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RPTS KESTERSON

DCMN HOFSTAD

THE OUTBREAK OF SALMONELLA IN EGGS

WEDNESDAY, SEPTEMBER 22, 2010

House of Representatives,
Subcommittee on Oversight
and Investigations,
Committee on Energy and Commerce,
Washington, D.C.

The subcommittee met, pursuant to call, at 12:06 p.m., in Room 2123, Rayburn House Office Building, Hon. Bart Stupak [chairman of the subcommittee] presiding.

Present: Representatives Stupak, Braley, Markey, DeGette, Doyle, Christensen, Dingell, Waxman (ex officio), Burgess, and Latta.

Staff Present: Phil Barnett, Staff Director; Bruce Wolpe, Senior Advisor; Rachel Sher, Counsel; Eric Flamm, FDA Detailee; Dave Leviss, Chief Oversight Counsel; Meredith Fuchs, Chief Investigative Counsel; Stacia Cardille, Counsel; Erika Smith,

Professional Staff Member; Scott Schloegel, Investigator; Ali Neubauer, Special Assistant; Karen Lightfoot, Communications Director, Senior Policy Advisor; Elizabeth Letter, Special Assistant; Lindsay Vidal, Special Assistant; Mitchell Smiley, Special Assistant; Krista Rosenthal, Minority Counsel, Oversight; and Alan Slobodin, Minority Chief Counsel, Oversight.

Mr. Stupak. This meeting will come to order.

Today we have a hearing entitled, "The Outbreak of Salmonella in Eggs."

The chairman, ranking member, and chairman emeritus will be recognized for a 5-minute opening statement. Other members of the subcommittee will be recognized for a 3-minute opening statement. I will begin.

Before we begin, I am going to ask unanimous consent that the contents of our document binder be entered into the record, provided that the committee staff may redact any information that is business proprietary, relates to privacy concerns, or is law enforcement-sensitive. Without objection, the documents will be entered into the record.

[The information follows:]

***** COMMITTEE INSERT *****

Mr. Stupak. Today's hearing, entitled "The Outbreak of Salmonella in Eggs," will mark the thirteenth hearing of the Oversight and Investigations Subcommittee since January 2007 regarding food-safety issues. We have examined Salmonella outbreak associated with peanut butter products manufactured by the Peanut Corporation of America, which resulted in criminal investigation. Additionally, we have investigated an E. coli outbreak traced to tainted spinach, the melamine-contaminated pet food, and other food-safety inquiries.

Today we will continue our examination into the food-safety problems that continue to plague farms, producers, and American consumers. This time around, we are dealing with two companies producing eggs in the State of Iowa and sold nationwide. One thousand six hundred eight people were infected with Salmonella Enteritidis from the eggs between May 1st and September 14th.

What we learned about the two egg operations in Iowa that produced the tainted eggs paints a very disturbing picture of egg production in America. When FDA inspectors entered the plants in August, they found facilities riddled with unsanitary and unsafe conditions.

According to the inspectors' preliminary reports, employees working within the hen laying houses did not wear or change protective clothing when moving from house to house. Live rodents were located in the laying houses, as the picture up here shows.

And you can see the eggs just to the left of the circle there. We have liquid manure oozing out of buildings. And there is another photograph there that shows it actually coming out of a doorway. We have dead and decaying chickens found at the sites; live and dead flies too numerous to count.

Most importantly, positive test results for Salmonella were found in both farms, including in the feed mill and in the water used to wash the eggs. Even more alarming, during the course of its investigation, the committee has obtained records that showed that Wright County Egg tested positive for Salmonella contamination in its Iowa facilities prior to the widespread outbreak of the illness. Environmental sample reports taken in and around the chicken cages between 2008 and 2010 indicate that Wright County Egg received 426 positive results for Salmonella, including 73 that were potentially positive for Salmonella Enteritidis, the same strain that sickened 1,600 people.

Perhaps these findings should not be a surprise given the record of the DeCoster Farm operation that owns the Wright County Egg facilities. In fact, DeCoster Farm had so many environmental and safety violations that the State of Iowa declared them habitual violators and assessed a total of \$219,000 in civil fines. DeCoster Farm is the only entity to receive the habitual-violator status from the State of Iowa.

The work of this subcommittee, coupled with the work of the Health Subcommittee and the full committee, on food safety

culminated in the bipartisan introduction of H.R. 2749, the Food Safety Enhancement Act. This legislation passed the committee by unanimous consent in the U.S. House of Representatives on July 30, 2009. The food-safety legislation has been stalled in the Senate for more than a year.

The provisions contained in our food-safety legislation would address several concerns raised by this outbreak. For example, the bill would require new trace-back regulations that enable the Secretary to identify the history of the food as quickly as possible but no later than 2 business days.

The food-safety legislation would give the FDA the needed authority to issue mandatory recalls and subpoena records of tainted food products. While in this case the two Iowa farms did issue voluntary recalls, the FDA should not have to rely on the company's goodwill when the public health is at risk.

The legislation will also give the FDA a guaranteed consistent source of funding through the registration fees. These fees will allow the FDA to conduct more inspections, to be proactive, to prevent outbreaks from occurring.

We will hear testimony from witnesses with different perspectives on the recall: victims of this outbreak, the manufacturers of the recalled eggs, and a representative from the FDA.

On our first panel, we have two victims that were affected by the Salmonella Enteritidis: Sarah Lewis and Carol Lobato.

Sarah is a 30-year-old mother of two, who contracted Salmonella from eating a tart at her sister's college graduation banquet. Sarah has been admitted twice to the hospital to be treated for Salmonella and is just now beginning to feel better. Sarah works at her parents' butcher shop, which they have owned since the 1970s. Sarah is very familiar with local and State regulations, as they are subject to constant inspections.

Carol is a 77-year-old mother of four and grandmother of four. When Carol and her husband took her grandson out to dinner in Colorado, she contracted Salmonella. Carol is very familiar with egg farms, as she was raised in Iowa on a chicken farm. Carol spent 5 days in the hospital, suffering from toxic shock, severe diarrhea, and vomiting.

Our second panel will include Austin DeCoster, owner of Wright County Egg; his son, Peter DeCoster, chief operating officer; Orland Bethel, president of Hillandale Farms of Iowa; and Duane Mangskau, production manager, Hillandale Farms of Iowa.

It is my sincere hope that these gentlemen will be forthcoming regarding the events of the outbreak and what they are doing to ensure eggs produced on their farms are safe for the American people.

On our third and final panel, we will have Dr. Josh Sharfstein, deputy commissioner from the Food and Drug Administration.

I look forward to hearing from our witnesses today about the

progress that has been made since the outbreak occurred and how we can strengthen our food-safety system.

Our committee began pushing for reform of the food-safety system more than 3 years ago. Our hearings have demonstrated the weaknesses in our food-safety systems that will remain until we enact an effective food-safety bill into law. Make no mistake about it: Without legislative action, it is not a matter of if, but when, more lives will be put at risk by another outbreak, as evidenced by today's hearing. This outbreak affected more than 1,600 individuals, 2 of which are here to tell their story today. Fortunately, no one has died.

In each of our 13 food-safety hearings, we are reminded that each year approximately 76 million Americans become sick from food-borne disease such as Salmonella, 325,000 are hospitalized, and 5,000 deaths will occur in the United States. It is time to give our regulators the tools they need to be proactive in the fight against food-borne illnesses and disease.

[The prepared statement of Mr. Stupak follows:]

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Mr. Stupak. I yield back the balance of my time. I next turn to the ranking member of the subcommittee, Mr. Burgess of Texas, for an opening statement.

Mr. Burgess?

Dr. Burgess. Thank you, Mr. Chairman.

I want to thank you and our witnesses who are here with us today for participating in this very important hearing. Because, once again, as you have already articulated, we find ourselves in the middle of a food-borne illness outbreak, this time involving the safety of a food item that we frequently buy, eat, and serve to our families.

Just this morning, I viewed pictures taken by the Food and Drug Administration at both companies' egg production facilities during the FDA inspections. These photos document some extremely unsanitary and unsightly conditions, including piles of chicken manure that was pushed up against an open doorway and leaking outside a laying house, dead flies by the thousands, rodent holes, structural damage to buildings, and chicken carcasses.

Now, these companies must be able to account for and respond to these photos. And I am also anxious to ask the Food and Drug Administration if the public can take comfort in the fact that these observations are not normal. I wonder if the FDA will be able to answer this question, considering that they have not inspected any other egg production facilities besides these two in

quite some time.

To date, the Centers for Disease Control has reported that over 1,500 illnesses are likely to be associated with Salmonella in eggs. I want to thank our first panel of witness, both victims of this outbreak, for appearing today to share your stories.

The outbreak of Salmonella in eggs is unique in that the Salmonella contamination is not from the shell but from the interior of the egg. Test results indicate that the laying hens themselves were infected with Salmonella and the hens passed the contamination through the inside of the eggs.

One very important fact about the investigation, perhaps an indication that this hearing is held before we have all the facts, is that the ultimate source of the Salmonella contamination is not yet certain. Concerns about the feed given to the young chickens and the unsanitary conditions of the suspect farms have been raised. I hope that the testimony provided today will move us closer to understanding the original source of the contamination and how to prevent it from ever happening again.

By early August, the trace-back investigations completed by the CDC, the FDA, and the State partners indicated a common source of contamination from a single farm owned by the DeCoster family. On August 13, Wright County Egg issued a voluntary recall of approximately 380 million. And on August 19, Hillandale, owned by Mr. Orlando Bethel, issued a voluntary recall of eggs after being suspected as a potential source of contamination.

Responsible corporate actors are crucial in maintaining a safe and reliable food industry. Companies must observe good manufacturing agricultural practices. The documents and subsequent photographs obtained by this committee raise serious questions about whether both of these companies were consistently maintaining such good practices.

Of particular interest are the documents that show the test results done on behalf of DeCoster Farms in 2008 through 2010. The occurrence of Salmonella positive environmental samples is frequent: 72 of environmental sponges were tested for Salmonella, and only 8 were negative.

Experts who have spoken to staff have indicated that environmental samples that turn up positive for Salmonella may be expected on a farm and do not necessarily indicate that the food and product is contaminated, but I want to know if these findings warrant cause for alarm and become troublesome if positive results become a pattern and are not rectified.

I want to ask the DeCosters about these tests and what the company gleaned from this information, and I am also interested in what the FDA has to say about this, as well.

Other documents obtained by the committee include numerous sanitation reports completed by the Department of Agriculture and marketing services, some of the hazard plans, unsatisfactory conditions -- unsatisfactory sanitary conditions, and an array of observations of Wright County Egg over a 4-year period of time. I

would like Mr. DeCoster to comment and explain these records.

Although the Food and Drug Administration has told my staff that eggs have historically been considered a high-risk food product, the FDA did not inspect these egg facilities prior to the outbreak. During the inspections discussed in the FDA Form 483, the investigators noted that each company failed to fully implement and follow procedures in their Salmonella-prevention plans, and now we have the pictures to document that failing.

Tests conducted in August by FDA investigators at Wright County Egg were positive for the same and other strains of Salmonella. These samples were taken from manure pits, walkways, chicken feeds, and other surfaces. I want an up-to-date report from the companies and the FDA explaining where the exact matches of Salmonella to the outbreak strain that caused human illnesses were found and how the companies and the Food and Drug Administration interpret these results.

It is important for the FDA, as well as the industry, to work cooperatively internally with other Federal agencies and with health and agricultural departments to reduce the number of and help prevent food-borne illness. A new egg rule became effective this July that addresses several of these concerns associated with eggs involved in this outbreak. However, it took the Food and Drug Administration over 10 years to act on this issue, illustrating the continued systemic, problematic, and bureaucratic weaknesses that plague the Food and Drug Administration. The

future FDA should not be a reactive body; it should be proactive.

Mr. Chairman, I support conducting this investigation and holding a hearing. I am concerned that we are not always done in a most bipartisan and useful manner. September 9, I sent a letter to you stating that I thought the CEO of the FDA, the commissioner of the FDA, Dr. Margaret Hamburg, should be here to offer the agency's official testimony. She and the Obama administration have repeatedly stated publicly that food safety and the resources of the FDA is a top priority and must be taken seriously, quickly addressed. In the 110th Congress, Commissioner Andrew von Eschenbach was here four times and testified on food safety.

The majority declined to invite a representative from the United States Department of Agriculture to testify, even though the committee sent a document request to the agency, held a briefing, and received thousands of pages of relevant information concerning their role in the regulation of these farms and this outbreak.

Staff has obtained and reviewed relevant revealing USDA documents, including USDA shell egg plant system audit reports, preoperative sanitation reports. And the USDA inspector notes an observation from Wright County Egg. This hearing would be more productive if a USDA official were here to answer questions related to these documents and perhaps answer the number-one question: Why didn't you say anything to the Food and Drug Administration?

The ultimate goals of this hearing are good, and I support the food-safety legislation this House has passed in 2009. I am eager for the Senate to move on this important issue.

Mr. Chairman, I thank you for your forbearance, and I will yield back the balance of my time.

[The prepared statement of Dr. Burgess follows:]

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Mr. Stupak. The gentleman's time has expired.

Mr. Waxman, chairman of the full committee, for an opening statement, please.

The Chairman. Thank you very much, Chairman Stupak, for calling this hearing.

And before I address the concerns of this hearing specifically, I want to thank you for a record of 4 years of diligence in pursuing issues of food safety. Your work stands out as a model of congressional oversight and investigation, and you have illustrated very clearly the need for stronger food-safety laws. You have had 13 hearings in the last 4 years. You educated the members of this committee and the American people about glaring deficiencies at all levels of our food-safety network.

Today we are going to examine two of the Nation's largest egg producers, Wright County Egg and Hillandale Farms of Iowa. They have been asked to appear today because of evidence that they produced eggs in filthy conditions that caused food poisoning in thousands of consumers across the country.

The DeCoster family, which owns Wright County Egg and raised eggs for Hillandale Farms in Iowa, has known about safety problems at these facilities for decades, yet they continue to persist. Over 30 years ago, eggs from a farm operated by the DeCoster family killed 9 people and sickened 500 in New York. Twenty years ago, Maryland ordered the DeCosters to stop selling eggs in the

State because of the contamination problem.

As the committee revealed last week, environmental testing at DeCoster facilities over the last 3 years tested positive dozens of times for potential contamination by a dangerous form of Salmonella. Yet, despite these warnings, the DeCoster facilities were operated with a shocking level of disregard for basic food-safety controls.

Food-safety inspectors from FDA finally went inside the facilities in August. And as a photograph I would like to have displayed shows, they saw decaying corpses of rodents. They also saw unsealed rodent holes along the walls of a henhouse. Conditions were so bad in one facility that the wall of the barn was bursting open because of the excessive manure.

DeCoster farms have had warning after warning, yet they continue to raise chickens in slovenly conditions and to make millions of dollars by selling contaminated eggs. The risks are real.

Our first two witnesses today are Ms. Sarah Lewis and Ms. Carol Lobato. Ms. Lewis ate contaminated eggs while celebrating her sister's college graduation. Ms. Lobato was sickened when she went out to dinner with her grandson. They were both hospitalized and gravely ill. And I commend both of them for their courage in speaking out today and being with us at this hearing.

Unfortunately, their horrific experiences were shared by many others. The eggs that are the subject of today's hearing sickened

over 1,600 people in 11 States.

This hearing will make abundantly clear that our food-safety laws need a thorough overhaul. Under the leadership of our chairman emeritus, John Dingell, the committee and the House passed a bipartisan bill last year that would protect consumers from these abuses. The House bill would require farms to report to FDA when they find their unsafe food has entered the food supply. It would give the FDA the clear authority to access records on egg farms during investigations. It would empower the FDA to mandate recalls when firms do not comply voluntarily. These are the kinds of tools that will ensure the safety of the food we consume.

Yet, as we hold this hearing today, one Senator, a lone Senator, Tom Coburn, is holding this vital safety legislation hostage in the Senate. His actions are preventing the FDA from strengthening its oversight and enforcement programs. In fact, they are preventing the Senate of the United States from debating the issue, offering amendments, and making decisions about the legislation.

And I have a plea for Senator Coburn: For the sake of Ms. Lewis, Ms. Lobato, and hundreds of thousands of Americans who are poisoned by Salmonella every year, please lift your hold and allow this vital safety legislation to move forward.

We are going to have some tough questions today for Jack DeCoster, the CEO of Wright County Egg, and Orland Bethel, the CEO

of Hillandale Farms. But I do want to thank them for appearing here voluntarily and for cooperating with our committee's investigation.

I also want to thank FDA Deputy Commissioner Dr. Joshua Sharfstein for testifying before us today.

Our goal is to make American families safer. That is why this hearing is so important and why we must reform our food-safety system so that we can eradicate or at least reduce food-borne illnesses.

Imagine: The FDA cannot get information from these farms. They don't have the ability to subpoena. They have to be given to them voluntarily. They can't issue a warrant. They have to try to issue a warrant to get information. There is no obligation by these farms to report to the FDA, even when they know there is a food-safety problem.

This is unthinkable. That is why the House unanimously -- this committee unanimously approved the bill and the House overwhelmingly adopted it. And now we want the Senate to act. Let's don't go home from Congress without passing food-safety legislation.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Waxman follows:]

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Mr. Stupak. Thank you, Mr. Waxman.

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

Mr. Latta. Thank you, Mr. Chairman, Ranking Member Burgess. Thank you for holding this subcommittee hearing on the outbreak of the Salmonella in eggs, as the incidence of contaminated food products are a serious concern for our public health.

I am very glad that the two witnesses on our first panel who were affected by these eggs are here today and are on the road to recovery and able to be with us.

This hearing is also of grave concern to me because egg production is critical to my State, Ohio, which is the second-largest egg-producing State in the Nation. I know many of you have heard me in the past say that I represent the largest manufacturing district in Ohio, but at same time I also represent the largest agricultural district in the State of Ohio. And in those numbers, I also am home to one of two of the top egg-producing counties in the Nation. When you look at 465.5 million eggs being produced in my district, that has an economic impact of \$102.4 million. Ohio is also 1 of the 10 States with an egg quality assurance program, with the aim to minimize Salmonella in eggs.

First of all, I think it is important that we remember that the purpose of this hearing is to get the facts. While we have the FDA Form 483 with its general observations about the

conditions at the Wright County Egg and the Hillandale Farms operations in Iowa that are being investigated, we do not have the establishment inspection report, which will provide more clear answers.

Furthermore, I am disappointed that the FDA commissioner is not here to testify, nor is a representative from the USDA. We need to get these answers and hear what went wrong from these producers so that the industry can learn from this recall. We do not want the public to lose confidence in our egg producers.

Several of the egg producers in my district are fourth-generation farmers and have been committed to producing a safe, healthy product for years. If we have overburdening regulations that are placed out there, many of these farmers may be forced out of business, unfortunately preventing a fifth generation from being able to farm.

The safety and security of our Nation's food supply is of the utmost importance to me. Mr. Chairman, I want to thank you very much for the opportunity. And I look forward to hearing the testimony from our witnesses on the panel today.

And, Mr. Chairman, if I may, I would also like to submit for the record from the Ohio Poultry Association a document on egg facts in Ohio.

Mr. Stupak. Without objection, that will be made part of your opening statement and we will receive the document.

Mr. Latta. Thank you. And I yield back.

[The prepared statement of Mr. Latta follows:]

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Mr. Stupak. Thank you.

Mr. Braley from Iowa for an opening statement, please.

Mr. Braley. Thank you, Mr. Chairman.

Some of my earliest memories are walking into my grandparents' henhouses in Iowa to gather eggs. There was something almost spiritual about this daily routine act. Growing up in Iowa, you couldn't avoid commercials promoting "the incredible, edible egg." Eggs were a staple in our diet. We ate them fried, poached, hardboiled, softboiled, overeasy, overhard, sunny side up, scrambled, in omelets. And that was just for breakfast. We truly believed that eggs were nature's most nearly perfect food.

Growing up in Iowa, I don't remember my mother buying eggs in a supermarket. We drove out to the country and we bought them right off the farm from the mothers of the kids we went to school with. We dyed them at Easter, and we threw them on Halloween, and we never, ever imagined that they could cause life-threatening illness and kill us.

That is why the recent revelations of an incomprehensible half-billion egg recall originating in my home State was so disturbing.

So why are we here? First and foremost, we need to examine how and why this happened to ensure the safety of American families and prevent this type of tragedy from happening in the

future.

Second, we need to identify and eliminate weaknesses in our State and Federal food-safety enforcement system and take strong measures to hold wrongdoers accountable and protect the good reputations of producers who consistently play by the rules and supply safe food that is at a high quality and a reasonable price.

The economic impact of egg producers in Iowa is indisputable. Iowa is America's number-one egg producer by a country mile. Yet, economic impact is no trump card when lives are at stake. Like many Americans, I am disturbed by the increasing number of food-borne illnesses in the United States. These incidents all raise important questions about the safety and security of our Nation's food supply.

As an Iowan, I am offended that some in the egg industry are suggesting that consumers are somehow responsible for getting sick because they didn't properly cook their eggs. Now is the time for accountability, not blame shifting.

As an Iowan, I was disgusted to read reports about Federal investigators finding live mice, infestations of flies, mountains of manure, and other unsanitary conditions in Iowa henhouses linked to the largest Salmonella outbreak of its kind in the United States.

It is clear that changes need to be made to our food system to provide assurances to parents that the food they feed to their families is safe. The House passed food-safety legislation last

year. You have heard about it. It would give the FDA authority to order mandatory food recalls, impose fines for food-safety violations, and require more frequent food facility inspections. It would also give the FDA access to company records in the case of an emergency. These are important first steps to make sure our food supply is safe.

We need to be doing a much better job of protecting American families from unsafe food. Every 4 years, Mr. Chairman, people come to my State for the presidential caucuses and see our magnificent gold-domed capitol. Yet few people take the time to go inside and look up at the rotunda, where our ancestors put the wisdom of the ages. My favorite saying in that rotunda is from the Greek lawmaker Solon, who said, "The ideal state: that in which an injury done to the least of its citizens is an injury done to all."

Until we get serious about uniform Federal food-safety practices in this country, we are far from becoming that ideal state. And until consumers feel as safe and secure buying eggs in their neighborhood supermarket as I felt in my grandparents' henhouse, egg producers in Iowa and across the country have their work cut out for them.

I yield back.

[The prepared statement of Mr. Braley follows:]

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Mr. Stupak. Thank you for your opening statement. But do you want on the record you threw eggs at Halloween?

Ms. DeGette, opening statement, please.

Ms. DeGette. Thank you very much, Mr. Chairman.

I want to add to the chairman's thanks to you for all of these hearings over the last number of years, the 13 hearings. I think I have been sitting with you, Mr. Chairman, for every single one of those hearings, everything from spinach to peanut butter, to jalapeno peppers, to meat, to nuts. Pretty much the American diet has been under scrutiny in the last few years.

And I just have one question. And the question that I have is, when is the Senate going to pass the very fine food-safety bill that this House passed over a year ago? I don't think it is any excuse that one Senator can hold up the bill. But if that is the excuse, then I would add to Chairman Waxman's demand that Senator Coburn release his hold on this bill.

But, beyond that, I think the Senate should stay in session until they pass this bill. The reason is, if we don't, we are going to be sitting here every 6 months, just like we have been for the last 4 years. And the problem with that, it is not just about us passing the legislation; it is about people like the witnesses who are sitting here today, Ms. Lewis and Ms. Lobato.

And, you know, I want to welcome all of you and say how glad I am that you are putting a human face on this again. I

particularly have to welcome the Lobatos because they have been family friends of my family, Mr. Chairman, for many, many years. We won't say how long, because then we will have to reveal our ages. But thank you for coming to talk to us about what is going on here.

You know, we can fix this problem. This egg outbreak, which is outrageous, could have been minimized. I mean, aside from the conditions at the henhouses and everything else, if this bill had been law, several things in this legislation could have mitigated this problem.

It took 3 months before this voluntary recall, and there were thousands of Americans that fell ill before we determined what the source of contamination was. There are three components to the legislation that this committee and the House passed that are now in the Senate bill that would have prevented this.

Number one, under our legislation, the FDA would be able to get the records to show where the contamination came from.

Number two, traceability. This was a provision that I worked to get into the legislation which would allow contaminated products to be quickly traced from the field, or, in this case, the henhouse, to the fork. And that would greatly decrease the amount of time it would have taken for us to identify the source of the contamination.

And the third thing is, the FDA would have now mandatory recall authority. So if the producers themselves didn't recall

the product, then the FDA could have.

All of these things together would have applied in this situation if this bill had become law. And so, frankly, Mr. Chairman, we can't wait until after the election. We can't wait until the next Congress starts. We need to make this bill law now. And I would urge every single person who is here or who is watching this to call their Senators and urge them to enact this law before we leave.

[The prepared statement of Ms. DeGette follows:]

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Mr. Stupak. The gentlelady yields back.

Mr. Doyle for an opening statement, please.

Mr. Doyle. Thank you, Mr. Chairman. I will be brief. I want to thank you for holding this hearing, and also to say what a pleasure it has been to serve with you on this panel over the years. We are going to miss your presence next year.

My thanks also go out to all the witnesses for agreeing to be here to testify, especially our first panel, Ms. Lewis and Ms. Lobato.

You know, I remember growing up and learning from my mom how to properly cook eggs because you never knew if the heartbreak of Salmonella was just around the corner. And it took me years before I found out that "Sam and Ella" weren't actually people in the eggs.

But even though Salmonella has always been a risk when dealing with eggs and poultry and even though consumers know they have to cook them the right way, people have a reasonable expectation that egg producers are doing all they can to identify and fix issues in production that could cause their hens to get Salmonella and pass it on to the eggs.

And it looks like it didn't happen here, so I look forward to learning why. Why did companies with a record of prior violations not ensure their facilities were clean and free of rodents? Why did positive tests for Salmonella not cause the producers to go

into overdrive to clean up their premises? Why did those eggs go to market, into restaurants, into consumers' homes, where they could make so many people sick?

You know, it is a blessing that there are no reported deaths from these cases. So I hope we can learn enough today to make sure there isn't a next time, because next time we might not be so lucky. So I look forward to hearing from our witnesses today.

And, with that, Mr. Chairman, I will yield back.

[The prepared statement of Mr. Doyle follows:]

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Mr. Stupak. Thank you, Mr. Doyle.

Mrs. Christensen for an opening statement, please.

Dr. Christensen. Thank you, Mr. Chairman.

Here we go again, unfortunately, at another hearing of food contamination. But thank you, Chairman Stupak and Ranking Member Burgess, for your quick response in holding today's hearing on the recent outbreak of Salmonella in eggs, which highlights yet another crack in our country's food-safety system.

In late August, the Food and Drug Administration officials reported that they found positive samples of Salmonella that linked two farms into a massive egg recall. Investigators reportedly found Salmonella in chicken feed sent to both Wright County Egg and Hillandale Farms. More than 550 million eggs from the 2 farms were recalled in August after they were linked to as many as 1,300 cases of Salmonella poisoning.

And I want to also join my colleagues in thanking some of those who were harmed by this outbreak for being here today to testify.

FDA indicated that contaminated feed was the source of the outbreak but possibly not the only source. Subsequent on-site inspections revealed grossly unsanitary conditions.

A common thread in the numerous hearings we have held on food safety, or the lack thereof, is the inadequate and fragmented regulation of food in this country. As in this case, there is

often a long history of noncompliance with safety and sanitation measures, resulting in problems. Wright County Farms, the company involved in this outbreak, has been associated with outbreaks since the early 1980s.

In the case of eggs, the Ag Department oversees chickens and grades eggs for their quality. The FDA is responsible for the safety of eggs on their shelves. FDA inspects farms after an outbreak of egg-borne disease has been detected, not before. This is just another example of the bureaucratic gaps in regulating food safety that continue to put consumers at risk.

As you have heard, last year the House passed H.R. 2749, the Food Safety Enactment Act, in response to our Nation's food-safety -- what we consider a crisis. But it remains stalled in the Senate. Among other regulatory changes, this bill would give the FDA the power of mandatory recall of diseased food, as well as oversight and access to the safety plans that food service facilities establish, as well as the tests that are conducted to measure safety and inspection records. Until these new regulations are in place, we will not be able to strengthen the food-safety oversight.

And I do realize that FDA did put some new regulations in place too late -- a little too late to really stop this outbreak. But I hope today's hearing will further emphasize the need for the Senate to pass this bill.

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

time.

[The prepared statement of Dr. Christensen follows:]

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Mr. Stupak. Thank you.

Mr. Markey for an opening statement, please.

Mr. Markey. Thank you, Mr. Chairman, for holding this hearing.

Thanks to Chairman Waxman for his leadership in bringing this issue out into the open.

And, to our witnesses, we wish you all a full and speedy recovery from this debilitating and life-threatening experience.

We can all easily agree that Americans should be able to have their eggs over-easy without having to worry that the eggs will make them queasy. But more than a thousand people have been severely sickened by eggs laced with Salmonella since the eggs first entered the food chain in May. More than half a billion eggs have been voluntarily recalled since August. As we have learned, the conditions found in the facilities connected to these eggs were horrific, like something out of Upton Sinclair's "The Jungle."

It is my fear that this recall may not be the end of the story. There are many egg-producing facilities in other States with strong corporate ties to the companies responsible for the Iowa recall that have not yet been inspected by the FDA.

And with Senator Tom Coburn's recent announcement of opposition to the Senate food-safety bill, the FDA may well continue to be denied the strong enforcement tools it needs to

crack down on unsafe practices that the House passed last year, leaving the corporate fox in charge of the henhouse indefinitely.

I know that Senator Coburn is a Republican. I know the Republicans in the Senate are trying to stop any legislation from passing. This is a public health imperative. There must be some exception for Republicans in the Senate when it goes to the health of millions of Americans. They must release this bill so we can protect millions of families.

This past July, the FDA's new egg rule went into effect, imposing additional safety requirements on large egg producers and ensuring that there will be more FDA inspections at the facilities. So the jury is still out as to whether the Iowa facilities implicated in this infestation represent just a few rotten eggs or whether the safety of this country's egg supply is more like Humpty Dumpty: shattered and in need of full-scale reconstruction.

According to reports, companies owned or operated by one of our witnesses today have a decades-long record of public health, labor, and environmental offenses. DeCoster Egg and Feed facilities in Maine and other States have a long history of being found to be responsible for Salmonella infection, dumping piles of dead chickens aboveground, animal cruelty, worker-safety violations, and other problems. Instead of walking on eggshells to comply with State and Federal regulations, the hardboiled corporate executives in Iowa kept facilities from inspections that

showed that ultimately they were overflowing with manure and infested by rodents and flies.

My home state of Massachusetts gets many of its eggs from the Maine facilities owned, operated, or otherwise tied to Mr. DeCoster. It is going to be important for us in Massachusetts, in New England, to know whether or not we are at threat, as well.

Thank you, Mr. Chairman, for having this hearing.

[The prepared statement of Mr. Markey follows:]

***** COMMITTEE INSERT *****

Mr. Stupak. Thank you, Mr. Markey.

That concludes --

Dr. Burgess. Mr. Chairman, may I ask for a moment for a unanimous consent request?

Mr. Stupak. You can ask. I am not sure it is going to be given, but --

Dr. Burgess. I would like unanimous consent to insert a statement into the record from Dr. Tom Coburn, in that he is not blocking this bill. It is Senator Reid who has failed to bring this bill to the floor. Senator Reid's comments that Senator Coburn is blocking the bill are false, and Mr. Reid knows they are false. And that needs to be entered into the record.

Mr. Stupak. All right.

The Chairman. I object. I don't believe that that is an accurate statement, so I would object it going into the record.

Mr. Stupak. Okay. The objection will not be made part of the record. If you want to submit something later, Mr. Burgess, to supplement your testimony, I am sure we can work with it. But right now nothing is going to be entered in the record, okay?

All right. That concludes the opening statements by the members of the subcommittee. I want to call our first panel of witnesses.

Our first panel, we have -- first is Ms. Sarah Lewis from Freedom, California, and Ms. Carol Lobato from Littleton,

Colorado.

I would ask you to please come forward, take a seat at the witness table.

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

Ms. Lewis. No.

Ms. Lobato. No.

Mr. Stupak. No? Okay. Then I am going to ask -- you both answered, no, you do not wish to be represented by counsel. Therefore, I will 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. They are now under oath.

We will look forward to your opening statement.

Ms. Lewis, if you don't mind, I will start with you. If you would like to pull that mike forward and press the button, a green light should go on. There we go. We are ready to go. Thank you. Thank you for being here.

**TESTIMONY OF SARAH LEWIS, VICTIM OF SALMONELLA OUTBREAK; AND CAROL
LOBATO, VICTIM OF SALMONELLA OUTBREAK**

TESTIMONY OF SARAH LEWIS

Ms. Lewis. Good afternoon. Thank you, Chairman Stupak, Ranking Member Burgess, and Chairwoman Waxman, and committee members. I am honored to be here today and speak to you about my experience with Salmonella poisoning that I got from the recent Wright County and Hillandale Farms egg recall.

My name is Sarah Lewis. I am 30 years old. I am a mom, a wife, and a proud daughter of a small-business owner that abides by all of our local and State regulations. I have two beautiful daughters: Hailey, 7; Kyndall, 4. I have a wonderful husband who has served our country proudly as a Marine, Chris Lewis.

Not only did this experience affect me, it affected my whole family. My sister Stacey also got Salmonella poisoning from the eggs. The night we ate the custard tart was at my sister's graduation banquet. My whole family was there: my mom, my kids, my husband, my mom and dad, my grandma, my sister, and her boyfriend. We were all there celebrating this amazing achievement for my sister, not even suspecting that that night would change our lives for a very long time.

My sister and I look back at that night and say, "What if our

grandma or one of my daughters would have eaten that tart that we would have received? They probably would have died." Knowing how sick we were scares the heck out of us now.

The night after the college banquet, I started having severe abdominal cramping and overall not feeling well. My husband said, "Sarah, go lay down. You are not feeling and looking so hot." During the night, I woke up vomiting and had severe diarrhea so bad I was so beyond embarrassed to have to even ask my husband for help. My mom, who lives next-door, came over and took one look at me and knew something was terribly wrong. And if you know me, all I wanted to do was stay home and try and feel better.

The next day, my mom took me to urgent care, where I was told they would give me a shot to help me stop throwing up. And if I was able to keep water down in 20 minutes, I could go home. Well, 21 minutes later, I was being admitted into the hospital for what would turn out to be the first of two long stays.

When I was admitted for the first time, I spent 12 hours in the ER, so sick they were scared to move me. They thought they were going to have to do emergency bowel surgery. Because the CT scan showed bowels that were so inflamed and so sick, I was put in ICU. I was so sick and so dehydrated and in so much pain I could not even see straight.

While in ICU, I started to develop severe tachycardia and was moved to the critical care heart unit for 3 days. During that time, I had to go through things I never even want to talk about

again. I was so mortified.

When I was discharged, I was so excited. This meant I would be able to go to my daughter's preschool graduation that night. This may seem like a very small thing to many of you, but it meant the world to me. And I thought, great, I can start the healing process and get back to being a mom, a wife, and a daughter.

Boy, was I wrong. Approximately 2-1/2 weeks later, still sick as a dog, I called my doctor. And when I got to the office, he took one look at me and told me I was going back into the hospital. And if, for one moment, you can imagine two little girls' faces when I had to tell them, "Mommy is going back into the hospital." It was the hardest thing I ever had to do. It was devastating for any 7- or 4-year-old kid.

When I was readmitted, I was so dehydrated they had to insert a PICC line into my arterial vein in my right bicep. Talk about traumatic. I was so scared. I was about to have a line inserted into my heart.

I proceeded to spend 5 more days in the hospital, with my girls crying and screaming every time they had to leave me. I truly do not know what I would have done without my family and friends during this time.

When I was released for the second time, I was sure I was on the mend. Wrong again. I developed a severe infection called "C. difficile colitis" from all the antibiotics and from being in the hospital. C. diff causes severe diarrhea and cramping, as though

I didn't have this already. I had to be on antibiotics every 6 hours for the next 14 days again. And all during this, I found out that the Salmonella was still present and raging in my body. This was just devastating news to my family and myself.

I still have severe cramping, diarrhea, fevers, and the stress and fear that the Salmonella is present in my body. Every day, when I leave to go to work or even just to the grocery store, my youngest daughter looks at me and starts crying. It just breaks my heart.

This whole time, I am trying to figure out what has caused my Salmonella poisoning. Then one morning, my dad is reading the newspaper, and there was an article about my sister Stacey and I, that we were part of the egg recall.

As I start reading about the egg companies, it causes my stomach to turn. My family owns a retail butcher shop, Freedom Meat Lockers. And as we go through weekly State inspections and quarterly county inspections, we have to maintain and uphold a standard that we are very proud of. We are rated the number-one butcher shop in all of California for cleanliness and sanitation. To think that my sister and I got sick from a company that does not care about their regulations and quality is beyond appalling to me and my family.

I do not come to you today just for me and my sister. I come for every man, woman, and child who has gotten sickened by Wright County Eggs and other producers who did not consider the

repercussions of their actions. I wish I could say this would never happen again. Please consider changing your FDA policies to more closely monitor the egg industry.

Thank you for your time in listening to my story.

Sarah Lewis.

[The prepared statement of Ms. Lewis follows:]

***** INSERT 1-3 *****

Mr. Stupak. Thank you, Ms. Lewis.

Ms. Lobato, your testimony, please. I am going to ask you to turn on that mike and pull it a little closer to your person there.

TESTIMONY OF CAROL LOBATO

Ms. Lobato. Good morning, Chairman Waxman, Chairman Stupak, and the members of the committee. Thank you for inviting me to Washington to share my story. I hope that, by doing so, together we can make our dinner tables and our entire food system safer for all of us.

My name is Carol Lobato. I live in Littleton, Colorado. I am 77 years old and, today, have been married to my husband for 54 years. We are retired and blessed with four children and grandchildren. Ed is a World War II veteran and was awarded the Bronze Star and Purple Heart for his services in Okinawa.

My story began the evening of July 10th of this year, the night that Ed and I took our grandson, Drew, to The Fort Restaurant in Morrison, Colorado. The Fort is an upscale restaurant that serves wild game and other exotic dishes. The Fort was the restaurant that hosted President Clinton and the other world leaders for the Summit of the Eight dinner in 1997.

One of the items that we ordered that night was an appetizer

of rattlesnake cakes. All of us tasted the dish, and none of us particularly liked it.

The next afternoon, I felt very sick. At the beginning, I started to shake and experience chills. Then came waves of vomiting and explosive diarrhea. My fever rose to 102. Later, the doctors called this septic shock.

Ed rushed me to the emergency room. There, doctors administered several tests, including chest X-rays; CT scan; blood, stool, and urine samples. They gave me IV hydration and sent me home after several hours and told me to return if the symptoms did not improve.

The next day, I went to see our family doctor, as I was experiencing diarrhea, stomach cramps, dizziness, and weakness. He examined me and sent me to Swedish Hospital in Englewood.

The ride to the hospital was very unpleasant. I was quite sick. My electrodes were depleted. My potassium level was dangerously low. And the doctors at the hospital immediately put me on IVs of antibiotics, potassium, and I also was on oxygen.

A few days later, the cultures come back as positive for Salmonella bacteria that was both in my bloodstream and my intestines. Since I take medication for rheumatoid arthritis, which compromises my immune system, I was particularly at risk for an infectious bacteria like Salmonella.

The infection wiped me out, to the point where I was unable to function. I could not even get out of bed without help. I

remained at the hospital for an agonizing 4 nights, 5 days before I was finally discharged to come home.

The Salmonella infection is not over for me. I have lost my stamina. I often experience indigestion, and it is difficult for me to enjoy certain foods. I feel very tired and require rest during the day. I lost 8 pounds in the hospital, which was the only plus of this ordeal. My doctors told me that I almost certainly would have died without aggressive intervention.

Ed and Drew, our grandson, were also ill, but their condition was not as serious as mine. The CDC and the Jefferson County Department of Health later determined that the rattlesnake cakes that we consumed at The Fort was the source of our illness. Through a trace-back procedure, investigators found that the eggs used in the rattlesnake cakes had not been properly cooked. They were from the Wright County Egg farm in Iowa. The Salmonella found in my cultures was the exact DNA match to the Salmonella found in the egg farm.

The CDC has recently published reports of at least 1,500 others in the country who have also suffered from the identical strain of Salmonella found in the contaminated eggs from Wright County Eggs and Hillandale Farms.

The FDA has now inspected the farms and found several violations. The published inspection report shows the following: chicken manure piles 4 to 8 feet high in the henhouses; live wild birds, not chickens, flying around in the henhouses; rodent

burrows along the baseboard of the henhouses; liquid manure seeping through the concrete foundation; standing water in the chicken manure pit; loose chickens walking through the manure piles and laying their eggs inside; 31 live mice observed in the henhouse; live and dead flies too numerous to count inside the henhouses; 65 unsealed rodent holes in the walls of the henhouse.

These findings are shocking to me, not only as a consumer, but because I have personal experience with chickens and eggs. You see, I grew up on an Iowa farm. I was one of five girls, and I shared the responsibility for doing the work and the chores that went with the family farm. That included raising chickens from little chicks to the time they were ready for market, and for the eggs that we gathered and sold.

Our farm never looked the way these two farms looked and have been described. We never had any problems because we kept our farm clean, took proper care of our chickens, and did things the correct way.

Three years ago, this country suffered a horrible Salmonella outbreak linked to contaminated peanut butter that sickened over 700 nationwide. Last year, this country was struck by another peanut butter Salmonella outbreak that sickened 700, killing 9, tragically. Both times, survivors like me come before this committee asking for help.

But this time, I am the one asking for you, on behalf of myself and my family and 1,500 others who were sickened, to please

make our food supply safer. Pass legislation that provides funding and more inspectors so that these companies keep us safe. Pass legislation that requires testing of products before they leave the factories. Pass legislation that rewards companies who do the right thing and punish those who refuse to do so. Because, if we don't, we will all be here again.

Thank you. Respectfully, Carol Lobato.

[The prepared statement of Ms. Lobato follows:]

***** INSERT 1-4 *****

Mr. Stupak. Thank you.

And thank you both for your testimony. Thank you for coming here to Washington, D.C., traveling here with your families. And I deeply regret that you have suffered as part of this massive outbreak of Salmonella, but your testimony has really helped us, telling Members of Congress your story, but also the American people. And it will help us, and hopefully we can move the legislation that you heard so much about this morning -- I should say, this afternoon.

Let me ask you a couple questions, if I may. In the binder in front of you there, there is Tab No. 16. Mr. Waxman and I showed photographs that were taken by Federal public health officials in the course of their inspections of the egg facilities. And, Ms. Lobato, you sort of mentioned them in your testimony, as you have had some experience with farms and that.

When you look at these photos, what goes through your mind about the conditions of these farms, Ms. Lobato?

Ms. Lobato. It is just a deplorable situation here. Filth.

Mr. Stupak. You know, Ms. Lobato, you said in your testimony -- you said, maybe we should consider rewarding companies for doing things right so we don't have these food outbreaks. Isn't the fact that a consumer would put confidence in, let's say, a Wright Farm or Hillandale Farm, isn't that enough reward? We shouldn't have to reward people to produce, in this

case, eggs in a proper, sanitary, safe condition, should we?

Ms. Lobato. They should be safe. They should all be safe --

Mr. Stupak. And without reward. Okay.

Ms. Lobato. -- coming from the farm.

Mr. Stupak. Okay.

Ms. Lewis, anything you want to add on the photographs or anything?

RPTS JURA

DCMN HERZFELD

[1:05 p.m.]

Ms. Lewis. It is appalling to me. My family owns a retail shop, and when I show pictures to people of our facility, they are amazed at how clean it is and how we give tours of the whole place. And we are not afraid to show people around. We don't have anything that is appalling as this. And --

Mr. Stupak. In your butcher shop, do you have a plan to take care of pests and rodents and flies?

Ms. Lewis. Absolutely. We have strict regulations and guidelines that we have to abide by, and we have weekly maintenance services that come out and tend to that. So it has never been a problem. We have never had an infestation of any kind in our facility. And my father Howard has owned it since 1970, and he took it over from his dad, and my dad and my mom have always upheld the standards that we are proud of. And like I said, we give customers tours. We will show them our facility. We are not afraid to show what we do to everybody who wants to see it.

Mr. Stupak. Do you find the inspections at your level in your butcher shop overburdensome?

Ms. Lewis. No.

Mr. Stupak. Too much regulation?

Ms. Lewis. We are State and we are quarterly county

inspected, and we don't worry about it. They come in, and the last thing was because somebody didn't have a hat on. So our plant is so clean that when they come in, they say it is honestly a pleasure to come into our facility, and they actually want people to come to our plant and view our plant and how my dad has everything tiled, stainless steel, and he has everything to a certain standard.

Mr. Stupak. So in areas like food safety, government regulation in your estimation as owning a butcher shop is good?

Ms. Lewis. Repeat the question. Sorry?

Mr. Stupak. Sure. Government regulation. We hear so much government shouldn't be in our lives, get them out of there. We don't need government regulations. In your own personal experience, has it been helpful to you in your business?

Ms. Lewis. Absolutely. I feel as though if we did not have regulations on our facility, there's other butcher shops, and if they didn't uphold to a certain standard, then the product that is out there is not going to be of a certain level. And if it is not, then this is what's going to happen, and this is not acceptable.

Mr. Stupak. In all of our hearings we've had, we always hear it is young people, older citizens, or people with a compromised immune system who are susceptible to food, whether it is E. coli or Salmonella or Listeria. You don't seem to fit any one of those categories.

Ms. Lewis. I actually do have a compromised immune system. I have asthma, and I have been on steroids on and off for a long period of time due to my asthma and my lungs. And so they figured that, due to my compromised immune system, that is why it hit me so hard. And I actually had heart surgery when I was 18, so I have a long history of health trouble. And so when this came into my system, it just overpowered my whole system, and it took over. And I am still not feeling well. And to think that anybody has to go through this is sickening.

Mr. Stupak. Are you off your medication now?

Ms. Lewis. No. I laugh. No offense. I have a little old lady box of medicine that I take every day. And I -- you know, I don't have a choice. I am on 5 to 10 different medications. And I have lost 30 pounds. And my sick joke is, okay, you can cure my Salmonella in 30 more pounds. You know what I mean? But it's not funny, and I don't want to be on all these medications to keep my immune system up. It is not acceptable for supposedly someone who is young and 30 and healthy. It is not okay.

Mr. Stupak. Ms. Lobato, you have completely recovered now from your experience?

Ms. Lobato. I can't say that, no. There are a lot of things I can't eat that just are really hard to digest and give you a lot of heartburn and upset stomach and so forth.

Mr. Stupak. Well, we are glad you are still here, glad you had your 54th wedding anniversary, and you are celebrating it with

us.

And, Ed, thank you for your service to our country.

With that, let me yield to Mr. Burgess for questions.

Dr. Burgess. Thank you, Mr. Chairman.

And thanks to both of you for sharing what are very compelling stories with us.

I don't know if you heard, in my opening statement I referenced some of the surveillance cultures that were done at the egg farm, that 72 swabs, and only 8 were negative for Salmonella. Now, obviously, to me at least, I, too, spent time on a farm as a youngster, and my family was involved with -- in the meat business on my mother's side. I would think that is an outlier. We will get a chance to ask the egg manufacturers directly.

But when you look at the oversight, Ms. Lewis, you've suggested that there are several places that regulate you. But you said those are State and county? So no USDA, no FDA coming into your shop.

Ms. Lewis. We are not a federally regulated plant. We are a State-regulated plant, And so the meat that does come in to us is USDA inspected. Absolutely.

Dr. Burgess. But just the notion that you would have that many positive tests and no surveillance by the Federal agency responsible for ascertaining egg safety, I mean, that seems a little bit large; does it not?

Ms. Lewis. Absolutely. If there is supposed to be a Federal

agent on premises at all times, that is his job as well as the owners' to make sure and to uphold those standards. And he is supposed to be walking around and checking everything, and that is why he's there. That's why they are a Federal regulated plant. There's reasons why you have a Federal agent in your building mandating it. There is reasons, and obviously those reasons were not met.

Dr. Burgess. Ms. Lobato, your experience with the egg business, when you had opportunities to observe it up close and personal, you never saw anything like these astonishing photographs that were shared with us this morning?

Ms. Lobato. Not at all.

Dr. Burgess. And that is sort of my recollection as well, although I will confess to you I've never spent time on a commercial farm, so I don't know the context in which to place these photographs.

Ms. Lobato. Our chickens would be what would be called free range now. They walked everywhere. They were all over.

Dr. Burgess. And I promise you, I am only buying cage-free, free-range eggs from this point on after seeing those photographs. They are fairly dramatic.

Now, Ms. Lewis, you said you became sick the early part of July. The recall started August 13th. Do I have the time frame correct there?

Ms. Lewis. The banquet was Saturday, May 29th, to my

knowledge.

Dr. Burgess. You were ill in May.

Ms. Lewis. Yeah.

Dr. Burgess. And then, Ms. Lobato, your exposure was later?

Ms. Lobato. July 10th.

Dr. Burgess. Unfortunately, when you look at some of these things in the recalls, we did tomatoes a couple years ago also with Salmonella, it does take time. To either of you, does that seem unreasonable; that time span from May 27th to August 13th or July 2nd to August 13th, when the recall was effected, does that seem like an unreasonable period of time? A tough question to ask because you both suffered with the consequences.

Ms. Lewis. Well, from my point of view, when you are eating a dinner at a banquet, you have 10 different things on your plate from butter to chicken to different things. And then on your salad, you as well have several different things. So you have to try and figure out if it came from what's on your dinner plate, your salad plate, your appetizer. So, yeah, I do think that it would take time to try and pinpoint where it came from.

Dr. Burgess. When were you questioned in the sequence of this about the source of your illness? Or did it just come up from the DNA testing?

Ms. Lewis. It came up from the DNA testing, and I read a newspaper article, and then I called --

Dr. Burgess. So you sought them out rather than them?

Ms. Lewis. Yeah, I did. I had to call the county nurse and be like: Is this me in the newspaper article and my sister? Is this? You know, am I that person? And she is like, umm. And I said, am I? And she said, yeah. And that is how I found out. I had to seek out the information.

Dr. Burgess. Well, I want to thank both of you for being with us. And, Ms. Lewis, I will just tell you from the perspective of a former practicing physician, the clostridium gastrocele complication which you suffered, one of the most fearsome things that you can undergo as a consequence of antibiotic therapy, I certainly had patients with that during my professional lifetime, and it is in and of itself an ordeal and a memorable one.

Mr. Chairman, just before I yield back -- and, again, thanks to our witnesses. Before I yield back the balance of my time, I do want to read Dr. Coburn's statement.

If Majority Leader Reid believes --

Mr. Stupak. Mr. Burgess, we have had objections.

Dr. Burgess. I still control the time, Mr. Chairman.

Mr. Stupak. Mr. Burgess, you have been directed that the statement would not --

Dr. Burgess. If Majority Leader Reid believes that this legislation is a matter of life and death, he should bring it to the floor immediately for a full and open debate. As majority leader, he sets the schedule. I do not -- Mr. Chairman, I just

have to say, I do not recall -- this is a bipartisan issue. I voted with you on the dang bill. I worked with you on the dang bill. Now, it is just preposterous that you have conducted or that the majority has conducted the hearing in this fashion. We have to sit here and listen to a Member of the Senate be excoriated by Members of your side when he is not the problem. Yeah, he may become a problem if Senator Reid brings it to the floor, but if Senator Reid won't bring it to the floor, he is not the problem. So, again, I just do not understand why you would turn what is a bipartisan effort into such a partisan, excoriated affair.

Mr. Stupak. Mr. Burgess, legislation came out of this committee because of the work of many people on this committee, the full committee, Democrats and Republicans, as bipartisan. And we passed that bill July of 2009, after 3 years of work by this committee. And, yeah, we are a little frustrated that the Senate, one person, can put a hold on a bill.

Dr. Burgess. That is Senator Reid. Senator Reid, the majority.

Mr. Stupak. One person can put a hold on a bill, and the legislation does not move. So if you have a beef, take it up with Senator Coburn, and maybe we can move our legislation.

With that let me turn it to Mr. Braley for questions, please.

Mr. Braley. Thank you, Mr. Chairman.

And, Ms. Lobato, I am very pleased to hear that you had a

lovely childhood growing up in Iowa. Did any of the comments I made in my opening statement ring true with you?

Ms. Lobato. Absolutely.

Mr. Braley. Now, one of the things that struck me about both of your testimony was that neither one of you prepared the food that made you sick, and that illustrates one of the challenges we have been trying to face on this committee, which is we have a hodgepodge of State and Federal food safety regulations that impose different requirements on different egg producers depending upon where their facilities are located. We are making some strides based upon the recent regulation that the FDA passed regulating egg-production facilities. But both of you are the living examples of how consumers are at risk, through no fault of their own, because of cooking techniques that they have no control over.

Now, one of the things I want to talk to you about is the mandatory recall authority, because, as you heard, our committee began pushing for reform of the food safety system for years and, as you heard, this is the 13th hearing this subcommittee has conducted on food safety in the last 4 years. Our committee authored and successfully passed H.R. 2749, the Food Safety Enhancement Act, and included in that legislation is a provision that would give the FDA much-needed increased authority to issue mandatory recalls of tainted food products. And I am going to ask both of you, would it surprise you to learn that the FDA currently

lacks the authority to issue a mandatory recall?

Ms. Lobato. That is surprising.

Mr. Braley. And while the two Iowa farms in question did issue voluntary recalls, do you two believe that FDA should have to rely upon the company's goodwill to do that when the public's health is at risk?

Ms. Lewis. No.

Ms. Lobato. No.

Mr. Braley. Now, one of the things that we know is that the legislation, like the House bill that we have been talking about, would give the Food and Drug Administration the power to require the recall of a contaminated food that is needed. Do you think that would be a good idea for food safety for the consumers in this country?

Ms. Lobato. It is a start.

Mr. Braley. Now, Ms. Lewis, you spent a lot of time talking about the incredible impact that your illness from the Salmonella contamination had on your quality of life.

Ms. Lewis. Absolutely.

Mr. Braley. And I think there is this great misperception in the public that these symptoms that people deal with from Salmonella contamination are like a minor case of intestinal flu.

Ms. Lewis. No. It was so severe, I didn't even want to leave my house. I didn't even want to go to work, and I work right across the street. I didn't want to take my kids to school.

To be blunt, you don't even want to sneeze or cough. It is miserable. Life as you know it completely changes.

Mr. Braley. And you don't even want to move.

Ms. Lewis. Oh, you can't move because you are in such physical pain from the stomach cramps, and you have like -- your whole body head to toe was in agony. I was in fetal position for I don't even know how long. I couldn't even move.

Mr. Braley. You also talked about the need to insert something called a PICC line into your bicep. Can you just tell us a little bit more about what that was and what it was designed to do?

Ms. Lewis. Yeah, absolutely. I was so dehydrated that they could not find a vein to insert an IV in, and they needed to get antibiotics, steroids, and fluids into me as quickly as they could. And my doctor suggested a PICC line, and it goes right here in your arm. And once it goes in, they do an X-ray to make sure that the line is properly inserted into your heart. And, to my knowledge, once it goes in, it's a pretty permanent port, and I have scars from it, and I will always have those scars. But it was something that I had to do; otherwise, I would not be able to have the medication I needed.

Mr. Braley. And, Ms. Lobato, I am giving you the chance to make the same type of comment. What was this like for you on a daily basis to deal with the symptoms from your Salmonella contamination?

Ms. Lobato. Well, you are just so severely sick. And, as Sarah said, you really can't go very far from the bathroom. And you are just sick. You are so tired, you are so fatigued, worn out. You just -- you see the bed, and you just want to flop in it. And another end result is that you really -- you have a hard time trusting food.

Mr. Braley. Let's talk about that briefly. Do you remember ever having a duck egg, Ms. Lobato?

Ms. Lobato. No. I don't think so.

Mr. Braley. That is what is amazing is that in the 1920s and '30s, duck eggs were more popular for consumers than chicken eggs, and it was a result of a Salmonella problem with those eggs that they basically disappeared from the American table. And, as a result of those problems, there were many food safety bills that were passed to address the problem and try to protect consumers.

We need to bring that same level of focus in 2010 and protect consumers from these food-borne illnesses. And thank you both for your testimony.

Ms. Lewis. Thank you.

Mr. Stupak. Mr. Latta for your questions, please.

Mr. Latta. Thank you, Mr. Chairman.

And, again, ladies, thank you very much for being with us today. And having been one that has had food poisoning twice, you know, a lot of us go to a lot of events, and you eat what they put out in front of you. And I can commiserate with you on what

happened to you, because I know for 2 to 3 days, my case, I know I was down. And you are absolutely right, you don't want to get too far from home. So I can really empathize with you on that.

Ms. Lobato, your background sounds like my mother's. She grew up on a 100-acre farm in Ohio, and they had cows and some pigs and chickens, and my mom to this day still likes brown eggs the best. But it is one of those things that our agriculture has kind of changed through the years.

But I have got to ask this question of both of you, because in reading your testimony and hearing you talk about and as has been brought up about that you didn't prepare the food, I have got to ask you this: What is rattlesnake cake, and how is that prepared? Is it raw? Is it baked? Fried? How is that prepared?

Ms. Lobato. Well, this is kind of a bit of an exotic restaurant, but it is built like a fort, and they specialize in meats of, well, supposedly the 1800s, early 1900s. And they have elk and buffalo and bison and all kinds of things. But one of the appetizers is rattlesnake cake, and it comes like a little crab cake, small, and they apparently boil the rattlesnake for 6 hours or something, then they grind it up, and it's with bread crumbs and eggs and spices to hold it all together, and it comes in a little plate as an appetizer and had some green sauce on the top of it, relish, garnish. And I understand that that's where the raw egg was or the uncooked egg was in the relish that was on the top.

Mr. Latta. So it wasn't in the breading that was holding the whole thing together?

Ms. Lobato. I don't believe so. I am not sure that that's been determined at this point.

But I just wanted to say, our farm was not a chicken farm per se. We had all kinds of animals, pigs and chickens and --

Mr. Latta. It does sound like where my mom grew up.

And, Ms. Lewis, with a custard tart, is that -- my wife is not here to help me out with these things. Is that something that is baked, or is that raw? Is there something raw in there? How is that prepared? Do you know?

Ms. Lewis. From what I was told, it's like a cheesecake base. And the bakery that made it, they always use a pasturized egg solution, and that day they happened to run out of that and started using whole eggs. And so that's where the Salmonella came from was the whole eggs. So but, to my knowledge, it is like a baked kind of dessert, and then -- to a certain point, so it still stays like a custard.

Mr. Latta. Well, thank you very much.

And, Mr. Chairman, I yield back.

Mr. Stupak. Thank you, Mr. Latta.

Ms. DeGette for questions, please.

Ms. DeGette. Thanks, Mr. Chairman.

Mr. Latta, this restaurant, The Fort, is actually a fort that's been around for many, many years. And as Ms. Lobato

pointed out, this was a restaurant where they even had a big event when the G-8 came to Denver some years ago. And so what I think Ms. Lobato is trying to say is this kind of contamination can happen anywhere, even at the very nicest restaurants or just little places, and that's what concerns all of us.

I want to ask both of you. Ms. Lobato, the food you ate was in, I think, July 11th, around the first part of July, correct?

Ms. Lobato. July 10th.

Ms. DeGette. And, Ms. Lewis, the food that you ate was at the end of May; is that correct?

Ms. Lewis. That is correct.

Ms. DeGette. So that was maybe 6 weeks apart between the two of you when you had those. Do you think that that's -- and of course, the recall didn't happen until late August. So do you think that's an unreasonable amount of time to identify the source of the contamination and to get these products off the shelves?

Ms. Lewis. Well, you know, it's funny, my sister Stacey and I were the number one and number two case in Salmonella in all of California. And so for her and I to be the first and second, you know, to me it seems like a long time. But to the person who is number 500, it happened maybe a couple weeks later when they found out, you know. So being the first and second person, of course it is going to seem like a longer period of time than it would to somebody who got sick later.

Ms. DeGette. But what I am saying is what you described was

the bakery that made those tarts had used a different kind of egg solution that day. So, theoretically, someone would -- it wouldn't have been that hard to figure out that that was different, and then to look where those eggs came back -- came from and trace it back to the farm in Iowa, right?

Ms. Lewis. True. But like I said before, there is also 10 things in my plate for dinner.

Ms. DeGette. Sure.

Ms. Lewis. There's 10 things on my plate for salad. There's an appetizer. So, in fact, did it come from X, Y, or Z? It's hard to tell at that time until you start actually pulling out everything and researching it. So as they start researching it, then I do feel, you know what I mean, it was done appropriately. But you can't tell if it is this or this because there's so many different components to what you receive at a banquet.

Ms. DeGette. Well, would you be surprised to know we actually can tell if it is this or this? And if you have a traceability system, you actually can trace it? I mean, part of the problem we have now is that the Food and Drug Administration, as you told Mr. Braley, they don't have mandatory recall authority, and we don't have traceability, so it is harder to figure out where the components come from. But technologically we have the ability throughout our food industry to be able to trace where things came from. So if they had taken all of the components on your plate and they had been able to trace them

back, it would have moved much more quickly. Does that make sense to you?

Ms. Lewis. That seems appropriate, yes.

Ms. DeGette. And did anybody else from that graduation party get sick besides you and your sister?

Ms. Lewis. There was, to my knowledge, another gentleman that got sick as well. We were at the graduation banquet, and then the next night was a prom, and people from that prom --

Ms. DeGette. Also?

Ms. Lewis. Yeah. I believe so.

Ms. DeGette. Also got sick.

So, you know, you had a group of people that got sick. We saw this with some of the other outbreaks as well, the peanut butter and other ones, where lots of people were getting sick. And when you see a big group like that getting sick, it's something that the State health officials really pay attention to.

And, Ms. Lobato, did you want to add to that?

Ms. Lobato. Well, I just wanted to say that the Department of Health for Jefferson County and for Denver were on my case while I was in the hospital. They called 3 days in and wanted to know what I had eaten at the restaurant, what I had eaten for the week before. So I was very impressed at how fast they were on the situation.

Ms. DeGette. Right. You know what we've been finding the last few years with these food-borne illness outbreaks, oftentimes

it's the public health officials who identify it. They are the first ones. But because we don't have a modern food safety and tracing system, it takes many weeks to then track down where that came from. So if you had the components of our legislation that we passed in it by -- sometimes you hear us sniping up here, but we actually passed this bill in a bipartisan way through the House. And if you had that in place, once those State officials identified what it was, it would be a lot easier then to trace it back to a source, and it would eliminate many new cases of illness because you could get the recall going much more quickly.

Thank you. Thank you both for coming again.

Mr. Stupak. Mr. Doyle for questions, please.

Mr. Doyle. Thank you, Mr. Chairman.

Ms. Lewis, thank you for your testimony.

And, Ms. Lobato, happy anniversary, and thank you.

You know, I appreciate the fact that you come here today because it is important we put a face on these problems. The chairman said earlier, people talk all the time about all this government regulation and let's get the government off our backs and no more regulation. Like we sit here every day thinking of ways to harass businesses and make them lose money and go out of business. But the reality is the fact that most Americans can take for granted that when they turn their water spigot on, the water they drink isn't going to poison them, or the food they eat is going to be safe, or the air they breathe in their neighborhood

isn't going to cause them grave harm, a lot of it is due to the fact that things like this happen. And one of the ways we address that is to come up with regulations to make sure that when food is being produced, it is done in a certain way. There's standards in place. The same with how our water is treated and what you can put in the water and what you can put into the air.

And sometimes you can have the best regulations in the world; and if you don't have it enforced, if there is not proper oversight, even good regulations fall short. We saw that in the Gulf of Mexico not too long ago with the terrible oil spill.

So I hope Americans see this today, they see two people, and they look at both of you and hear your stories and say, that could be my grandmother, that could be my mom, that could be my sister, and people realize there is a reason for this; and that, yeah, we do need good regulations, and we need good oversight. And when everybody does things the way they are supposed to do it, people can make money, and businesses can thrive, and we can all feel good about the fact that what's put on our tables or when we go to a restaurant, that something terrible isn't going to happen to us after we leave that restaurant.

And that is really the purpose of the hearing today is to get to the bottom of these things. And I think more than anything we will hear today, it will be your personal stories, I think, that will touch many of the people in the U.S. Senate and whoever has got that hold over there.

You know, on the Senate side, it's a strange institution. One of these guys can hold up legislation no matter what it is. I had a bill that passed here this year that a Senator had a hold on, so I went over and talked to him, and he lifted his hold; and then another Senator put a hold on the bill, so I went over and talked to that Senator, and he lifted his hold. Then I was told there was a secret hold on the bill, and now we don't know which Senator has a hold on it. So it is a strange institution over there, and sometimes it takes stories like this to move them to action.

So thank you for coming today and helping us out and helping your fellow citizens in America have safe food to eat. Thank you.

Mr. Chairman, I'll yield back.

Mr. Stupak. Thank you, Mr. Doyle.

Seeing no further Members ask question, I want to thank you again for coming and for helping us out. And I know you came here on your own free will and with your own experience, and so we appreciate it. And so on behalf of Congress and the American people, thank you for being here.

Dr. Burgess. Mr. Chairman.

Mr. Stupak. Mr. Burgess.

Dr. Burgess. I wonder if I might be recognized for the purpose of entering into a colloquy with the chairman.

Mr. Stupak. Sure. Go ahead.

Dr. Burgess. Mr. Chairman, is it not true that under

committee rule 3, subsection D, under Questioning, the right to interrogate a witness before the committee or any of its subcommittees alternates between the majority and minority, Members. Each member shall be entitled to 5 minutes in interrogation of the witnesses.

Is that your understanding of the rule?

Mr. Stupak. To question witnesses, that is correct.

Dr. Burgess. Five minutes of time was to be controlled by the ranking member of the committee, and 30 seconds of that time were taken from me. Could I ask the chairman's indulgence to restore that time on the next panel of witnesses?

Mr. Stupak. No, Mr. Burgess. You were instructed that there was -- your unanimous consent was denied, and you tried to violate the wishes of this subcommittee by going backdoor. You said you were done with your questions. It is not unusual for Members to end less than 5 minutes, we yield back our time and move on. I asked you not to go on and read it. You insisted upon reading it. I let you read until your 5 minutes expired, and then I muted your mike. So you had your 5 minutes. You chose to use your last 30 seconds or whatever to read a statement. So I am not going to give you more time with the next witnesses.

Dr. Burgess. Mr. Chairman, with all due respect, you muted my mike immediately upon my beginning to read the statement. And, further, in regards to that controlling of 5 minutes, as you know, it is a well-established pattern, especially in this committee,

that Members may use their time to talk about whatever they wish. Sometimes they offer soliloquies that I think are entirely far afield from where we are, but I don't object to them doing that. And certainly I don't recall anyone ever being treated in the way of having their microphone silenced. I looked upon that as a period of censorship that you exercised, and I have got to tell you I feel very strongly about this, that I think that was wrong, and I think this committee needs to rectify it.

Mr. Stupak. The record is clear what happened. If we have to read it back later, we can. You had your 5 minutes. Even after the objections of this committee, you decided to go ahead and read a statement which you asked unanimous consent be submitted into the record. The Members on our side objected. You should not the -- if you want to follow the rules of the House, you would not have tried to backdoor it by reading it in. I let you go -- excuse me. Don't interrupt me. I let you go until your 5 minutes was up. You had your full 5 minutes. And this has happened before. I have been here 18 years. In fact, even up here, though I could mute your mike because it says "private," and it says "mute off." This is not the first time it happened. It has happened many times.

You have to go by the rules of this committee and by the ruling of the chair. You cannot take and make your own rules as we go along. You are violating the wishes of the committee, you are violating the rules of this subcommittee, you are violating

the proper decorum as the way we conduct hearings. My job, my responsibility is to move this hearing forward, conduct it in an fair and impartial manner. I did that.

Dr. Burgess. Mr. Chairman, I would submit that rule 3, subparagraph B was violated by the chair and not by the ranking member.

Mr. Stupak. We are not going to agree, so let's move on.

Mr. Stupak. Let me call our next panel of witnesses.

On our second panel we have Austin "Jack" DeCoster, owner of Wright Country Farm; Peter DeCoster, chief operating officer, Wright County Egg; Orland Bethel, president, Hillandale Farms of Iowa; Mr. Duane Mangskau, production manager, Hillandale Farms of Iowa.

Just waiting for people to settle down here a little bit.

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 gentlemen wish to be represented by counsel?

Mr. DeCoster, you want to press that button? And I would ask you to give us the name of your counsel.

Mr. Austin DeCoster. Jan Kramer.

Mr. Stupak. And during your testimony, before you answer a question, if you would like to consult with your counsel, you have a right to do so.

Mr. Austin DeCoster. Thank you.

Mr. Stupak. Anyone else?

Mr. Peter DeCoster. Yes. Mr. John Bodey.

Mr. Stupak. Mr. Bethel.

Mr. Bethel. Yes. Yes, I have counsel here.

Mr. Stupak. Would you state counsel's name?

Mr. Bethel. Tom Green.

Mr. Stupak. And, again, if you wish to consult with them during questions, you may, but questions have to come from you -- or, the answers have to come from you. I'm sorry.

And Mr. Mangskau?

Mr. Mangskau. No.

Mr. Stupak. No counsel with you. Okay. So we have that on the record.

And, again, anytime during the questioning you wish to consult with your counsel, you may.

So I am going to ask you to please rise, raise your right hand and take the oath.

[Witnesses sworn.]

Mr. Stupak. Let the record reflect each witness answered in the affirmative. They are now under oath.

We will now hear a 5-minute opening statement from our witnesses. You may submit a longer statement for inclusion in the hearing record. So Mr. DeCoster on my far left, Jack, if you want to start your opening statement, please do. Press the green light there on that microphone and pull it forward, and we can hear you.

STATEMENTS OF AUSTIN DeCOSTER, OWNER, WRIGHT COUNTY EGG; PETER DeCOSTER, CHIEF OPERATING OFFICER, WRIGHT COUNTY EGG; ORLAND BETHEL, PRESIDENT, HILLANDALE FARMS OF IOWA; AND DUANE MANGSKAU, PRODUCTION MANAGER, HILLANDALE FARMS OF IOWA

TESTIMONY OF AUSTIN DeCOSTER

Mr. Austin DeCoster. Commissioner, Mr. Chairman, and members of the committee, thank you for the opportunity to testify. My name is Austin DeCoster. I go by "Jack." My son Peter and I are here to answer your questions.

[Disturbance in hearing room]

Mr. Stupak. All right. We ask the room be cleared. I would ask that you suspend for a few minutes. I would ask that you would cease and desist, please, sir. The hearing must continue. We will resume these hearings. It is not unusual for us to have an few outbursts whether it's on this side of the dais or the other side.

Mr. DeCoster, go ahead, please.

Mr. Austin DeCoster. We were horrified to learn that our eggs may have made people sick. We apologize to everyone who may have been sickened by eating our eggs. I have prayed several times each day for all of these people for improved health.

For generations our family has been producing eggs, and I

have spent my life as a chicken farmer. I have been blessed to be able to work with my sons on our farms as well. Over the years we have grown to be pretty big in producing eggs; unfortunately, we got big quite a while before we stopped acting like we were small. What I mean by that is we were big before we started adopting sophisticated procedures to be sure we met all of the government requirements.

While we were big but still acting like we were small, we got into trouble with government requirements several times. I am sorry for those failings. I accept the responsibility for those mistakes in our operations. Eventually I realized that to put those problems behind us, we would have to become very good at meeting all the government requirements, so for about 10 years now we have been focused on doing just that.

We are moving forward. We have put in place effective employee training systems, additional monitoring and control procedures to assure compliance with government requirements. When necessary, we hire top experts to be sure the procedures are right. Also, in critical areas, including reduction of Salmonella Enteritidis, we have been going beyond government requirements in an effort to improve our operations with all these systems. We have made important strides, and I am proud of our work. Still, these challenges never stop.

Mr. Stupak. Does that complete your testimony?

Mr. Austin DeCoster. Yes. That completes it.

[The statement of Mr. Austin DeCoster follows:]

***** INSERT 2-1 *****

Mr. Stupak. Okay.

TESTIMONY OF PETER DeCOSTER

Mr. Peter DeCoster. Mr. Chairman, my name is Peter DeCoster. I am the chief operating officer for Wright County Egg of Galt, Iowa. In other words, I run the Wright County Egg Farms. Permit me to begin with a short overview of Wright County Egg farming operation in Iowa.

Three hundred fifty people are employed at our Iowa farms. We have 5 farms with 73 hen-laying barns, each about 33,000 square feet in size. Almost all of the barns are a two-story structure with the hens located in the upper part of the barn. In all, Wright County has 5.8 million laying hens. Our farms produce approximately 2.3 million dozen eggs per week, or about 1.4 billion eggs per year.

In addition, Wright County Egg operates the barns at the Hillandale Farm near Alden, Iowa, with 10 barns and approximately 1 million laying hens, producing more than 435,000 dozen eggs per week.

Each of the six farms we operate is at a different location. No two farms are less than 1 mile from another. In addition to our farms, at a separate location Wright County Egg operates a feed mill which produces our poultry feeds. It was inspected by

Iowa with no major deficiencies found. The inspection report was transmitted to us by the FDA in May.

Some background on the Salmonella Enteritidis and how our egg farms are monitored for the bacteria may also be useful.

Regrettably, SE is a fact of life in the egg industry. That is why all egg cartons bear the "safe food handling" instructions and the FDA model code requirements that eggs be thoroughly cooked.

Like everyone else who has been producing eggs for decades, we have fought SE for a long time, and we have not always been successful. Today we have extensive SE reduction practices that were unknown in previous years. To protect against SE contamination, our farm follows stringent standards for egg production, processing, and transportation to ensure both the quality and safety of our eggs when they reach our customers.

In addition to the following food safety guidelines and the new FDA egg safety rules, our farm also established in July of 2009 a voluntary overall Salmonella intervention and risk reduction program which sets specific protocols in the areas of chicks and breeder flocks, biosecurity, cleaning and disinfecting between flocks, test management, vaccination, and refrigeration. Further, Wright County Eggs has been working with two top scientists to enhance our biosecurity and bird health needs. They provide outside counsel to decide effective programs, monitor their performance, and make operational requirements as necessary.

Of particular potential assistance to your investigation, Dr.

Charles Hofacre has advised us on bird health matters. Dr. Hofacre is recognized as one of the world's leading authorities in SE control, and I appreciate his presence in the hearing room today.

As a tool in our SE reduction program, Wright County Egg began SE vaccinations of our flocks. That vaccination program and the voluntary environmental testing program that guided it and other operational decisions is outlined in our written testimony.

So we have had extensive SE reduction programs designed to meet all regulatory requirements and go substantially beyond the requirement with additional measures, notably our SE vaccination program. So we were stunned to learn that our eggs appeared to be responsible for an SE disease outbreak.

In mid-August, FDA requested that Wright County Egg undertake a voluntary recall of our eggs. We promptly did so in cooperation with FDA. Our first recall was announced on August 13, 2010, which involved three of our farms. Then our second recall was announced on August 18, 2010, and addressed eggs from the other two farms. An extensive food safety investigation followed.

At this time we cannot be absolutely certain of the root cause of the contamination of the eggs we produced; however, we view that the most likely root cause of contamination to be the meat and bone meal that was an ingredient in our feed.

At this point I would appreciate a projection of the first slide we provided to the committee.

Meat and bone meal was produced at a rendering facility. Part of the production process in rendering includes cooking carcasses to a temperature that would eliminate SE. However, as always in food safety matters, there is the potential for recontamination either at the rendering facility and the transportation from the rendering facility, or subsequently after the meat and bone meal is delivered to Wright County Egg. In particular, contaminated meat and bone meal that entered our bin with the ingredient could have contaminated the bin and additional meat and bone meal that was subsequently added to the bin.

Next slide.

Not only is this suspicion consistent with the FDA test results, but it also is consistent with the fact that the only Hillandale Farms operation to produce eggs that tested positive for the SE contamination was the Alden farm, which received its feed from the Wright County Egg's feed mill. So all of the flocks that have been proven to be the source of this SE outbreak received feed from the Wright County Egg's feed mill.

My written testimony outlines the exhaustive operational changes that Wright County has undertaken to take every precaution against this ever happening again. By focusing on our flocks, our feed, and our worker biosecurity protocols, we intend to demonstrate our commitment to the production of eggs that are of high quality and safe.

We look forward to answering your questions so an accurate

understanding of what caused this food-borne disease outbreak
might be achieved. Thank you.

Mr. Stupak. Thank you.

[The information follows:]

***** COMMITTEE INSERT *****

Mr. Stupak. Mr. Bethel, your opening statement, please, sir.

Mr. Bethel. Mr. Chairman, I do not have an opening statement.

Mr. Stupak. Okay. Thank you.

Mr. Mangskau.

TESTIMONY OF DUANE MANGSKAU

Mr. Mangskau. Mr. Chairman, Dr. Burgess, and other subcommittee members, my name is Duane Mangskau, and I am Hillandale Farms of Iowa, Incorporated's, production representative.

I grew up in Minnesota, and upon graduation from high school spent nearly 13 years working on a family farm with my father and brother in Ellendale, Minnesota. In the late 1980s, I entered college to study business administration. While completing my studies in 1991, I learned about feed and poultry production while working for an independent-owned grain and feed company.

After graduation, I continued working with feed and poultry flocks with the farmers' cooperative located in Oakland, Minnesota. Based upon my knowledge of poultry flocks, I was invited to manage production for the Interstate Value Added, IVA, Farmers Cooperative when it began construction in 1998. I served as the production manager and later the general manager of operations at the IVA facility in West Union, Iowa, until it was purchased in December of 2007.

I left the West Union facility in March of 2008 and returned at the request of Hillandale Farms of Iowa in March of 2010. I now serve as Hillandale's production representative at the West Union facility.

It will probably help our discussion today if I define a few industry terms. When I talk about egg production, I mean the first of three steps in getting eggs to our customers. Egg production encompasses every aspect of farming and raising the hens up until the eggs are ready for processing. The next step, egg processing, involves cleaning, grading, and packaging the eggs. The final phase, which involves marketing and distribution, has traditionally been Hillandale's area of expertise.

In order to get fresh quality eggs to market, Hillandale must be able to rely on good production and good processing. From 2008 until recently, Hillandale relied on Wright County for production in Iowa.

In its 50 years of existence, I believe that Hillandale Farms, while not perfect, historically has had a record and reputation for supplying the Nation with safe quality eggs. In fact, to the best of my knowledge, Hillandale Farms had never been involved in a recall until 3 weeks ago, when the FDA told us that seven people had become ill from Salmonella at a Mexican restaurant that received Hillandale Iowa eggs. There are many other potential sources of Salmonella contaminations in restaurants, and we were, to be honest, shocked by the allegation.

During the prior 4 months, we had shipped about 170 million eggs from Iowa, and it was difficult to understand why FDA was saying that our eggs were responsible for seven people sick at one restaurant.

The recall has, however, forced Hillandale to take a hard look at our operations and will, in the long run, make our operations better.

On August 20, we voluntarily recalled the relevant eggs, diverted all other eggs from those facilities to breaking facilities, and have been cooperating with the FDA, State officials, our customers, and this subcommittee ever since. And even if the source of the Salmonella illness is never confirmed, where we have fallen short in Iowa, we are committed to improving our operations. At Alden, where Hillandale Farms has no ownership interest, we have terminated our marketing relationship with its owner, Wright County, because we were disappointed in the test results there. At the West Union facility, we have redoubled our safety efforts and fully addressed all of the issues identified on the FDA's 483 report. We would like to emphasize, however, that no egg from West Union has tested positive for SE.

Nonetheless, Hillandale has retained the former Associate Commissioner of Foods at FDA and the former head of food safety at several Fortune 200 companies, including H.J. Heinz, Campbell Soups, and Tricon Restaurants, to conduct an intensive assessment of food safety at our West Union facility and offer recommendations. You have our commitment that we will implement any and all of these recommendations.

Moreover, Hillandale Farms will continue to cooperate with all government officials, including this subcommittee. And I look

forward to answering any questions that you may have. Thank you.

Mr. Stupak. Thank you.

[The statement of Mr. Mangskau follows:]

***** INSERT 2-2 *****

Mr. Stupak. That concludes testimony. We will open for questions. I will begin.

Mr. Bethel, I will start with you, if I may. Following the outbreak of the Salmonella, Federal public health officials inspected your egg facilities in Iowa over the course of 7 days. During the course of the FDA's investigation, your employee Mr. Mangskau, who is providing testimony to the committee today, accompanied the agents as they conducted the inspection.

I would like to ask you about an e-mail you received on August 21, 2010. In this e-mail you received, Mr. Mangskau summarized his notes from the inspection. He wrote:

Barn 7. Put lids on the dead chicken barrels to reduce vector access.

Barn 8. Wet manure due to water leaks. Didn't say it needed to be removed, but they didn't like it.

Barn 9. Saw old dead birds in a few cages and old chicken heads on egg belts.

So here is my question. And, again, you are under oath, sir. Mr. Bethel, prior to receiving Mr. Mangskau's e-mail, were you aware of the conditions he noted at the Hillandale egg facilities in Iowa?

Mr. Bethel. I respectfully decline to answer the question based on the protection afforded me under the Fifth Amendment of the Constitution.

Mr. Stupak. Mr. Bethel, I understand that you are invoking your right against self-incrimination, which is your prerogative under the Fifth Amendment to the Constitution of the United States. Is it your intention to invoke the right to refuse any questions during this hearing?

Mr. Bethel. Yes.

Mr. Stupak. Then I will refrain from asking you additional questions about this subject matter and request that other Members also refrain from asking you further questions.

Mr. DeCoster -- I'm sorry, Mr. Burgess?

Dr. Burgess. Just simply, will I allowed to question Mr. Bethel?

Mr. Stupak. You can. But, I mean, I think he has made it pretty clear he is going to take the Fifth Amendment to any questions, though.

Dr. Burgess. I reserve the right to question the witness.

Mr. Stupak. You reserve the right during your time.

Mr. Jack DeCoster, if you will. In your testimony, you admit that your facilities had problems in the past. That is indisputable. There have been several outbreaks associated with your eggs in two States. Specifically Maryland and New York have been mentioned today in which your eggs were actually banned.

Your response in your written testimony, you indicated that when you were small, and that you have had -- put those problems behind us, was what you said. My question to you is this. If you

have cleaned up your operations as you say, why did this outbreak happen?

Mr. Peter DeCoster. Mr. Congressman, if I could answer that?

Mr. Stupak. Well, that is directed at your father. So let him answer if he can. Can he answer that question?

Mr. Austin DeCoster. Well, I will try to answer it, but I am having trouble hearing. Could you speak up a little bit more, please?

Mr. Stupak. Sure. In your testimony, you admitted your facilities have had problems. That is indisputable. There have been several outbreaks associated with your eggs in two States we have heard about today, both Maryland and New York, where your eggs were actually banned. Your response, and in your written testimony, you said: This all occurred when DeCoster Farms were small, and that you have put those problems behind you.

So my question is if you have cleaned up your operations as you say, why did this outbreak occur?

Mr. Austin DeCoster. Well, this is a -- Mr. Chairman, this is a complicated subject. I have to take it piece by piece kind of. Will that be okay?

Mr. Stupak. Sure. Let's go piece by piece, and take the document binder right there. Go to binder -- to tab number 16. And we will go through it piece by piece.

Mr. Austin DeCoster. Sixteen?

Mr. Stupak. Right here. Look under tab 16.

In August, the FDA inspectors went into your facilities. The conditions they found were appalling. Let me show you some photographs from the inspection. It is a photograph that I put up during my opening statement of decaying chickens in your egg-laying facility. You said you were following sophisticated procedures to keep your facilities clean. How do you explain dead chickens in your laying -- hen-laying houses?

Mr. Peter DeCoster. Mr. Congressman, this particular --

Mr. Stupak. I'm sorry. I am talking to Mr. DeCoster, Jack DeCoster.

Mr. Peter DeCoster. But he doesn't run the operation. I do.

Mr. Stupak. Right, I know, but he testified that he cleaned up; that when you were small, you didn't have these problems.

Okay. Do you want to answer?

Mr. Peter DeCoster. Yes, sir.

Mr. Stupak. Okay. How do you account for dead chickens then?

Mr. Peter DeCoster. Well, there's eight dead hens here that are in the back of building. And, you know, kind of like a large city, there's 80,000 birds in the building.

Mr. Stupak. Sure.

Mr. Peter DeCoster. Occasionally we will have some mortality. And these are taken to the back of the barn now. Our policy is to have these in a barrel.

Mr. Stupak. But they weren't at the time, were they?

Mr. Peter DeCoster. No. No, sir, they're not.

Mr. Stupak. Okay. Go through the other photos, the mice along the conveyor belt for the eggs.

Mr. Peter DeCoster. But this here would not be acceptable.

Mr. Stupak. Right. Either are mice by this.

And go through there. Look at the manure coming out of the building from the foundations, the door. This isn't something that just happened overnight. That manure pile is about 7 to 8 feet tall. It is seeping out through cracks. So, number one, you have got too much manure. It is flowing out of your buildings. You've got cracks, you've got dead mice, you've got dead chickens, you've got maggots. That stuff just didn't happen. I agree, you have a -- you're a big operation, but with big operations come big responsibilities.

So how did you clean up your act if you started small and now you've cleaned up your act?

RPTS KESTERSON

DCMN HOFSTAD

[1:59 p.m.]

Mr. Peter DeCoster. In the case -- if I could just, kind of, go one at a time here on the photos.

The one that shows the door being gapped open with the manure, these houses -- as you can see, it is a house that is basically 18 foot at the ease there. It is a two-story structure.

Mr. Stupak. Sure.

Mr. Peter DeCoster. The hen population is in the top story. The building is designed to have these manure pits. And I know this has got a lot of press, but this is a standard practice in the industry to have manure underneath the birds and then be taken out.

Mr. Stupak. Sure.

Mr. Peter DeCoster. The problem we had here -- the manure accumulation in the pit, I agree with you, is not overnight. The doors coming open like this is basically an overnight problem. The weather through this past winter and this past spring in Iowa has been unbelievable, the likes that we have never seen before. And the local co-op who takes our manure out for us was just behind. They had got behind. I take full responsibility --

Mr. Stupak. Or maybe you have too many birds in the house?

Mr. Peter DeCoster. What?

Mr. Stupak. Maybe you have too many laying hens in the

house, that the house can't handle all the manure coming down?
You have too many birds?

Mr. Peter DeCoster. No, sir. The house has got 80,000 birds. It is actually designed for 101,000.

Mr. Stupak. Okay.

Mr. Peter DeCoster. The reason we have 80,000 is we follow the UEP Animal Welfare Guidelines.

But this problem was cleaned up that very day that this picture was taken. And what the picture doesn't show you is that there was a manure crew on-site taking this manure out.

Mr. Stupak. Okay. Did DeCoster Farms, you as operating officer -- you knew about the FDA putting out a final rule in July. Did you comment while that rule was being developed? Did you comment, submit comments to the FDA on how you thought the rule should be?

Mr. Peter DeCoster. I don't believe I commented on the rule that came out in 2009.

Mr. Stupak. Okay. So you didn't need the rule to understand that this was unacceptable.

Mr. Peter DeCoster. Yeah, this doesn't have really much to do with the rule.

Mr. Stupak. Right. I realize that.

Mr. Peter DeCoster. And then what -- the problem I have with this is not the manure in the pit, sir, but the fact that the door is gapped open and it can allow mice inside our facilities.

Mr. Stupak. Sure. There is also another photo of manure coming out of the side of some holes. There's holes in your building, and the mice would have been going in those holes, but they probably couldn't get in because the manure was coming out.

So, with that, my time has expired. Mr. Burgess for questions?

Dr. Burgess. Thank you, Mr. Chairman.

Mr. Bethel, I understand you asserted your privilege under the Fifth Amendment, but, nevertheless, I do want to ask you one question. Please feel free to answer it if you wish.

An e-mail dated August 31, 2010 from you to John Glessner states, quote, "Hillandale needs to totally disassociate itself from Jack, and it has to be real. Hillandale has a good business base, but it will be all gone if I don't move quickly. And I will not try to deceive the public," closed quote.

First, do you recall sending this e-mail? Is the reference to "Jack" Jack DeCoster? And further, why did you state that Hillandale needs to disassociate itself from Jack DeCoster?

And why did you feel a need to state that you will not try to deceive the public? Had someone previously asked you to deceive the public? And, if so, would you please share with the committee who that would be?

Mr. Bethel. I respectfully decline to answer the question based on the --

Mr. Stupak. Sorry, Mr. Bethel, would you please turn on the

mike and pull it forward and then read your statement again?

Mr. Bethel. I respectfully decline to answer the question based on the protection afforded me under the Fifth Amendment of the Constitution.

Dr. Burgess. I appreciate that. As the chairman did not excuse you as a witness, I felt obligated to ask you that question, because it was a significantly important part of our investigation.

So, Mr. DeCoster -- and either Mr. DeCoster -- let me ask you this: You have seen the photographs. We have talked about the photographs taken by the Food and Drug Administration inspectors at your farms to document the observations made in Form 483 and show what appear to be astonishingly unsanitary conditions.

How would you characterize these photographs? And do they warrant the alarm and concern being voiced here today? And, if not, share with us why not.

Mr. Peter DeCoster. Yes, sir. Thank you.

The photo -- and I haven't looked at all of them in detail, Mr. Congressman. But the rodents that were brought up in the 483, if we could take that one first. There was 31 rodents that was counted by FDA, and those 41 rodents were found in going through over 107 barns that we own. These barns cover approximately 66 acres of ground, just on the upper level, not counting the manure pits. So --

Dr. Burgess. Now, you know, rather than going through and

dissecting out the data, do you think the alarm that has been evidenced here today, is that warranted?

Mr. Peter DeCoster. I would like to invite each and every member of this board to come and view --

Dr. Burgess. I wish we had had that opportunity also, Mr. DeCoster, but it wasn't afforded to us by the majority.

Let's go on. I may submit some questions to you in writing, but, as you see, the chairman has a pretty quick gavel with me.

Prior to the FDA egg rule, there were no Federal requirements, testing requirements, for Salmonella at egg production facilities, but some States and some industry groups voluntarily set guidelines.

So if the Salmonella testing is not required by law, when and why did you start testing for Salmonella?

Mr. Peter DeCoster. Our reason for testing for Salmonella, we first originally started testing to see if we may have it. We didn't have any trace-backs, we didn't have any reported illnesses. There was no government agency that says that we should test. We tested voluntarily because we was trying to learn if we had the problem, and then if we did have the problem, what would be the best practices that we could set forward --

Dr. Burgess. Yeah. Now, I'm going to interrupt you again. I'm not trying to be rude. But let me just suggest that if you took 72 swabs in 1 day and all but 8 tested positive, you've got a problem.

Mr. Peter DeCoster. Well, yes, sir, and we --

Dr. Burgess. Can I suggest that to you?

Mr. Peter DeCoster. Well, you can suggest it, sir. But I would like to talk to Dr. Chuck Hofacre. He is the leading expert on this. And he has been guiding us through this whole --

Dr. Burgess. And I will tell you what, let me submit that to you in writing, because I do want to get an additional question in.

Prior to the egg rule, when your company received a positive environmental result for Salmonella, what corrective action did you take? And did you automatically test the eggs as a precautionary measure?

Mr. Peter DeCoster. The results -- we have been taking this kind of as -- over a period of time, we have been learning more and working with Dr. Hofacre. But we have implemented things such as vaccinating, and then vaccinating the flocks twice as we learn more. We have eliminated molting in our system. And we have also eliminated the use of meat and bonemeal.

Dr. Burgess. I'm going to stop you because I'm about to run out of time.

When did the FDA come to you and suggest that you needed to recall your eggs? Do you remember the calendar date?

Mr. Peter DeCoster. I'm going to say the first, initial contact was a phone call, and that would have been August 12th.

Dr. Burgess. And what date did you institute the recall?

Mr. Peter DeCoster. The very following day. We received that call that late afternoon, and the very next day we issued the recall.

Dr. Burgess. Were you required to do so?

Mr. Peter DeCoster. No, sir. This was a voluntary measure that we --

Dr. Burgess. Thank you, Mr. Chairman. I appreciate your indulgence.

Mr. Stupak. Thank you.

Does any other Member wish to ask Mr. Bethel a question? Because I'm about to excuse him since he has invoked his Fifth Amendment. I had asked Members to refrain from asking him a question. The reason why I did not dismiss you after is because Mr. Burgess was insisting on asking you a question. It is not -- because if I wouldn't have given him the opportunity, he would have accused me of censorship. So I thought I would give him that opportunity.

So does any other Member -- seeing no other response, Mr. Bethel, you certainly invoked your rights, and that is your right and privilege here. And thank you for being here, but you will be dismissed from this panel.

Mr. Bethel. Thank you.

Mr. Stupak. Mr. Waxman for questions.

The Chairman. Thank you, Mr. Chairman.

Mr. Jack DeCoster, how long have you been in the business of

chickens and eggs?

Mr. Austin DeCoster. Since 1949, September 5th, when my dad died.

The Chairman. Uh-huh. So you inherited the business from your father, as your son is doing the business with you?

Mr. Austin DeCoster. Yes. He had 125 hens. I took them over.

The Chairman. Now, you have had a history of over 30 years of problems with Salmonella-infected eggs, and you had a pretty sordid record. You said it was because you were a small operation and you got bigger and you still operated as if you were a small operation. You had problems in the 1990s, and you had problems in Maine and Maryland. Now you're in Iowa, and you don't want to have any problems anymore. So you said you really tried to change your operation. You modernized and cleaned up the facility.

But that's not what the record indicates. FDA conducted an inspection. They did this last August. I want to read you some passages and ask you to respond.

They found, quote, you "failed to achieve satisfactory rodent and pest control, as evidenced by the following: live and dead flies too numerous to count. The live flies were on and around egg belts, feed, and shell eggs. In addition, live and dead maggots too numerous to count were observed."

Does this sound like a clean facility to you?

Mr. Peter DeCoster. Mr. Congressman, if you don't mind, I

would like to answer the 483 questions for Iowa.

The Chairman. Well, I'm happy to hear from you because you're very much involved in running the operation now. But your father has been in this business for longer than you have, and he wanted to make sure he is living up to a higher standard. I want to know if he feels this is a higher standard.

Mr. Austin DeCoster. Okay. Well, higher standards in the State of Maine, where I live --

The Chairman. Well, I'm not asking about Maine. I'm asking about the report of the inspection from the FDA. You were determined to run a clean operation, and then they found all these dead flies and maggots and other problems. Does that bother you?

Mr. Austin DeCoster. It bothers me a lot. But I feel like Peter -- we have a certain way we handle flies, a certain way we handle mice. We have hired Maxcy Nolan, who is considered an expert.

The Chairman. When did you hire him?

Mr. Peter DeCoster. Maxcy has been coming out to our facility since last summer. And he set up our fly and rodent program.

The Chairman. Well, I want to read to you another finding from the FDA, and you may want to consider firing this guy.

The FDA said you "failed to take steps to ensure that there is not introduction or transfer of SE" -- Salmonella Enteritidis -- "into or among the poultry houses. This was

evidenced by the following observations: uncaged birds. Chickens having escaped were observed in the egg-laying operation in contact with the egg-laying birds. The uncaged birds were using the manure, which was approximately 8 feet high, to access the egg-laying area."

What this means is that the chickens had escaped the henhouse, they were walking in the manure pit, and then mixing in with the caged birds. Do you agree with the FDA that this is a violation of appropriate safety standards or procedures?

Mr. Peter DeCoster. We are, kind of, jumping around a little bit. We are going from rodents to flies to loose chickens. But if we want to stick with the loose chickens for a minute, there was -- they observed two or three loose chickens that had got out of their cages in a couple different houses. And in the course of our barn men doing their work, they will access a cage, whether it be a sick hen, a water nipple that may be leaking or need repair, and a chicken can escape when they open the door. Or if they forget to close the door completely, a chicken can escape.

Now, these chickens --

The Chairman. Mr. DeCoster, let me interrupt you to say this. You have had problems in the past, right? Over 30 years of problems in different States. You had a call from the FDA to recall your eggs, and you voluntarily did that, and then the inspection took place.

Mr. Peter DeCoster. Yes.

The Chairman. That's when the FDA found all these problems. You've claimed that you were going to modernize and clean up your facility, but it doesn't appear that you have modernized and cleaned up your facilities. It sounds like, to me, that both of you are refusing to take responsibility for a very poor facility.

According to the FDA inspections, they found all these rodents. You would think, after you were called on to recall the eggs, you would have made sure your facility was cleaned up. Maybe you did. Maybe this is as clean as you got it, but it still looked pretty dirty.

How do you respond to that?

Mr. Peter DeCoster. Well, hopefully I will be allowed to finish this time. But, I mean, we are jumping all over the place. You're not giving me fair time to answer the question. And then --

The Chairman. Well, then I'm going to -- I'm going to have your father respond, because he talked about how he wanted to clean up the facility. And I want to ask him to tell us whether he approves of the conditions and how his son operates the facility.

Mr. Peter DeCoster. Mr. Congressman --

The Chairman. After this FDA inspection, all of these problems they just found, after the recall already started, do you think this is a satisfactory way for the facility to be run?

Mr. Peter DeCoster. Mr. Congressman --

The Chairman. I have asked your father. I have asked your father. I'm asking the questions.

Mr. Jack DeCoster?

Mr. Austin DeCoster. Yes, I follow what you are saying. Okay? However, this is a very big operation. We have a certain way we go about running it. Regardless --

The Chairman. You had problems when you ran it that way, and you were going to clean it up. So, where you are now is, you feel, cleaned up and adequate?

Mr. Austin DeCoster. Sir, please, let me talk, okay?

We have a certain way that -- our barn man goes into the chicken house. He has a certain way he does this work. Okay? He starts in the morning, he pulls out the dead chickens. He spends a certain amount of time checking the egg belts, taking the dead chickens out, checking the water, checking the lights. Then what he does, he goes and he sweeps all of the barns. He goes into the pits. He checks the leaking water that is coming down from upstairs into the pit. He checks loose birds in the pit. He puts light bulbs in if there's any missing light bulbs. He was supposed to be checking this door that was pushed out. That door would not stay like that very long.

The Chairman. Mr. DeCoster, we only have a certain amount of time, and my time is pretty much over. But I do want to tell you this.

Mr. Austin DeCoster. I'm sorry.

The Chairman. It is hard for me to reconcile your words, that you wanted to clean up and you did clean up the facility, with the record before the committee. The conditions in your facility were not clean, they were not sanitary. They were filthy. And given the 30-year record of violations, it appears that you are a habitual violator of basic safety standards. And I must say, for you to come before us and say, "It is the feed; we had nothing to do with it," it is hard for me to believe and accept at face value.

My time has expired, but I just want you to know my thoughts about it.

Mr. Stupak. The gentleman's time has expired.

Mr. Latta for questions, please.

Mr. Latta. Thank you very much, Mr. Chairman.

Mr. DeCoster, Peter, looking at this report, this 483, the date of issue is August the 30th. How often has the FDA been inspecting?

Mr. Peter DeCoster. That's the first time the FDA has been to our facilities.

Mr. Latta. For any of your facilities? Okay.

Mr. Peter DeCoster. Well, for the barns, the chicken barns.

Mr. Latta. Okay. Let me ask, is the USDA on your premises at all times or at the different houses?

Mr. Peter DeCoster. The USDA EMS does grading of our processing plants, all of our processing facilities. We have the

voluntary program of USDA, which, you know, we incur the cost.

Mr. Latta. Okay. But, again -- I know I have been in different houses and facilities, and there is usually someone from the USDA. Is there a USDA person on the premises part of the time, all the time?

Mr. Peter DeCoster. USDA would be in the processing plant during the hours of operation, generally from 6:00 in the morning until whenever we finish in the afternoon.

Mr. Latta. Okay. Do you have the Department of Agriculture in Iowa inspecting out there? Does the Department of Agriculture in Iowa inspect facilities?

Mr. Peter DeCoster. No, sir. The DNR would inspect any environmental-type issue, but Department of Ag has never been out to inspect.

Mr. Latta. Okay. What does your DNR do?

Mr. Peter DeCoster. It stands for the Department of Natural Resources.

Mr. Latta. Right, right, but, I mean, what is their role on the farm, then?

Mr. Peter DeCoster. Their role is basically on any environmental issue. If manure threatens the water of the States would be one of the major ones.

Mr. Latta. Okay. When they do their -- now, they do, like, an inspection of the houses around the facility? Do they do water-quality tests like in -- you know, I come from the largest

county in the State of Ohio that has ditches. I've got 3,000 miles of ditches in my home county. And so, you know, are they doing water-quality tests in ditches? Is that what they are doing? Are they away from the facility, or are they on the facility's site?

Mr. Peter DeCoster. The only thing they would inspect on the facility is a complaint or if there is an annual inspection on the lagoons.

Mr. Latta. Okay. Now, and talking about, like, with the lagoon -- and I heard what you said about it was a wet spring out there, and I know it was a wet spring in Ohio, trying to get crops out. What is your manure management plan? Do you have to file that with someone?

Mr. Peter DeCoster. Yes, there's manure management plans on every CAFO in Iowa. Our manure management plan, because we do the sale of our manure with the local co-op, who uses it for fertilizer, they have the manure management plan.

Mr. Latta. Okay. And who do you file that CAFO plan with?

Mr. Peter DeCoster. The DNR.

Mr. Latta. The DNR. Okay, do they -- okay. Now, because I know we were just talking about looking at water quality and things like that, does the DNR then do an inspection around the buildings, then, on that for the CAFO?

Mr. Peter DeCoster. Not on a regular basis. But the DNR, after, I guess, reading some of the articles in the newspaper,

came up and did an inspection around our layer barns and said everything looked okay. I haven't heard anything more.

Mr. Latta. Okay. Now, let me ask you, then, when you say they come not that often, how often would they come around from DNR on that end?

Mr. Peter DeCoster. Normally, under those type of circumstances, if they are called out to do it.

Mr. Latta. So they wouldn't do it on, like, a 6-month or 12-month basis?

Mr. Peter DeCoster. No.

Mr. Latta. Okay. Now, who hauls your -- you know, how often do you have to clean your barns? Are your barns deep pit, or do you have conveyer --

Mr. Peter DeCoster. The majority of our barns are deep pit, like the pictures show here, but we do have one facility that is a belt battery, where the manure is removed on a daily basis and put in another barn.

Mr. Latta. And then, with the deep pit, how do you get that out? Are you using, like, skid steers, Bobcats?

Mr. Peter DeCoster. Yes, skid steers. Bobcat would be a brand that would be used. But they go through these doors that are shown in the picture.

Mr. Latta. And then, how often would they do that?

Mr. Peter DeCoster. Our program was to clean every barn every other year. We did that for a measure of fly control.

Fresh manure, you tend to have a better environment for the flies. So we was going with every other year, which we have changed that policy last year to remove the manure every year.

Mr. Latta. Thank you.

Mr. Chairman, I think my time has expired, and I yield back.

Mr. Stupak. Thank you, Mr. Latta.

Mr. Braley for questions, please.

Mr. Braley. Thank you.

Gentlemen, you weren't here earlier when I delivered the ode to the Iowa egg. And I can tell you, I have personally been supporting the Iowa egg industry for 53 years, and there is no bigger fan of the products you produce.

But I also was sitting down to breakfast in a restaurant when I first heard about this story. And I can tell you, it literally made me sick to my stomach and caused me to order something different on the menu.

And then I was down at the Iowa State Fair earlier this year, in the Varied Industries Building, looking at a lot of very nervous egg producers with the Iowa Egg Council.

So I'm going to ask each one of you, do you feel any personal responsibility to the impact that this recall, this massive recall, is having on Iowa egg producers?

Mr. Mangskau?

Mr. Mangskau. It is too bad that this occurred, and we do feel sorry for any inconvenience and cost that it has caused the

industry.

Mr. Braley. I apologize to the two Misters DeCoster, but it's easier if I just refer to you by your first names, if that's all right.

Mr. Peter DeCoster. That's fine.

Mr. Braley. Peter?

Mr. Peter DeCoster. Yeah, absolutely. I mean, this -- this is an issue I feel terrible has occurred, and it is affecting our industry.

Mr. Braley. Jack?

Mr. Austin DeCoster. I feel very bad about it, very bad. It is a horrible thing.

Mr. Braley. Well, the problem that egg producers in Iowa and all over the country are facing is a series of headlines like the one in today's New York Times, "An Iowa Egg Farmer and a History of Salmonella"; the Los Angeles Times, "Filthy Conditions Found at Egg Producers"; "Egg Farms Violated Safety Rules"; "FDA Details Numerous Violations At Egg Farms"; "Egg Recall: Mouse, Fly Infestations Date Back 10 Years, Workers Say"; Tainted Eggs Reveal Lapse in State Protocol."

And the problem that a lot of us have here on this committee is a sense that there is a disconnect between the problems identified in these stories and identified in the FDA's investigation and the sense of responsibility.

And we had two witnesses who testified at the earlier panel

who talked about the personal impact that this Salmonella contamination had on them.

Here is the story in today's New York Times: "On a July night in 1987, scores of elderly and chronically ill patients at Bird S. Coler Memorial Hospital in New York City began to fall violently ill with food poisoning from eggs tainted with Salmonella. 'It was like a war zone,' said Dr. Philippe Tassy, the doctor on call as sickness started to rage through the hospital. By the time the outbreak ended more than 2 weeks later, 9 people had died and about 500 people had become sick. It remains the deadliest outbreak in this country attributed to eggs infected with the bacteria known as Salmonella Enteritidis. This year, the same bacteria sickened thousands of people nationwide and led to a recall of a half a billion eggs. Despite the gap of decades, there is a crucial link between the two outbreaks. In both cases, the eggs came from farms owned by Austin J. DeCoster, one of the country's biggest egg producers."

And, Jack, I think one of the things that people around the country are asking is, if your company's commitment to food safety is as strong as you have indicated in your opening statement to this committee, how is it possible that, after all this time, we have another DeCoster egg producer involved in a half-billion-dollar recall?

Mr. Austin DeCoster. Well, the question is complicated, sir.

Mr. Braley. I would like the record to reflect that the

counsel for the witness has handed him a document.

Mr. Austin DeCoster. Congressman, this SE happened 23 years ago in one of our farms in Maryland. We destroyed the flocks. After we destroyed the flocks, we cleaned it all out, washed it all up, and then put the new pullets in it. And then, it wasn't very long after that that we -- after we put the new pullets in -- which we bought these pullets from a company in Indiana. It wasn't ones that we raised, or at least not all of the ones we put in the complex.

And after we get it all filled up again with new birds, all clean, we thought -- and we had, also, a person from Pennsylvania, a doctor, coming down to our flocks and testing all of them, reporting that they was okay. And then we had a reason to take a bird or a few birds down to the Salisbury Laboratory in Maryland. And we took them down, and they found SE in a bird or -- I don't remember too clearly right now, but they at least found Salmonella in the birds.

So then FDA came over to our place. And way back then FDA came over, and they tested every one of our flocks and our chicken houses. And if I remember this correctly -- this was a long time ago -- but we had to take out at least half of all the flocks again, maybe -- it was a seven-house complex. We had to take at least three to four flocks out. We had to wash it all again, and then we filled it back up again.

And then, as I remember it, the next time it was okay.

Mr. Braley. Mr. Chairman, my time has expired. But I would ask unanimous consent to submit for the record the editorials that I referred to earlier in my questioning.

Mr. Stupak. Without objection -- before they are entered, a request to see them. So if you would provide them, we will look at them. Then, without objection, we will put them in.

[The information follows:]

***** COMMITTEE INSERT *****

Mr. Stupak. Mr. Dingell for questions, please.

Mr. Dingell. Thank you, Mr. Chairman. And I commend you for this hearing and for the extraordinary leadership that you have given in our efforts to reform and to enhance the powers of FDA.

My questions are going to remind me of a day in 1990 when this subcommittee went into the questions of food safety and, indeed, in Salmonella in eggs.

I would like to welcome you both, Messrs. DeCoster. And I'd begin my question by saying this: The Food and Drug Administration's staff reports on this matter, which I ask unanimous consent be inserted in the record --

Mr. Stupak. Without objection.

Mr. Dingell. -- refer to inquiries about your facilities.

[The information follows:]

***** COMMITTEE INSERT *****

Mr. Dingell. And they say, "Barns were infested with flies, maggots, and scurrying rodents. Manure piled 4 to 8 feet high in certain areas. Leaking manure pits. Employees working without protective clothing. And uncaged hens tracking manure from manure pit to other areas of the operation."

Is that true?

Mr. Peter DeCoster. We've -- if we could take one of these at a time. The comment about the employees --

Mr. Dingell. Well, it is either true or not. Is it true, or is it not true? Yes or no?

Mr. Peter DeCoster. I would say that it's partially true.

Mr. Dingell. Partially true. Well, that's like being partially pregnant. It's pretty hard to do.

Now, having said this, you were having trouble in the 1990s, and it resulted in a calamitous situation at the Bird S. Coler Memorial Hospital in New York, just referred to by one of my colleagues.

I'm curious here, do you dispute any of the allegations made in the reports by Food and Drug, yes or no?

Mr. Peter DeCoster. On the 483?

Mr. Dingell. The reports of the Food and Drug staff to Food and Drug, do you dispute any of the statements in those with regard to the conditions at your farms?

Mr. Peter DeCoster. Yes, sir. When we did our --

Mr. Dingell. Specifically which ones do you dispute?

Mr. Peter DeCoster. Okay, the one that you brought up about the people going from one barn to another. That was not specified in the FDA's rule, that it says even in their guidance document --

Mr. Dingell. Okay. Is that your only dispute?

Mr. Peter DeCoster. No, sir.

Mr. Dingell. What others do you dispute?

Mr. Peter DeCoster. Well, the dispute we had also -- they named some manure doors that they said was pushed open from manure, and they were not. There was only 4 doors that were like that out of the 292. The --

Mr. Dingell. Now, do you dispute the finding that there were live mice and dead flies too numerous to count in your facilities?

Mr. Peter DeCoster. I would say there was live and dead flies. This is a farm; they are chicken barns. We have a very stringent fly program that Dr. Maxcy Nolan has laid out that is even tougher than the FDA rules.

Mr. Dingell. Do you dispute the statement of Food and Drug that these conditions do not promote safety and quality?

Mr. Peter DeCoster. I guess I'm not familiar with that statement.

Mr. Dingell. Okay. What plans do you have in place to prevent Salmonella contamination?

Mr. Peter DeCoster. We have outlined a very extensive plan that we submitted to the FDA.

Mr. Dingell. Would you submit those plans for the record, if you please?

Mr. Peter DeCoster. Yes, I'd be more than happy to.

[The information follows:]

***** COMMITTEE INSERT *****

Mr. Dingell. All right. Now, I understand that two positive SE samples were collected from your feed mill. Is this true?

Mr. Peter DeCoster. Yes. There was two swabs that were positive.

Mr. Dingell. The source is thought to be a raw ingredient acquired from a third party. Is this true?

Mr. Peter DeCoster. That's what we believe, sir. We have not --

Mr. Dingell. Now, what levels of responsibility do you have for the ingredients you receive from third parties and subsequently use in your operations?

Mr. Peter DeCoster. We've put in a full array of testing. We're taking samples from every incoming load. We've talked to all of our vendors, for them also to do testing. We are going to do a composite on these loads weekly and send them in for testing. We are going to do a monthly swabbing of our feed mill. We are currently in the process of completely cleaning and disinfecting the entire mill from top to bottom. And we have done extensive employee training to make sure that the mill is kept tightened up, so that there is no open hatches as noted in the --

Mr. Dingell. What steps do you take to ensure that those planned or announced safeguards are implemented?

Mr. Peter DeCoster. We have a daily inspection by the mill manager. Then we have an outside supervisor who is going to

inspect the facilities once a week and give me a full report.

Mr. Dingell. Do you still have -- do you still have your hog operations?

Mr. Peter DeCoster. We own some hog facilities, but we don't own any hog --

Mr. Dingell. I'm sorry?

Mr. Peter DeCoster. We don't operate hog facilities. We just lease them.

Mr. Dingell. I see.

Mr. Chairman, I note with some distress that my time is up, and I thank you for your courtesy.

Mr. Stupak. Thank you, Mr. Dingell.

Ms. DeGette for questions, please.

Ms. DeGette. Thank you, Mr. Chairman.

Mr. DeCoster, your company hires a private auditing company to audit Wright County Farms annually, correct?

Mr. Peter DeCoster. Yes, ma'am.

Ms. DeGette. And this company is AIB, which is a private, for-profit food-safety auditing firm, correct?

Mr. Peter DeCoster. Right. They are --

Ms. DeGette. Thank you. Okay.

And if you will turn to Tab 5 of the notebook in front of you, on June 7th and 8th, 2010, your farm was actually inspected by AIB, correct?

Mr. Peter DeCoster. Yes, ma'am.

Ms. DeGette. And AIB actually issued a superior certificate to the farm, correct?

Mr. Peter DeCoster. Yes, they did.

Ms. DeGette. And this has been happening -- you get inspected annually. And if you'll take a look at Tab 7 of your notebook, on August 20th, 2008, the farm was also -- oh, I'm sorry, that's a different one. Let's just stick with Tab 5 for a minute. I'll talk about Tab 7 in a second.

So AIB audited your company in 2008 two times, four times in 2009, and at least one time in 2010. And every time, you were found to be superior. Is that correct?

Mr. Peter DeCoster. Yes. This is an inspection of the processing facility --

Ms. DeGette. Uh-huh.

Mr. Peter DeCoster. -- and not of the chicken barns.

Ms. DeGette. Okay.

And what I wanted to talk about with Tab 7, if you'll look at that, unbelievably to this committee, in 2009 AIB was the same auditor that audited the Peanut Corporation of America and also gave them a superior recommendation.

Do you see that in your notebook, as well?

Mr. Peter DeCoster. Yes, ma'am.

Ms. DeGette. So here's the thing, is both the Peanut Corporation of America and Wright County Egg paid AIB to audit their companies and receive superior ratings right before both

companies sold products that sickened thousands of people with Salmonella.

And, Mr. Chairman, I bring this up to say that just relying on third-party auditors is not going to guarantee consumer safety, which is why, getting back to all of our point, we need to pass this bill.

I wanted to ask you a couple of questions, Mr. Mangskau. In your opening statement, you said, "In order to get fresh, quality eggs to market, Hillandale must be able to rely on good production and good processing," correct?

Mr. Mangskau. That is correct.

Ms. DeGette. You can't have good production and good processing without a clean and up-to-standard facility, correct?

Mr. Mangskau. Yes.

Ms. DeGette. And you also said in your opening statement that you were surprised it was difficult -- quote, "difficult to understand" why FDA was saying your eggs were responsible for seven people sick at one restaurant, correct? Because you thought that your processes were good; is that right?

Mr. Mangskau. That's correct.

Ms. DeGette. Okay.

Now, the FDA inspected your facilities August 19th through August 26th, 2010, and they found numerous, quote, "unsealed rodent holes, liquid manure streaming from a crack in the manure pit, and uncaged hens tracking manure through the laying

facilities."

Do you think that that's up to a standard of care, sir?

Mr. Mangskau. Those -- the rodent holes were open because we were baiting them.

Ms. DeGette. Okay. Do you think those findings are consistent with the high standard of care at the facility, yes or no?

Mr. Mangskau. No.

Ms. DeGette. Thank you.

Now, you said a minute ago, when someone asked you about -- Mr. Braley actually asked you about the effect on the egg industry, and you said you apologized for any inconvenience.

Do you have any idea how much the egg industry's profits have gone down because of these recalls?

Mr. Mangskau. I would not know.

Ms. DeGette. Do you know that, Mr. DeCoster?

Mr. Peter DeCoster. No, ma'am. I don't have knowledge of that.

Ms. DeGette. All right.

Well, Mr. Chairman, I think we'll find that out, because I am sure it's millions and millions of dollars.

Mr. DeCoster, I wanted to ask you one last question, and that is: Chairman Waxman was talking to you about the condition of the facilities, which you apologized for. But you also seem to think that perhaps the Salmonella came in in the feed, correct?

Mr. Peter DeCoster. That's what we are believing at the moment.

Ms. DeGette. Okay. So here is my question. You're running large egg facilities. Do you have a regular system where you test the feed that comes in, to make sure that it is not contaminating the chickens that eat it?

Mr. Peter DeCoster. We don't test -- we did not test for --

Ms. DeGette. Are you going to establish such a system now, sir?

Mr. Peter DeCoster. Yes, ma'am. That is what I was talking about earlier with the testing every load and doing a weekly composite and sending that into the lab.

Ms. DeGette. Right.

Mr. Peter DeCoster. We're currently doing that.

Ms. DeGette. Probably you should have been doing that all along, huh?

Mr. Peter DeCoster. Yes. In hindsight, yes, ma'am.

Ms. DeGette. Thank you.

Thank you, Mr. Chairman.

Mr. Stupak. Thank you, Ms. DeGette.

Mr. Doyle for questions, please.

Mr. Doyle. Thanks.

Mr. Mangskau, I want to ask you about the role you played in Hillandale's egg operations in Iowa. When did you start working for Hillandale Farms?

Mr. Mangskau. I was hired in March of 2010.

Mr. Doyle. And, at the time of the recall, what were your responsibilities at the two facilities?

Mr. Mangskau. I was overseeing the plant at West Union and working -- trying to work into the opportunity to have more control of the day-to-day productions at the Alden facility.

Mr. Doyle. Now, I understand that one Hillandale facility is located in Alden, Iowa. And in a letter to committee staff, dated September 17th, 2010, the lawyers for the company wrote that, in this facility, Hillandale, quote, "has virtually no authority over the production and processing aspects."

And in regards to the second facility in West Union, your company lawyer stated that Hillandale has limited responsibility for the production and processing phases of that facility.

Mr. Mangskau, can you clarify what role Hillandale played at these two facilities?

Mr. Mangskau. When I was hired in March by Hillandale Farms, they wanted me to come back and work with the West Union facility initially, start to take a role in the day-to-day operations there, and, as time went on, hopefully to work into some day-to-day control at the Alden facility.

Mr. Doyle. Uh-huh. Who owned the buildings on these farms?

Mr. Mangskau. To the best of my knowledge, Wright County Farms owns the Alden facility and has a shared interest in the West Union facility.

Mr. Doyle. How about the chickens? Who owns the chickens?

Mr. Mangskau. I don't have any direct knowledge on who owns those.

Mr. Doyle. How many Hillandale employees do you have at each of these facilities?

Mr. Mangskau. The people at West Union are Hillandale employees. It varies up and down, and there's probably in the forties in payroll there.

Mr. Doyle. In your testimony, you stated that Hillandale has terminated its marketing relationship with Wright County Egg at the Alden facility. To your knowledge, does Hillandale have any other business relationships in other States with Mr. DeCoster or any of his associates?

Mr. Mangskau. That's outside of the scope of my job duties.

Mr. Doyle. So I guess I get Hillandale didn't make the eggs; Wright County did. But you're a major egg producer too, and you're in a position to know whether you're running a clean and safe operation.

Let me ask you, in light of this recall, how has this changed the culture at Hillandale on how you produce eggs and do business?

Mr. Mangskau. Well, it's definitely going to make us take a closer look at what we do. We have hired two consultants to come in. The gal that was at the FDA and the person with food safety at several Fortune 200 food companies, we brought them in. They are going to be doing recommendations to improve our food-safety

programs.

We have discontinued our agreement with the Wright County Farms at Alden. We will no longer be receiving pullets that Wright County has raised for the West Union facility. We are bringing on another staff position at West Union to increase and do a better job of documentation on quality control.

Mr. Doyle. Okay. Well, you know, Hillendale Farms is a brand I see in my store all the time in Pittsburgh, and I venture to say that I've eaten hundreds of your eggs. I want to continue to feel good about picking those boxes up when I go to the supermarket.

You know, the important thing that comes out of this hearing and subsequently if we can finally get a bill out of the Senate, we just want to make sure that every consumer, when they go into that store, has a good feeling about a brand when they see it. And your company has a pretty good reputation in my neck of the woods, so I was surprised to see your name mentioned when this broke out.

But I hope it is a wake-up call to everybody in the industry, that Americans expect -- have a right to expect that, when they buy your food, your products, that you're not going to make them sick or, worse yet, cause them to die.

Mr. Chairman, I see my time has expired.

Mr. Stupak. Thank you, Mr. Doyle.

That concludes the questions from the panel. I'm going to

excuse this panel. And thank you for coming today, but you will be excused.

We'll go to our third panel in a moment here.

On our third panel today we have Dr. Josh Sharfstein, deputy commissioner, Food and Drug Administration.

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?

Dr. Sharfstein. No.

Mr. Stupak. Okay. Then I'm going to ask you please rise, raise your right hand, and take the oath.

[Witness sworn.]

Mr. Stupak. Let the record reflect the witness has stated that he will -- he testified in the affirmative that he understands he is now under oath.

Dr. Sharfstein, welcome. And you may begin your opening statement, please.

**TESTIMONY OF JOSHUA M. SHARFSTEIN, M.D., PRINCIPAL DEPUTY
COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION**

Dr. Sharfstein. Thank you. Good afternoon, Chairman Stupak, Congressman Burgess, and members of the subcommittee. I am Joshua Sharfstein, the principal deputy commissioner of the U.S. Food and Drug Administration. Thank you for the opportunity to appear before you today to discuss the recent food-borne illness outbreak caused by Salmonella Enteritidis.

I would like to provide some general background on egg safety, discuss the outbreak and response, and then talk about what FDA and Congress can do to further protect the food supply.

Salmonella Enteritidis, or SE as it is known, is a pathogen known to contaminate eggs. Contamination can occur when bacteria is passed from the chicken to the inside of the egg or when bacteria passes through fractures in the shell. If not fully cooked, eggs with Salmonella Enteritidis can cause human disease.

If an egg farm is out of control for Salmonella Enteritidis, then many thousands of illnesses can result. It is estimated that contaminated eggs cause as many as 140,000 illnesses a year in the United States.

In 1999, FDA announced an Egg Safety Action Plan to reduce this enormous burden of illness. FDA staff pushed for a decade to put into place specific safety standards at egg production facilities. The agency finalized its rule in July 2009, with

provisions to take effect starting in July 2010.

FDA's egg rule requires producers to have a clear plan for preventing SE contamination and to implement recognized control measures that reduce the risk of contamination, including buying chicks and young hens only from suppliers who meet standards for producing SE-free birds; establishing rodent, pest control, and other bio-security measures to prevent the spread of bacteria throughout the farm; conducting testing of the poultry house environment for *Salmonella Enteritidis*, and if an environmental sample is found positive, testing eggs and disinfecting the house before adding new laying hens; diverting eggs that have been found to be positive to processed uses; and refrigerating eggs at 45 degrees Fahrenheit during storage and transportation.

Before implementation of this important rule took effect, the number of SE cases nationwide began to grow in late spring. By July, CDC had noticed a significant increase, and several States had begun conducting epidemiological investigations to identify the source of the problem.

FDA set up an emergency response team to help sort through the various theories of what was causing the outbreak and identify its source. The agency relied upon its field staff in multiple States. And, working with CDC and our State and local partners, we traced the problem to eggs produced at several Iowa farms. As soon as this trace-back was completed, FDA recommended, and Wright County Egg agreed, to a major recall of eggs from the linked

farms.

FDA also sent inspectors in to look at the conditions of the nearby farms also under Wright Egg and Hillandale as additional epidemiological evidence accumulated. Because of concerns about the conditions of these farms, FDA recommended and Wright County Egg and Hillandale Farms agreed to additional recalls.

Significantly, these recalls, totaling 500 million eggs, came about 2 weeks before any positive lab findings. FDA acted before confirmatory evidence became available, using our best judgment to protect the public health.

What caused the SE outbreak? FDA inspectors found numerous problems at both farms. These included significant deficiencies in pest control, significant problems with the handling of manure, and significant gaps in bio-security measures to prevent cross-contamination. We also identified SE matching the outbreak strain in the feed mill supply on the farms which are associated with Wright County Egg, in environmental samples at multiple locations on the farms, and in the water used to clean the eggs at the Hillandale Farm.

We believe that there are multiple potential sources of introduction for SE on these farms. Once introduced, these farms did not have the systems in place to control the spread. In fact, some of the deficiencies likely contributed to the spread of SE, leading to widespread contamination.

Prevention of food-borne illness is what consumers expect and

deserve from our food-safety system. With our State and Federal counterparts, we are reviewing this outbreak to understand what the agency can do to improve its work on behalf of the public.

Now that the egg rule is in place, FDA is moving to quickly inspect other egg facilities. To assure that strong preventive efforts are in place, we intend to inspect all 600 or so large egg facilities that are now subject to the rule by the end of calendar year 2011.

In order for these inspections to be as successful as possible, there is something Congress can do to help us. Proposed legislation will give FDA more tools as we are doing these inspections to assure compliance, including enhanced administrative detention authority, civil money penalties, stronger criminal penalties, and mandatory recall.

This critical legislation will also do a lot more than help make eggs safer. It would give FDA the tools to establish appropriate prevention standards much more efficiently across the food supply, and it would strengthen FDA's ability to hold companies accountable for meeting these standards with a new inspection mandate, new resources, and stronger enforcement tools.

The legislation would also strengthen our ability to respond to problems through new traceability standards, mandatory recall authority, and closer collaboration with our State partners to build upon and leverage their frontline capacities.

We hope this Congress will take the historic step of enacting

comprehensive food-safety legislation to give FDA the resources and tools we need for a modern and effective food-safety system.

Thank you very much. I'm happy to take questions.

[The prepared statement of Dr. Sharfstein follows:]

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Mr. Stupak. Thank you, Doctor.

I will begin with the questions.

Salmonella Enteritidis is a major cause of food-borne illness in the United States. In fact, in your testimony you said 140,000 people become -- Americans become sickened each year from it. And it is my understanding approximately 30 deaths per year are directly related to the consumption of eggs contaminated with Salmonella.

My question -- and, as we have heard today, Mr. Dingell started about 1990, where he had a Salmonella-in-eggs hearing with this committee. Mr. Braley mentioned the New York Times. You mentioned 1999, the FDA began to develop a rule. It is my understanding that the Clinton administration in 2000 put forth a proposed rule. And it is my understanding nothing happened until 2004; then President Bush put forth a proposed rule.

Then what happened between 2004 and July of 2010? Why did it take, if you will, 11 years to get a rule out on this? Did different administrations just abandon this effort? I mean, the Obama administration has been here since January of 2009, and you put out a proposed rule out in July of 2009, if I am -- am I correct?

Dr. Sharfstein. That is correct.

Mr. Stupak. And then there is a year of comments and back-and-forth, correct? Public comment?

Dr. Sharfstein. It was a year for implementation. I mean, we actually -- I started at the very end of March as the acting commissioner, and by July we had issued the proposed rule. This was a very high priority for the administration.

Mr. Stupak. Do you know what happened, as you put forth the proposed rule in July of 2009, what happened between 2004 -- I understand President Bush put it forward -- what happened between 2004 and 2009? Five years we lost.

Dr. Sharfstein. You know, I wasn't at the agency at that time. You know, there --

Mr. Stupak. Could you have the agency put up a timeline and see what happened, starting back in 1999 when it was first proposed? Because, for a lot of people, it seems pretty preposterous that it takes us 11 years to put forth a rule.

Dr. Sharfstein. Well, you know, I can tell you that some people who are career employees at FDA have been interviewed about that question.

Mr. Stupak. Okay.

Dr. Sharfstein. And I will quote one, Bill Hubbard, who you may know --

Mr. Stupak. Yes.

Dr. Sharfstein. -- who has testified before the committee. And this is a direct quote from him, that "The FDA simply couldn't get through to the White House. They were very hostile to regulation. I was told that each time FDA tried to get the rule

cleared through OMB, the response was that there were, quote, 'not enough bodies in the street,' that the number of cases, hospitalizations, and deaths did not rise to the level that justified greater regulation of egg producers. Obviously, public health officials felt strongly that there was a strong justification, but the prevailing attitude at the time within the administration was that regulation was an evil that should be avoided unless there was a compelling argument for government action."

That was what Bill Hubbard stated.

Mr. Stupak. Okay. I guess after today we have enough compelling arguments on why we need this final rule for eggs.

But the final rule was put out July 9th, 2010, and it aims at reducing the amount of eggs contaminated with harmful Salmonella. The rule applies to egg producers with 3,000 or more egg-laying hens. This means both Hillandale Farm and Wright County Egg must comply with the new rules.

In questions, both the gentlemen from Hillandale and DeCoster Farms knew about the new rule, but what do we need to implement this rule?

I have a copy of the summary from the FDA on these two farms -- or on these farms here that we have had the egg recall. Starting in September 4th, 2008, to June 12th, 2009, there were approximately 178 violations. After the rule was out, starting on July 31st, 2009, through July 26th, 2010, there's 207 violations.

So it looks like during this period of time when you had the proposed rule, it doesn't look like these farms are trying to do anything to comply with the rule. We have actually increased Salmonella outbreaks after the rule has been proposed.

Dr. Sharfstein. You're referring to their testing of Salmonella at the facility, I believe.

Mr. Stupak. Correct.

Dr. Sharfstein. Those results were not disclosed to FDA. And, under our rule, if you get a contaminated finding in the facility, you have to go ahead and test the eggs. So there would be a different response to those findings under the rule.

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[3:00 p.m.]

Mr. Stupak. All right. So, underneath the proposed rule, or the final rule, I should say, if I have a positive test, I have to report it to the FDA.

Dr. Sharfstein. If you have a positive test as part of the testing procedure, it is, in fact, available to the FDA.

Mr. Stupak. But they would have to notify you, correct?

Dr. Sharfstein. I don't -- I'll have to get back on whether they affirmatively notify us. I think --

Mr. Stupak. All right. Okay. Well, let me ask you this.

Dr. Sharfstein. -- it's not reported to us, but it's available to us.

Mr. Stupak. Okay. Let me ask you this: How would the newly implemented egg rule -- what does that really mean for the American consumer? What can we expect?

Dr. Sharfstein. It means a lot. Because it means that we can go now to all the major egg facilities and we can make sure that they have very important preventative safeguards in place, including an approach to rodents that keeps the rodents out of the eggs, an approach to general contamination, an approach to refrigeration, and an approach to testing, so that they can have confidence that the farms in the United States, as, you know, overseen by FDA with an independent look, are following things to

prevent illness in the first place.

Mr. Stupak. Okay. This final rule that's now in place and has the effect, applies to those farms, egg-producing farms, with 3,000 or more egg-laying hens. How many farms is that in the United States? We have heard from two today, but how many are there?

Dr. Sharfstein. I know that there are about 600 that are 50,000 or more. I think there are several thousand that are between 3,000 and 50,000. We'd have to get the exact number to you.

Mr. Stupak. Okay.

My time has expired. Mr. Burgess for questions.

Dr. Burgess. Thank you, Dr. Sharfstein, for being here.

So now you have the ability to inspect egg-producing facilities? Is that correct?

Dr. Sharfstein. That's correct.

Dr. Burgess. And now, this --

Dr. Sharfstein. Well --

Dr. Burgess. -- just came under your jurisdiction in July?

Dr. Sharfstein. No. What started in July --

Dr. Burgess. Well, let me ask you a question. Did you have the ability to do these egg inspections in 1999, 2004, 1990, all of these other dates that have been mentioned?

Dr. Sharfstein. FDA had jurisdiction over egg production farms, but we didn't have these standards against which we could

inspect.

Dr. Burgess. Were you prohibited from inspecting?

Dr. Sharfstein. No.

Dr. Burgess. Let me ask you this. And I guess you've already answered the question about how many egg production facilities are under your jurisdiction: 600 large-scale productions with greater than 50,000 hens. Now, over the last 5 years, could you give us a total number of inspections that have been done?

Dr. Sharfstein. We have been in some of these facilities because of outbreaks. And we could give you the number of inspections, but we have not done general inspections. And I think that there are two reasons for that.

Dr. Burgess. Okay. The number of general inspections, then, would be zero.

Dr. Sharfstein. I don't believe we did any inspections proactively.

Dr. Burgess. Okay. I am just trying to ascertain.

Dr. Sharfstein. Sure.

Dr. Burgess. You know, it's come up to us in newspaper articles, the DeCosters, they've kind of attracted some attention in the past.

Dr. Sharfstein. Uh-huh.

Dr. Burgess. Why wouldn't you look? Well, actually -- and Bob Latta brought it up a moment ago -- you had a companion agency

on the street, in the henhouse, if you will.

Dr. Sharfstein. Right.

Dr. Burgess. Did they not see an 8-foot-tall pile of manure? Did they not see a door that was broken down with a manure pile pushing outside? What do they look at while they're there, just the size of the egg and whether it's grade A?

Dr. Sharfstein. Well, I can't speak for USDA. But, you know, there are -- so it may be better --

Dr. Burgess. On an issue that's so important and sickened so many people -- by your estimation, 100,000 cases a year -- and it's a high-risk food, why wouldn't there be a tendency for cross-communication between a Federal agency under the USDA and the Food and Drug Administration?

Dr. Sharfstein. FDA has been very concerned about this potential risk. That's why FDA fought to put this rule --

Dr. Burgess. Obviously not enough. If the USDA is not -- I mean, an 8-foot pile of -- I mean, we showed the pictures. That's got to get your attention. I mean, I know you're just there to measure with a little micrometer the diameter of the egg. But, holy cow, how do you just not notice that? And if you know this is a high-risk food and a high-risk practice and the DeCosters kind of have a history, why wouldn't someone say something?

Dr. Sharfstein. Well, I --

Dr. Burgess. Okay. We've got a food-safety bill -- we have got a food-safety bill that's over in the Senate. And we've heard

all kinds of stuff today about the problems. I supported the food-safety bill. I worked on it. I tried to amend it, I tried to make it a better product. Ultimately, it wasn't perfect, but I voted for it, both in committee and on the floor of the House.

But, really, what did you have in that bill that you didn't already have? I mean, the recall -- we heard the DeCosters testify. The minute the recall was suggested to them, boom, they flipped the switch, they recalled the eggs. So it wasn't like you had to go to court to get a court order to do it. They voluntarily did that.

So, all right, we're going to have a mandatory recall with the new bill. That's great. But it didn't affect the outcome here. What would have affected the outcome here is if one Federal agency had used common sense and talked to another Federal agency. How do we legislate that between the FDA and the USDA?

Dr. Sharfstein. FDA and USDA are working on improving communication. But I think the -- from my perspective, this rule is what gives FDA the ability to be at these facilities, inspecting for prevention. And the law allows us to make those inspections -- would allow us to make those inspections as effective as possible.

Dr. Burgess. My time is very short. Let me ask you a question about the law. You brought it up yourself; you talked about civil and criminal culpability.

Dr. Sharfstein. Right.

Dr. Burgess. Is there criminal -- is there the ability to bring criminal charges against one of these producers now, if the conditions are found to be so egregious that they should have been stopped?

Dr. Sharfstein. Yes. There would be enhanced criminal penalties under the bill.

Dr. Burgess. But criminal penalties exist today.

Dr. Sharfstein. Right.

Dr. Burgess. Nothing is stopping you or nothing is preventing the Department of Justice from pursuing this if they decide to do so.

It's unusual to have Salmonella inside the egg, isn't it?

Dr. Sharfstein. Not at this facility, I don't think.

Dr. Burgess. But just in general. Now, would there be any way the consumer would know? I mean, if you've got a rotten egg, we all know, you crack a rotten egg and it would be trouble. But this wouldn't create that kind of trouble, would it?

Dr. Sharfstein. Correct. Correct.

Dr. Burgess. Have there been any other cases where Salmonella has occurred inside -- in any other of the food recalls, the egg recalls that the FDA has overseen, have there been issues with Salmonella internal to the egg?

Dr. Sharfstein. Absolutely.

Dr. Burgess. So do you have -- you have other studies that you have done where you can compare and contrast what you're doing

now with what has happened in the past? And I'd appreciate if you would provide that to us. And I will provide that question in writing.

Dr. Sharfstein. I think this is a known risk, and that's why FDA has fought so hard to --

Dr. Burgess. But, generally, it's on the outside of the egg, not internal to the egg. So I'd just like an accounting of where the FDA has been in the past with this.

[The information follows:]

***** COMMITTEE INSERT *****

Dr. Burgess. Finally, let me just ask you -- you said you started in March of 2009. I appreciated the kindness you showed me when I went out for a tour of your facility. That's 18 months. So when can we expect, under your tenure -- and I'm sorry we don't have the CEO of the FDA here today -- but under your tenure, when can we expect this to be better? You've had 18 months. You've known it's a problem. When is it going to improve?

Dr. Sharfstein. I believe that we're in a position, through these inspections, to inspect the facilities that produce 80 percent of the eggs by the end of fiscal year 2011. And I believe, as we do that and we assure under the rule that we put into place very quickly in the Obama administration, we will be able to feel a lot more confident about the conditions under which the vast majority of eggs are produced.

Dr. Burgess. So we won't be back here next --

Mr. Stupak. The gentleman's time has expired.

Mr. Waxman for questions, please.

The Chairman. Thank you, Mr. Chairman.

Dr. Sharfstein, it seems to me you have had a number of problems. You didn't have this egg rule in place. It's now in place. Can you tell us succinctly what it will do to help FDA prevent this problem in the future?

Dr. Sharfstein. Sure.

The egg rule requires certain types of preventive measures

that keep Salmonella from getting in the eggs. And these include standards around rodent control, it includes standards around refrigeration, and it includes testing protocols, because Salmonella does, even in the best-managed facilities, get in, but you've got to identify it quickly and control it. So those are three examples.

And the firms must have their own plan, and they must keep to the plan. And by being able to inspect against the plan, we can have a high level of assurance that we will not see these situations again.

The Chairman. Then why do we need the law to be changed as per the House-passed bill on food safety? How will that help you?

Dr. Sharfstein. It will help -- we are looking at 600 inspections by the end of fiscal year 2011. Right now, we have very limited authority to do administrative detention, we have no ability to do civil penalties, we have limited criminal penalties. There are a number of things that will directly help us in this task of inspecting the other 600 facilities that we would like to inspect by the end of fiscal year 2011.

And then, of course, the bill goes far beyond just eggs. And there are other products out there where there are not standards, and we don't want to spend a decade putting those standards into place. We want preventive standards in place much faster for other products so we are not back here every 6 months, as the committee has noted, talking about another major food recall.

The Chairman. Mr. Burgess seemed to -- in the way he asked the question, I got the sense he was saying you don't really need this law because you have a lot of authority now.

Can you demand a recall, or do you have to rely on the company to voluntarily recall a product?

Dr. Sharfstein. Well, I appreciate that Congressman Burgess supports the bill.

The Chairman. Yes, he does.

Dr. Sharfstein. And I think that, right now, we cannot demand a recall. It has to be voluntary. And I do think, you know, in this case we are very pleased that, as soon as we recommended a recall, you know, even before we had confirmatory lab testing, the company did it.

But we have 600 to go. And if we wind up in prolonged court battles with some of those companies, we don't know what could happen. It is much better, if we need to protect the public, for us to be able to order a recall.

The Chairman. How about penalties? If you find that some companies have been acting inappropriately -- and, obviously, penalties deter for the future -- what can you do now?

Dr. Sharfstein. Now? There are certain types of criminal penalties, but it requires, you know, very -- and, actually, I could get you the exact penalties. But it obviously requires a big investigation to get there. We do not have the authority to assess civil money penalties, which the bill would give us.

So it would be a much more flexible type of tool, much more -- give us stronger teeth for what we want to do to protect the public via prevention-oriented inspections.

The Chairman. Well, that's civil penalties. How about criminal penalties? If you have a company that, over a 30-year period, constantly gets into trouble because they have Salmonella in, let's say, eggs, and they have been assessed civil money penalties, they've been told by the States they can't sell their eggs in the States -- certain States any longer, what more can you say if they continue to act in a way that causes this problem to reoccur?

Dr. Sharfstein. Well, criminal penalties are, you know, an option available to the agency, and they would be strengthened under the bill.

The Chairman. Under the bill. But right now, do you have to go to the Justice Department?

Dr. Sharfstein. Correct.

The Chairman. And has the Justice Department ever sought criminal penalties, to your knowledge, against a food processor or food producer?

Dr. Sharfstein. I'd have to get back to you.

The Chairman. Okay. It seems to me, to my recollection, it's very, very unlikely. And because it's so difficult to go to court and prove these cases, they usually settle with some slap on the wrist.

I guess my time has expired.

Do you feel that the FDA is now in a position to do more because of the rule that's finally in place, but with the food-safety legislation that passed the House, overwhelmingly, on a bipartisan basis, that will give you the additional tools, resources, and additional legal tools to make sure this whole thing will work and we're not going to have hearing after hearing on Salmonella in peanut butter, eggs, spinach, or whatever?

Dr. Sharfstein. Here's my bottom line: We need this bill. We need this bill to protect the safety of the food supply. We need this bill to help us prevent another egg outbreak just like the one that we've experienced and the one that we heard from the earlier witnesses that devastated their lives.

The Chairman. Thank you.

Thank you, Mr. Chairman.

Mr. Stupak. Ms. DeGette for questions, please.

Ms. DeGette. Thank you, Mr. Chairman.

Dr. Sharfstein, I want to talk to you about both preventing food-borne illnesses and then also quickly identifying them and removing them. Obviously, it's in all of our interest to prevent these illnesses from occurring in the first place, and I think that would be your top priority, as well. Is that the main focus of the new egg rule, as well?

Dr. Sharfstein. Correct.

Ms. DeGette. Preventing the salmonella from getting in the

eggs.

And, by the way, I just wanted to clarify, it is not uncommon for Salmonella to be inside the eggs, correct? It's not just on the shell of the eggs.

Dr. Sharfstein. Yeah, I think it's well-understood that one of the major routes of transmission is through the chicken into the egg.

Ms. DeGette. Okay.

And so, one thing that struck me with the previous panel testifying is they said they think it's -- despite all of the other issues, the large piles of manure, et cetera, they think it is in part because of contaminated feed. Do these new egg rules address the feed issue?

Dr. Sharfstein. The new egg rules do help with the feed issue. But let me say that FDA has not reached this conclusion that you heard earlier from --

Ms. DeGette. Right. I understand that. But it would seem to me, no matter what the source of the Salmonella inside the egg was, be it the manure or the rodents or anything like that, whatever source it would be, if you're testing the eggs, you should be able to identify that they are contaminated, and then you wouldn't send them out, right?

Dr. Sharfstein. That's correct.

Ms. DeGette. So the testing is a big part of it.

Dr. Sharfstein. That's correct. And it's the responsibility

of the company to identify if there is a risk --

Ms. DeGette. Right.

Dr. Sharfstein. -- from whatever source. And then, when they find the contamination, take action to control it.

Ms. DeGette. And then go back and figure out what caused it and remove that, correct?

Dr. Sharfstein. Exactly. Exactly.

Ms. DeGette. Now, the second thing I wanted to ask you is, does the FDA currently, if the Senate does not pass the food-safety bill, have the resources to do all the inspections that are going to be needed under these new egg rules?

Dr. Sharfstein. You know, as you know, FDA has been significantly strapped for resources. And, you know, you should know there are 150,000 or so domestic food facilities, and FDA does about 18,000 food inspections every year. We are prioritizing under the rule these egg facilities, so we will do them. But the legislation, which gives us additional resources as well as additional tools, will make a tremendous difference in FDA's ability to prevent future outbreaks.

Ms. DeGette. And to inspect these facilities, correct?

Dr. Sharfstein. And to do all the inspections we are expected to do.

Ms. DeGette. Okay.

Let me talk to you for a minute about, then, after there is contamination, after the contaminated food leaves.

Dr. Sharfstein. Sure.

Ms. DeGette. Chairman Waxman talked to you about mandatory recall authority. And, as you pointed out, in this case, the company did, when told, voluntarily recall the eggs. But that is not always the case, is it?

For example, the peanut butter outbreak, where the company resisted recalling the contaminated peanut butter for quite some time and the government didn't really have the authority to do anything, correct?

Dr. Sharfstein. I can tell you there have been, definitely, instances where there's been some tension between FDA and firms over doing a recall.

Ms. DeGette. And just the threat of a mandatory recall might make a firm hop to and recall tainted food even on their own before the FDA had to exercise that mandatory recall authority.

Dr. Sharfstein. And FDA would intend to be extremely reasonable about using this because we understand, you know, that companies could be worried. We would be reasonable. But, yes, we would very much like to have that ability.

Ms. DeGette. Let me talk to you about another issue that I care a lot about, because I worked hard to include it in the food-safety bill, and that is the traceability provisions.

On our first panel, one of the witnesses said, part of the problem is there's a lot of food on the plate and we have to identify which of the foods is contaminated and where it came

from.

But having traceability for all of those food systems, that's interoperable -- not necessarily the same traceability system, but systems that are interoperable, that would help the FDA more quickly identify the source of the contamination, wouldn't it?

Dr. Sharfstein. Yes.

Ms. DeGette. And that's something that the FDA doesn't have the ability to order right now under current law, correct?

Dr. Sharfstein. That's correct.

Ms. DeGette. So the food-safety bill would really help once -- if there was food that was contaminated, it would help identify the source much more quickly and enable that recall to happen so further people aren't sickened.

Dr. Sharfstein. That's an extremely good point. I've spoken about the enforcement provisions of the bill, I've spoken about the prevention provisions of the bill --

Ms. DeGette. Correct.

Dr. Sharfstein. -- but the trace-back provisions are very important also.

Ms. DeGette. Thank you.

Thank you very much, Mr. Chairman. I yield back.

Mr. Stupak. Thank you, Ms. DeGette.

Mr. Braley for questions, please.

Mr. Braley. Dr. Sharfstein, welcome.

I have a very significant constituent who lives and farms in

New Hartford, Iowa, and he has made an important statement about these egg recalls I want to read to you.

"The recent egg recalls have troubled consumers and weakened confidence in our Nation's food supply. When Americans visit their local grocery store, they should be able to trust that the food they are purchasing to feed their family is safe to consume."

That was a statement that Senator Grassley made in a letter to USDA Secretary Tom Vilsack, our former Governor.

Do you agree with that statement?

Dr. Sharfstein. Yes.

Mr. Braley. Now, one of the concerns that we have is that, right now, among the 50 States and the Federal Government, there is this hodgepodge of State requirements that relate to the production of eggs that may vary from State to State, and yet those individual State enforcement activities are part of this complementary network of food-safety enforcement that we have in this country.

And I would like you to share with us your opinion as to whether we can continue to rely on a system where one State's requirements may have lower thresholds of food safety, which then goes into a stream of commerce and goes around the country to other States, and whether we can continue to afford that type of enforcement system, given the problems identified with this egg recall.

Dr. Sharfstein. I would say that our goal is an integrated

Federal food-safety system where we are working with our partners at the State and local level off the same playbook. And there has been a tremendous amount of work at FDA to move this forward. There was recently 50 State meetings where we discussed what this system would look like. And the legislation would propel that forward in a number of ways.

So our goal is for there to be a clear standard across the country and for the States and localities and the Federal Government to be in much greater sync than they are today.

Mr. Braley. What were some of the breakdowns that led to this half-billion-dollar egg recall between the FDA and the State officials in Iowa?

Dr. Sharfstein. I'm not sure that I would describe it as breakdown between the State officials and the FDA. I think that what FDA recognized is the importance of having clear, prevention-oriented standards that then could be inspected against.

And, you know, that's why very shortly after, you know, I started at FDA and the administration's Food Safety Working Group came together, the administration prioritized getting this egg safety rule out, having a period implementation, and getting it going as quickly as possible.

So our focus is on getting that in place. And that gives us a basis, the foundation to really work closely with States and localities around clear standards. What the bill would give us is

the ability to do that in other areas to reasonable standards, integrated with States and localities, to prevent illness.

Mr. Braley. And I want to talk about why this is so important. We know that, every year, there are about 5,000 deaths related to food-borne illness in this country. Isn't that correct?

Dr. Sharfstein. That's correct.

Mr. Braley. And, every year, there are approximately 325,000 hospitalizations in this country related to food-borne illnesses. And we heard from witnesses here today about how devastating that can be to their quality of life.

Dr. Sharfstein. That's right. And, as a physician, I have taken care of patients who have died from food-borne illness.

Mr. Braley. So the other thing that we know about the bill that we passed in the House is that there is a cost-sharing that goes along with this responsibility and that most of the cost associated with the enforcement, under the food-safety bill we passed, would be the result of fees in the food industry. Is that correct?

Dr. Sharfstein. That's correct.

Mr. Braley. And so, haven't these hearings that we've been holding in this committee, haven't they demonstrated why it's so important to save these lives and keep people out of the hospital by making food safety a higher priority in this country?

Dr. Sharfstein. Yes, I think that the work that the

committee has done in this area is extremely important. And we really do appreciate the bipartisan support that this bill has gotten.

Mr. Braley. Thank you. That's all.

Mr. Stupak. Thank you, Mr. Braley.

Mr. Markey for questions.

Mr. Markey. Thank you, Mr. Chairman, very much.

As you know, Mr. DeCoster, whose Iowa facility has been implicated in this outbreak, is also tied to a number of egg-processing businesses in Maine. Some of these businesses may merely rent land from Mr. DeCoster, while others may have closer ties, like purchasing chicken feed from other facilities that Mr. DeCoster runs.

As I am sure you know, facilities owned and operated by Mr. DeCoster in Maine have a long history of public health, environment, worker abuses and animal cruelty violations.

So, just to be clear, have there been any recent Salmonella infections that were later linked to eggs or facilities from New England?

Dr. Sharfstein. Not that I am aware of, but we'll get back to you.

Mr. Markey. Okay. Thank you. I think that's important for us to know. To the best of my knowledge, the answer is no, but I think we should nail that down so that residents of Massachusetts or other New England States are not concerned.

Dr. Sharfstein. Well, let me say this. I think, in the past, we have measured success or failure just by an outbreak. But the way we're looking at it now is, we would like to have the assurance that there is good preventive --

Mr. Markey. Great.

Dr. Sharfstein. -- controls in place. And one of our priorities in doing these inspections is really getting that assurance. So not just that there isn't a massive outbreak, but that there's actually prevention-oriented standards.

And in picking which firms and which places to go, where to look first, we are going to be prioritizing companies that have had problems in the past. We will be reaching out to other agencies, and we've been working with OSHA, for example, to identify if there are findings that other agencies have had. We have had an agreement with USDA that we will be learning from their inspectors. So we intend to use all the information at our disposal to prioritize which companies need an FDA visit quickly.

Mr. Markey. So, just to go from the general to the specific, because I appreciate the direction in which the FDA is heading, so you plan to prioritize your inspections so that you start with the riskiest facilities, like those in Maine or other States that have a history of violations or those that buy feed or chicks from companies like Mr. DeCoster or other repeat violators who own or operate. Is that correct?

Dr. Sharfstein. Right. We will be using a wide variety of

data, including information from other agencies like USDA and OSHA, to help us prioritize the highest-risk facilities.

Mr. Markey. So, just to take it one step further, the Nuclear Regulatory Commission gears its inspection regime towards those who have had the longest history of violations.

Dr. Sharfstein. Right.

Mr. Markey. You intend on doing the same thing?

Dr. Sharfstein. Absolutely.

Mr. Markey. And this Maine facility falls into that category?

Dr. Sharfstein. You know, I couldn't specifically talk about a specific facility, but I can tell you we will look at not only the history of facilities but corporate issues. If we have concerns about a particular owner, for example, that makes us think that other farms could have a problem, that will influence our prioritization.

Mr. Markey. But if it is amongst the greatest violators, then that's where you're most likely to be going first?

Dr. Sharfstein. That's correct, yes.

Mr. Markey. Okay. Good. So that's an important -- and you can hear a sigh of relief going on all over New England right now because of the record there. And, again, right now there is no evidence, but we want to make sure that we go in to get the answers as quickly as possible.

The gentleman who testified here today, or did not testify

here today, Mr. DeCoster, clearly has no regard for regulations until the point at which he actually gets caught. You know, that's a constant refrain that we hear from people who get sworn in to testify at that table. You know, we went from BP to Salmonella, and it's a long history of witnesses at that table, and they're always then quite concerned that their actions have been misunderstood.

Do you think that you can, under your current regulations, guarantee that habitual violators like Mr. DeCoster can be quickly caught and held accountable?

Dr. Sharfstein. Well, what I testified to is that we are going to go out to these 600 facilities, but our tools, what we can do when we get there, are limited; and that the legislation that is pending would be extremely helpful for us to do the job well, because it would give us a whole other series of tools to enforce the law.

Mr. Markey. Thank you. Thank you for your service. Welcome back to our committee.

Dr. Sharfstein. Thank you.

Mr. Markey. And thank you, Mr. Chairman. I appreciate it.

Mr. Stupak. Thank you, Mr. Markey.

That concludes all questioning.

And thank you, Dr. Sharfstein, for being here.

And I want to thank all witnesses for coming today and for their testimony.

The committee rules provide that Members have 10 days to submit additional questions for the record to witnesses. I ask unanimous consent that the contents of our document binder be entered into the record, provided that committee staff may redact any information that is business proprietary, relates to privacy concerns, or is law enforcement-sensitive. Without objection, documents will be entered.

That concludes our hearing. This meeting of the subcommittee is adjourned.

[Whereupon, at 3:30 p.m., the subcommittee was adjourned.]