that doesn't let that happen.

Ms. Cowart, do you have anything to add to that?

Ms. COWART. No, sir, I agree with that in terms of what you are talking about. I think the broader picture of how that gets done is something that we would really like to be a part of helping with the solution.

Mr. BARROW. Well, get ready because I think you are going to have a chance to play a role in that.

Ms. COWART. Thank you.

Mr. BARROW. Thank you, Mr. Chairman.

Mr. STUPAK. Mr. Pallone for questions. You are the chairman of the Health Subcommittee with our legislation and FDA globalization bill that we are trying to get through for food and drug safety, so glad to have you here.

Mr. PALLONE. Thank you, Mr. Chairman. I wanted to be here for the whole hearing but I had a hearing on offshore drilling in my other committee, and that is important in my district so that is

why I couldn't come until now. But I did want to mention, you mentioned the comprehensive FDA bill that you and Mr. Dingell have introduced and I just wanted to say that I was pleased to see that we included some of the provisions in a food safety bill that I have been trying to push for a number of years that are now in that comprehensive bill, specifically preventative measures to ensure that food safety has been addressed.

I wanted to ask Mr. Sundlof a question. In the case you are examining today, many more companies than just PCA have been involved. In fact, over 50 companies use PCA's peanuts in their finished products, and what worries me about the situation is that first PCA did nothing to prevent their contamination, and as others have highlighted, knowingly put contaminated products on the market, but second, none of those other companies conducted adequate tests on their food items to detect and stop the tainted peanut products from making their way to consumers, and under current law there is no requirement that the companies who are actually putting food into the hands of consumers audit or check up on their supplies to ensure the ingredients they are getting from these suppliers are safe. Now, I believe that we need to give the FDA the authority to require food manufacturers to establish food safety plans and these plans would require food companies to evaluate what food safety risks exist, determine how best to address and protect against those risks and establish processes and procedures to control those risks. Finally, these food safety plans would require companies to maintain records documenting that they have complied with those plans and those of course would be available to the FDA. You mentioned all this in your testimony but I just wanted to make it clear, you do agree that the FDA should have this authority to require these manufacturers to establish food safety plans?

Dr. SUNDLOF. Yes, I do, and in fact, we do have two areas of food that do require these kinds of preventive control systems. One of them is seafood and the other one is juice. They have to produce them under a HACCP program.

Mr. PALLONE. Now, do you also agree that having these sorts of requirements in place would have gone a long way towards avoiding the kind of major catastrophe that occurred here?

Dr. SUNDLOF. It is unclear because the company, it is not clear they would have kept adequate records in this case because they did get positive samples and those chose or they shipped product anyway. If we had gone in and inspected their records and had gotten access to those records before this outbreak, certainly that would have been a warning to us and we potentially could have prevented this.

Mr. PALLONE. I mean, just in a general sense, would you agree that each company in the chain of manufacturing has an obligation to ensure that the ingredients they are using as well as their final products are safe for Americans to consume?

Dr. SUNDLOF. Yes, absolutely.

Mr. PALLONE. And then the second thing, Mr. Chairman, I wanted to ask was about the fines. Mr. Sundlof again, PCA knowingly put contaminated products on the market. They knew their ingredients were going to be used by many companies in their various

products. They knew the risks of this disease and yet they did nothing, but the most alarming thing to me is the lack of repercussions for the behavior. Under current law, the more severe penalty available for committing a single prohibited act with respect to foods is a misdemeanor, which carries a potential sentence of imprisonment of up to 1 year or a monetary fine. But the FDA to successfully prosecute these companies and impose a penalty has a lengthy investigation and has to coordinate with the Justice Department and it is highly intensive in terms of the resources of the FDA and Justice. I also question whether the threat of a misdemeanor conviction has any deterrent effect at all, especially in light of the situation. FDA now has the authority to levy civil monetary penalties for certain drug and medical device violations, an administrative authority that permits FDA to proceed without involving the Justice Department, and for certain drug violations FDA can impose a fine of up to $1 million for all violations adjudicated in a single proceeding but FDA does not have that authority with respect to foods with the exception of illegal pesticides. In your opinion, are civil monetary penalties less burdensome for the agency to impose than criminal penalties, and do you agree that having the ability to impose an administrative monetary fund would be a useful enforcement tool for the FDA?

Dr. SUNDLOF. Congressman, it is not something that I have had discussions with. Certainly it is something that we will be talking about in the wake of this salmonella outbreak but it is not something I have an opinion on at this point.

Mr. PALLONE. And you don't want to express an opinion at this point?

Dr. SUNDLOF. I don't.

Mr. PALLONE. All right. I wish you would, but I can't force you. Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Pallone.

Let us go for another round. I think we are going to have votes here soon but let us try to get a couple more questions in before we release this panel.

Mr. Garrison, when I take a look at the document binder, it seems between Exhibits 15 to 37 are Georgia's inspections of this place, and if I am correct—by "this place" I mean PCA. That is about 22 different inspections, and it looked like early on, 2004, 2005, 2006, you did not only inspections but also scale inspections. Is that correct?

Mr. GARRISON. Yes, sir, that is correct.

Mr. STUPAK. Then why the drop-off after 2006? I think you had one in 2007 and one in 2008?

Mr. GARRISON. On the scale inspections or on the food inspections?

Mr. STUPAK. Both.

Mr. GARRISON. The scale inspections were conducted under another section of my division. On the food inspections, it was basically due to attrition throughout the department.

Mr. STUPAK. And budget cutbacks you spoke of?

Mr. GARRISON. Budgetary issues and those type of things.

Mr. STUPAK. So you never did any inspection of this plant, the Blakely, Georgia, plant, for salmonella then even though that was sort of the goal to do it once a year, right?

Mr. GARRISON. No, sir. We would have done an inspection at least twice per year during this period of time.

Mr. STUPAK. But let me ask you this. Had you ever had any knowledge, anyone in your department or agency, that they were having trouble with salmonella at this plant in Blakely, Georgia?

Mr. GARRISON. No, sir, it was never reported to any of our inspectors or even through our consumer complaint logs.

Mr. STUPAK. OK. Your last inspection was October 23, 2008, and when you take a look at it, it has a little bit of history of past problems that they had in this place, especially water. Water is sort of a red flag in peanut butter that there could be contamination or salmonella. Isn't that so?

Mr. GARRISON. You want to eliminate moisture from the peanut process.

Mr. STUPAK. And that is even one of the reasons why you roast peanuts and heat them up is to get rid of the salmonella? It has to be more than 170 degrees, if I remember correctly, correct?

Mr. GARRISON. The temperature would really depend on the roaster speed and the temperature there. It is a combination of the two during the roasting procedure.

Mr. STUPAK. OK. On October 23, when you take a look at it, and I am looking at the FDA's report in January, they indicate even in October like they are missing dates as to the firm's temperature inadequate or just left off the reporting charts, and that was never noticed by your inspectors. Wouldn't they look for the temperatures for roasting peanuts if you are doing an inspection?

Mr. GARRISON. When our inspectors go in, they will look at the current temperatures are being observed at the time that they are inside.

Mr. STUPAK. They wouldn't look at past temperatures to see if they are being reported?

Mr. GARRISON. Those would be records that they would not have to supply us with.

Mr. STUPAK. I had asked Ms. Cowart, and it was Exhibit 38 there, when she did a walk-through when she was consulting with PCA and she found three reasons why there could be salmonella, number one, the Chinese product could have already been contaminated before it got there, but then after that it was in the production and packaging. If Ms. Cowart, if she just does a walk-through and notices these things in this plant, why wouldn't your inspectors notice them because they are looking for the same things, aren't they?

Mr. GARRISON. Ms. Cowart had knowledge that the facility had a problem with salmonella. That is something that the State didn't have and that is what we are pushing for is for these plants in Georgia if they have problems, they have to let us know. We have to have every tool available to us.

Mr. STUPAK. Sure, but as inspectors, salmonella, water, peanuts, bad combinations. I just think you would pick up on those things.

Mr. GARRISON. Exactly. You know, the inspections are a snapshot in time. What Ms. Cowart had seen during her inspections may not have necessarily been there when our inspectors went through.

Mr. STUPAK. Well, that is why you look at the temperature records and things like that, correct?

Mr. GARRISON. When they have to supply them to us. That is why we go back to the HACCP requirements that Dr. Sundlof spoke about with the juice HACCP and the seafood HACCP. They are required to maintain those records, to sign off on those records——

Mr. STUPAK. But there is no way you can get those records unless they voluntarily give them to you, right?

Mr. GARRISON. In these type facilities, that is correct.

Mr. STUPAK. Dr. Sundlof, I have been asking this question for 2 years and the answer has always been no. Go back to 2007, Peter Pan, you mentioned in your testimony here today, did you ever get those records for Peter Pan from ConAgra?

Dr. SUNDLOF. I don't know the answer to that. I will ask Mike Chappell if he knows.

Mr. STUPAK. So 2 years and you don't have the records from 2007 and yet you continue to say you don't need subpoena power. Don't you think you subpoena power?

Dr. SUNDLOF. Again, I don't know whether or not we do have the records, sir.

Mr. STUPAK. I have just been handed a report. Ohio officials now have linked a woman's death to nationwide salmonella outbreak, so I guess we are now up to nine deaths and growing.

Let me ask you this, Dr. Sundlof. Go to tab 11 there, which is FDA's amended 483 report from January inspection. I would like to know about each of these violations. Should they be caught in a Good Manufacturing Practices inspection, and if you could do a yes or no, like observation number three on page five, this is about the temperature being not recorded. I mentioned in October six times it wasn't recorded, November 2008, 24 days you never recorded the temperature, in December and January, nothing was recorded. Should that have been caught by inspection, a GMP inspection?

Dr. SUNDLOF. Yes.

Mr. STUPAK. All right. How about the pallets being three feet, observation number four, three feet from the finished product, and water stains running down in the cooling unit fans in the cooler. Should that have been observed by GMP inspection?

Dr. SUNDLOF. I am going to have to ask Mike Chappell.

Mr. STUPAK. Mr. Chappell, should that have been caught, water stains, with the GMP?

Mr. CHAPPELL. Certainly one of the things that we do during inspection is look for environmental situations and a water stain is indication of a previously——

Mr. STUPAK. In observation number five, plant is not constructed in such a manner to allow ceilings to be kept in good repair. Should that have been caught in a GMP inspection?

Mr. CHAPPELL. One of the things that we look for to see the general condition of the building, and there are certain things that we

look for, and if the building is properly constructed, it is easy to repair those, and if not, it is not.

Mr. STUPAK. So that is yes then, they should have caught that in the GMP?

Mr. CHAPPELL. Yes.

Mr. STUPAK. OK. How about observation number six, design of equipment and utensils failed to preclude adulterated food with contaminants, specifically felt material is present on the final roller at the discharge. This material cannot be adequately cleaned or sanitized. Should that have been caught in a GMP inspection?

Mr. CHAPPELL. If indeed that particular equipment was in place and in use at that time, that would be an——

Mr. STUPAK. That would be a yes then. OK. How about number seven, proper precautions to protect food and food contact surfaces from contamination with microorganisms cannot be taken because of deficiency in plant construction and design. So that would be there all the time. So that should have been caught by GMP, would it not?

Mr. CHAPPELL. I think plant design is certainly one of the things that we would look at, especially at it relates to product flow and segregation.

Mr. STUPAK. So that is a yes. How about number eight, specifically the sink located in the peanut butter room is used interchangeably as a point for cleaning hands and utensil tools and for washing out mops. That is not Good Manufacturing Practice, is it?

Mr. CHAPPELL. It is not, but again, though, if indeed the investigator was there at a time it was not being used for both things, they might not necessarily have pointed that out.

Mr. STUPAK. Right, but a sink shouldn't be in the final product area anyway, should it? Because that is water again, isn't it?

Mr. CHAPPELL. Yes.

Mr. STUPAK. OK. How about number 10, besides the dead and live roaches, let me ask you this. The bumper pads were inadequate, openings of six inches or more were observed along sides and tops of trailers. These trailers contained raw and roasted products, can be left backed up for 7 to 5 days leaving openings in the plant. Is that GMP? Is that Good Manufacturing Practice?

Mr. CHAPPELL. That should have been observed, yes.

Mr. STUPAK. These violations I have just listed here, all six or seven of them, all should have been caught in a normal GMP inspection. Then why weren't they in the prior inspections?

Mr. CHAPPELL. The prior inspection the FDA conducted was 2001, so I think it depends on the conditions at the time——

Mr. STUPAK. Well, there was a GMP inspection, there was an inspection for cause on the metal shavings, but some of these are just structural. You can see water stains, things like that. That should have been caught, should it not?

Mr. CHAPPELL. It certainly should be observed during the inspection.

Mr. STUPAK. All right. I guess my time is up. Mr. Deal?

Mr. DEAL. Thank you. First of all, let me clarify some things that I think may have been confused here. First of all, peanuts are not an inherently dangerous product. In fact, they are inherently safe. Some of us still eat them raw. Isn't that correct?

Dr. SUNDLOF. Peanuts, because they lack water, do not support the growth of bacteria. What we have seen in the ConAgra case and in the recent case with PCA is that once salmonella is introduced into these peanut products, it doesn't die, it just stays there, and then when it becomes ingested, then the bacteria is able to reproduce and cause disease.

Mr. DEAL. But that is further in the process. Inherently they are a safe product unless you get the occasion for something like the Chinese organic and there you are talking about something in the organic area where the fertilizer, it contains salmonella in many instances and that is not the traditional method and not the traditional peanut product that comes to these plants. Am I correct?

Dr. SUNDLOF. Just let say, you know, peanuts are grown in the dirt and in the dirt there are lots and lots of bacteria and salmonella can certainly be one of those. Generally the peanut processors require a roasting step——

Mr. DEAL. And that is the kill cycle?

Dr. SUNDLOF. That is the kill cycle.

Mr. DEAL. So whatever might have been there, even though they are not inherently dangerous, a proper kill cycle would supposedly eliminate that?

Dr. SUNDLOF. That is correct.

Mr. DEAL. And that is why the temperatures of the roasters, etc., are critical pieces of information?

Dr. SUNDLOF. Yes.

Mr. DEAL. All right. Once you get through the kill cycle, then it should not have salmonella in the peanut?

Dr. SUNDLOF. Right, and that is when the Good Manufacturing Practices have to make sure that salmonella is not reintroduced after the roasting process?

Mr. DEAL. And that is the reason you can get inconsistent samples one day versus the next day. Presumably if you get a bad sample and a bad report that the lab reports back to the manufacturer, their presumption, and I think anybody's commonsense presumption is that they not only would destroy the product that is bad but also that they would take the corrective action in cleaning up the facility, doing the other good management practices that would have caused the bad sample to occur. Am I not correct, Dr. Cowart?

Ms. COWART. Yes, sir. That insurance, yes, sir.

Mr. DEAL. So it is not then inconceivable or totally within reason that you might get a bad sample, somebody gets the results, they clean it up, they don't get a bad sample the next time somebody comes by or the next time an inspection takes place. But I think the thing we all are focusing on is the kinds of things that will be able to prevent the bad actors from coming along. We have a bad actor here. He did not respond in a way that would be a normal response that everybody had reasons to expect they would respond. So I guess the thing we are trying to do is to come up with ways and methods whereby we can try to prevent the bad actor from being able to slip through the holes, and that would be including maybe reporting of internal testing to outside agencies such as the State department of agriculture or perhaps even the FDA, the mandatory keeping of internal records that would be required to be disclosed to the inspectors when they come by so that they would

know whether or not there had been periods where the kill cycle was not operating properly or they would know if they had gotten a bad test result back. I think those are the objectives that all of us have in mind. Is that not the general format, Dr. Sundlof, that we should be approaching this from?

Dr. SUNDLOF. Certainly I think we need to have systems in place that are, number one, preventive, and number two, alert us early on when there is a problem.

Mr. DEAL. And I think we all agree with that, and the question is, how do we achieve that goal, and since we are in the middle of a vote, I am going to conclude, but let me conclude by having thanks to all of you for your participation here. You have enlightened us and we do appreciate your attendance at this hearing.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you.

Mr. Braley, any questions?

Mr. BRALEY. Yes, thank you.

Dr. Cowart, I would like to ask you about a document known as a certificate of analysis. As succinctly as possible, tell us what a certificate of analysis is.

Ms. COWART. A certificate of analysis for our laboratory is the final results that we have obtained through our testing program that is issued to the client for the sample they submitted.

Mr. BRALEY. And what does a company do with a certificate of analysis?

Ms. COWART. With a certificate of analysis, they would look at their sample description and understand where that came from, and based on the results they need to take action, depending on the positive or negative results they get.

Mr. BRALEY. And let me just show you why what we are talking about is so important. This is a list of the 1,900 product recalls at the FDA as of February 10, 2009. So when you issue a certificate of analysis, you are issuing a certification from your company to be relied upon, which has legal consequences. Isn't that correct?

Ms. COWART. I think for the company, it is their responsibility to do with it what they need to do so it is our result on the sample, yes, sir.

Mr. BRALEY. And you have a contractual obligation to make a good-faith effort to perform that test to the best of your abilities because you know they are relying on your analysis for their business purposes and their regulatory compliance?

Ms. COWART. When we issued our certificate of analysis, yes, sir, we believe they are relying on us to do that.

Mr. BRALEY. So I would like you to take a look at a certificate generated by your company, JLA, which is at tab 51, page 1, and we have got it up on the monitor so you can follow along. In this certificate of analysis, your company confirmed the product from Peanut Corporation of America tested positive for salmonella, and you can see the lot number is 8168–ABCD and it is dated June 23, 2008. Is that correct?

Ms. COWART. Yes, sir.

Mr. BRALEY. Mr. Deibel, let me show you another certificate of analysis on the same tab, 51, page 3. This is your private lab's

analysis of the same lot number on the same date but your result shows that salmonella is negative. Is that correct?

Mr. DEIBEL. That is correct.

Mr. BRALEY. So just to understand, PCA sent two samples from the same lot to two private labs, JLA found salmonella and Deibel did not, so let us see what PCA did. PCA generated its own certificate of analysis. This is in the same tab, 51, on page 2, and PCA's report shows that its product tested negative for salmonella. This is a certificate of analysis that PCA prepared for its customers, correct? You will have to answer affirmatively.

Mr. DEIBEL. Based on what we are looking at, yes.

Mr. BRALEY. Dr. Sundlof, what is FDA's position on this? Isn't it true, Doctor, that is illegal for a company to report on a certificate of analysis a negative salmonella report when it knows that there is another lab test that shows a positive result?

Dr. SUNDLOF. I cannot speak to the legality of that. That certificate of analysis is between the laboratory and the company. Certainly, you know, if we find that they did introduce contaminated food into the marketplace, then they are in violation of the Food, Drug and Cosmetic Act.

Mr. BRALEY. Well, are you saying that you don't know or that it doesn't apply in this context whether that would be illegal for a company to do?

Dr. SUNDLOF. I think that is part of the criminal investigation and I can't expand on that.

Mr. BRALEY. Well, based on everything we have heard today, wouldn't you agree that if that is not in an illegal practice, it certainly should be?

Dr. SUNDLOF. Certainly if they were supplying false information to the FDA, that would certainly be an illegal practice.

Mr. BRALEY. Well, and we have heard testimony here that if any lot result tests positive, that takes precedent over any comparative negative test result, correct?

Dr. SUNDLOF. That is not written anywhere in the law or the regulations but it is common knowledge within the industry that you can't test your way to negative.

Mr. BRALEY. So if it is common knowledge within the industry, isn't it true that it would make sense to have that also be applicable in the statute and the regs?

Dr. SUNDLOF. We would be happy to work with that.

Mr. BRALEY. And can you tell us how can this practice be allowed, because it is not just egregious, it is really fraudulent to the American people, isn't it, the American consumers who purchase these products?

Dr. SUNDLOF. If they are purchasing food that is purported to be something that it is not, absolutely.

Mr. BRALEY. Thank you.

Mr. STUPAK. Mr. Walden has a question.

Mr. WALDEN. Well, Mr. Chairman, I know we have to get to the floor for a vote. I do have a couple of questions I would like to be able to submit in written form to the panel for your written response. Unfortunately, we have run out of time, but I would concur with my colleagues and thank you for your participation today. It has been helpful in our efforts, and obviously we have got some

changes to make in the Federal Government to protect the food supply for all Americans, and we are going to do that, so thank you. Thank you, Mr. Chairman.

Mr. STUPAK. And that concludes all questioning. I know there are many other questions members have. I want to thank all of our witnesses for coming today and for your testimony.

The committee rules provide that members have 10 days to submit additional questions for the record. I ask unanimous consent that the contents of our document binder be entered in to the record provided that the committee staff may redact any information as business proprietary, relates to privacy concerns or is a law enforcement-sensitive matter. Without objection, documents will be entered in the record.

That concludes our hearing. This meeting of the subcommittee is adjourned. Thank you all again.

[Whereupon, at 2:17 p.m., the subcommittee was adjourned.]