FOOD SAFETY ENHANCEMENT ACT OF 2009 DISCUSSION DRAFT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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[1] Ms. Bailey did not respond to submitted questions for the record.

FOOD SAFETY ENHANCEMENT ACT OF 2009 DISCUSSION DRAFT

WEDNESDAY, JUNE 3, 2009

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

The subcommittee met, pursuant to call, at 10:05 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone [Chairman of the subcommittee] presiding.

Members present: Representatives Pallone, Dingell, Eshoo, Green, DeGette, Schakowsky, Baldwin, Ross, Matheson, Harman, Barrow, Christensen, Castor, Sarbanes, Murphy of Connecticut, Space, Sutton, Braley, Waxman (ex officio), Stupak, Markey, Deal, Whitfield, Shimkus, Buyer, Rogers, Murphy of Pennsylvania, Burgess, Blackburn, Gingrey and Barton (ex officio).

Staff present: Karen Nelson, Staff Director/Chief Health Counsel; Rachel Sher, Health Counsel; Eric Flamm, FDA Detail; Elana Leventhal, Legislative Assistant; Virgil Miller, Professional Staff; Alvin Banks, Staff Assistant; Ryan Long, Minority Chief Health Counsel; and Chad Grant, Minority Legislative Assistant.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. The meeting of the subcommittee is called to order, and today we are meeting to review the Food Safety Enhancement Act of 2009 Discussion Draft. I will recognize myself for an opening statement initially. This discussion draft was released by Chairman Waxman, Chairman Emeritus Dingell, Chairman Stupak, Representative DeGette, Representative Sutton and myself early last week. And the draft builds on several bills already introduced in this Congress including H.R. 759, a bill that I, along with Chairman Dingell and Stupak, introduced earlier this year.

The Energy and Commerce Committee has done a lot of work on the issue of food safety. In this subcommittee alone, we have had four hearings on this topic in the last two years. The information we learned during these hearings as well as during the numerous conversation we had with stakeholders groups and the FDA has been incorporated into the draft before us today.

And I believe this draft bill represents a strong, well thought out approach to improving the FDA and its food safety activities. We have heard time and again that our current food safety system is broken. It is a system that relies heavily on the FDA rather than

placing the responsibilities on the manufacturers to ensure the safety of their products. It is a system that is geared towards responding to food outbreaks rather than one that is aimed at preventing them.

And this system does not work, and recent outbreaks of E. coli in spinach and salmonella in peppers and peanut butter highlight that fact. Unfortunately, these are not isolated instances. Each year, 76 million Americans get sick due to unsafe food products. Every year, 325,000 individuals will be hospitalized and 5,000 will die from food borne hazards.

It is estimated that the medical costs and lost productivity due to food borne diseases cost us $44 billion annually. And these illnesses are completely preventable.

The good news is that there seems to be agreement that something must be done and that it must be done quickly. The President has made food safety of one his priorities. He has assembled a food safety working group to come up with principles on this issue.

Chairman Waxman, Mr. Dingell, Mr. Stupak and I have worked closely with key stakeholders on this discussion draft, and as we move forward with the legislation, we hope to continue those conversations as well as conversations with our counterparts on this committee.

The bill we are discussing today will modernize the food safety laws currently in place. It places a strong emphasis on prevention and shifts the responsibility for food safety onto those who actually make the food. It also provides the FDA with the necessary resources and enforcement authorities to ensure that all companies are in compliance with the new requirements. This draft bill would require all food manufacturing companies to register annually with the FDA so that the agency has an up-to-date list of all facilities who sell products in the United States.

It focuses on prevention by requiring companies to conduct thorough hazard and risk analysis of the products that they are making. It mandates that companies put in place preventive controls to mitigate and minimize those identified hazards. And it requires companies to document all the steps they have taken to implement and verify the controls to ensure they are effectively minimizing hazards.

The bill also addresses the shortfalls of our current traceback system by requiring the FDA to establish an electronic interoperable record keeping system that manufacturers would be required to use. This measure will allow the agency to quickly trace the source of an outbreak back to its origin and prevent and minimize the number of individuals affected by a food borne illness.

While shifting responsibility for food safety onto the manufacturers, the draft also recognizes the crucial role the FDA needs to play in this realm. This draft requires the agency to set standards for food safety and hold the food industry accountable for meeting those standards. It provides the FDA with stronger enforcement authorities, such as recall authority and access to records.

The bill also increases the inspection frequency for food facilities, requiring that the FDA inspect facilities at an established minimum frequency.

Now we are going to hear today from industry experts about the various provisions in this discussion draft, and I look forward to those conversations. I hope that we can all continue to work in this collaborative manner as we move to markup of food safety legislation in this committee.

I am very pleased to welcome Dr. Margaret Hamburg of the FDA today. We had a meeting last week while we were doing the Energy markup. We were in the back having some conversations, and I was very impressed with her. This is the first time she will be testifying before this committee, and I thank her for being here.

I also want to thank our other witnesses for appearing before us today. I especially want to welcome back Mike Ambrosio. He is, of course, from my home state. Good to see you again, Mike. And I will now recognize Mr. Deal for an opening statement.

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

Mr. DEAL. Thank you, Chairman Pallone, for holding this hearing today, and thanks to our distinguished witnesses who have joined us to review this draft of the Food Safety Enhancement Act of 2009. I look forward to your testimony and to the questions that our committee will actually have of the panels.

As a resident of the state of Georgia, which has already received a focal point focus of the issue of food safety, I know firsthand the perspective that our Nation has on the issue of the lack of safeguards and fallback measures that many people expect of a 21st century food supply chain in our country.

We all agree food safety is a priority, and I support giving FDA the resources it needs to ensure our Nation's food supply remains safe and reliable for American dinner tables across the country.

Additionally, implementation of preventive controls such as hazard analysis and critical point plans included in the draft under discussion is an important step forward in ensuring unsafe food products don't reach store shelves in the first place.

As we know, preventing compromised food from entering the market is the best line of defense to preventing food related illnesses. I also believe it is important to enhance FDA's ability to conduct onsite inspections of food facilities. The inspection schedule established under the draft does recognize risk profiles for food in terms of how frequently facilities should be inspected. But the regimen set forth in the discussion draft fails to address the cost/benefit factor of conducting such frequent inspections and could possibly result in insufficient oversight of certain higher-risk facilities due to time and manpower limitations of our inspectors.

It is my hope that our witnesses today can provide input with regard to an appropriate inspection schedule, which achieves the goal of ensuring safe food for the American people without placing an undue burden and strain on the FDA, which is already challenged under current food safety obligations.

This legislation authorizes an annual pay-to-play registration fee for domestic and foreign food facilities of $1,000 to supplement appropriations made by Congress to FDA. In discussion, however, we have not been able to determine from the majority or the FDA ex-

actly how much funding is necessary to meet the requirements of this bill.

I believe it would be premature to impose significant fees on industry and in turn the American consumers without any reference as to how much funding is actually needed. If the majority remains intent on imposing such registration fees, we must also be certain these fees are limited to cover the activities such as a minimal fee paid to the FDA for an application to cover the cost of review and processing.

If the goal is to improve food safety, we must ensure that funds are not funneled into other activities that may or may not have anything to do with improving food safety, a situation which I believe could occur under the language of the current proposal. Obviously these are issues, among many others, that I feel hopefully this committee will be able to address as we move this issue forward, and I look forward to the hearing today and the results that come out of it.

I appreciate Chairman Pallone and Chairman Waxman's bipartisan efforts on this issue, and look forward to having a product that all the members of this committee can support. And thank you, Mr. Chairman, for the time.

Mr. PALLONE. Thank you, Mr. Deal. Chairman Waxman.

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

Mr. WAXMAN. Thank you very much, Mr. Chairman. This subcommittee and our full committee is beginning the process today of passing critically important legislation designed to revamp our Nation's food safety system. The Food Safety Enhancement Act of 2009 and this hearing marks a key milestone.

Over the past few years, a series of food borne disease outbreaks in spinach, peanuts, and peppers, just to name a few, have laid bare some major gaps in our antiquated food safety laws. Oversight work by GAO and by our own Oversight Committee has also helped us understand where we need to focus our efforts to bring our food safety laws into the 21st century.

The draft legislation that is the subject of today's hearing is based on the FDA Globalization Act of 2009 introduced by Chairman Emeritus Dingell, Chairman Pallone, and Chairman Stupak. And I commend them for their work on that bill and their continued efforts in shaping this new bill.

I also want to recognize the assistance we have received from the Obama administration. We have worked closely with the FDA to identify problems with the current food safety law and to find workable solutions. We will not be passing legislation that sets up the agency to fail. The bill requires that the agency set tough standards, but we have given them the flexibility to prioritize and address the most important risks first.

The draft also incorporates helpful suggestions from Ranking Members Barton and Deal and Representative Shimkus. I believe we can reach a bipartisan agreement and look forward to continuing to work with all the members of this committee.

In working with the FDA on this legislation, one thing was abundantly clear. The administration is absolutely committed to overhauling FDA's food safety program. I think we will all see that commitment today when we hear from Commissioner Hamburg.

The recent food outbreaks have exposed glaring holes in FDA's basic food safety authorities. FDA does not have routine access to any records kept by the food manufacturers. FDA cannot require companies to conduct a recall of unsafe foods. The agency can only ask and hope that the company complies. FDA also lacks basic modern enforcement tools like administrative civil monetary penalties. The Food Safety Enhancement Act will give FDA these and other critical authorities.

One of the most important changes that will occur under this bill is a focus on prevention. The legislation does not anticipate that FDA alone will protect us from unsafe food. The hallmark of any effective food safety goal must be a shared responsibility for food safety oversight between FDA and industry.

The act will strike the right balance in this shared responsibility. The bill will require manufacturers to implement preventive systems to stop outbreaks before they occur and will give FDA the tools it needs to hold them accountable if they fail. Under the bill, FDA will also have clear authority to issue and require manufacturers to meet strong enforceable performance standards to ensure the safety of various types of food.

I commend many of those in industry for recognizing the importance of this prevention model and coming to the table to support it.

Let me turn briefly to one of the more contentious issues in the bill, the registration fees. I wish we did not have to resort to industry fees to supplement funding for FDA's work. However, when it comes to FDA's food program, the shortfall in revenues is extreme. The FDA's own science board told us that the FDA is so starved for resources that American lives are at risk. We cannot realistically expect appropriations alone to provide sufficient resources to close that gap.

The recent outbreaks have also taken a major toll on the food industry. In the recent peanut outbreak, Kellogg's alone lost $70 million. Faced with such a dire situation, I think it is reasonable to ask the food industry to chip in. A robust food safety oversight system will provide a great benefit to industry by preventing future outbreaks and rebuilding consumer confidence.

Let me be clear. We are not asking industry to cover the entire cost of the bill or any single part of the bill like the cost of inspections. The bill establishes a set fee of $1,000 per year per facility. FDA is prohibited from increasing that fee in future years except to cover the cost of inflation. The bill simply asks industry to chip in its fair share.

I also want to address another concern I have heard, the presence of FDA on farms. FDA has always had the authority of foods on farms, and they have generally relied on state and local authorities for food safety oversight on farms because they have a strong on-farm presence. I am confident that farmers have nothing to fear from this bill. The bill calls for FDA to set its standards through

regulation, which means that FDA will go through a public notice and comment process.

Our committee is busy in the middle of three months period. Last month, we passed a comprehensive energy and climate change legislation. Soon we will take up health care reform, but food safety is so critical that I have carved out time right in between to pass this legislation. Over the next few weeks, I intend to work with all our committee members, Democratic and Republican, with the FDA, with the affected industries, to achieve a consensus on a food safety bill that we can pass out of committee. We can't afford to wait any longer.

I look forward to hearing from our witnesses today. Thank you, Mr. Chairman.

[The prepared statement of Mr. Waxman follows:]

Statement of Chairman Henry A. Waxman
Subcommittee on Health Hearing on
"Discussion Draft of the
'Food Safety Enhancement Act of 2009'"
June 3, 2009

Today, we begin the process of passing critically important legislation designed to revamp our nation's food safety system: the Food Safety Enhancement Act of 2009. This hearing marks a key milestone.

Over the past few years, a series of food borne disease outbreaks – in spinach, peanuts, and peppers, just to name a few –have laid bare some major gaps in our antiquated food safety laws. Oversight work by GAO and by this Committee has helped us understand where we need to focus our efforts to bring our food safety laws into the 21st century.

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The bill simply asks industry to chip in its fair share.

I also want to address another concern I have heard: the presence of FDA on farms. FDA has always had authority over foods on farms. FDA has generally relied on state and local authorities for food safety oversight on farms, because they have a strong on-farm presence. However, the large number of recent outbreaks that have originated from food contamination on farms has shown us that more oversight is needed. FDA must develop national science-based safety standards, to reduce incidents of on-farm food contamination.

I am confident that farmers have nothing to fear from this bill. The bill calls for FDA to set its standards through regulation, which means that FDA will go through a public notice and comment process. Thus, stakeholders will be able to work with FDA to ensure that the best possible standards and practices are adopted.

Our Committee is in the middle of a busy three month period. Last month we passed comprehensive energy and climate change legislation. Soon, we will take up health care reform. But food safety is so critical that I've carved out time to pass this legislation. Over the next few weeks, I intend to work with all our Committee members, Democratic and Republican; with the FDA; and with affected industries, to achieve consensus on a food safety bill that we can pass out of Committee. We can't afford to wait any longer.

I look forward to hearing from our witnesses today.

Mr. PALLONE. Thank you, Chairman Waxman. The gentleman from Kentucky, Mr. Whitfield.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Well, thank you, Mr. Chairman, and we appreciate your having this hearing on this very important issue today. We all recognize that FDA has many very important responsibilities, and we have known through hearings for the last number of years that the resources available are always in question, but we recognize also that there is a definite need for reform of FDA. And we are delighted that Dr. Hamburg is here with us today to provide testimony and the other panel of witnesses as well.

We look forward to working with the majority on this important legislation. And having said that, we do have some significant concerns about some provisions in this legislation, particularly the risk-based inspection portion, particularly that relating to the low-risk facilities. Also the traceability provisions that I understand, for example, would apply to every convenience store in the country. In addition to that, the recall provisions in this legislation, the country of origin provisions, particularly as it relates to the Web site requirements and then also, of course, the power that we give to FDA for subpoenas and other instruments to obtain company records. I think we need to look at those provisions much more closely.

But obviously this is an important piece of legislation. We look forward to working with you and listening to the testimony of our witnesses today. Thank you.

Mr. PALLONE. Thank you. Next is our Chairman Emeritus, Mr. Dingell, and thank you for all you have done on this legislation.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, thank you, and thank you for holding today's legislative hearing on the Food Safety Enhancement Act of 2009 Discussion Draft. We have worked together, you and I, with Chairman Stupak and others over the years. And I am delighted to say that this legislation is ready for enactment and is almost old enough to vote.

I want to say that I am delighted that Chairman Waxman and my good colleagues, Ms. DeGette and Ms. Sutton, have joined us in our work on this bill.

We are about to try and fund an agency which is hollow, which does not have either the personnel or the revenue or the money or the or the resources which it needs to do its job. And we are about for the first time since 1962, when I was a young member of this body, to try and see to it that it gets its authorities updated to deal with the real problems in the world of trade and in the world marketplace.

I am pleased that we are taking the necessary steps to advance this legislation and address the important issue of food safety. I am

hopeful that we will shortly be doing something with regard to pharmaceuticals.

I want to thank the witnesses who have joined us today and look forward to hearing their testimony. And, Dr. Hamburg, welcome to the committee. Congratulations on your confirmation. I was encouraged by the administration's early recognition that food safety is a problem that needs to be addressed. The administration food safety working group is a signal to how serious the President considers this issue.

And I want to thank you for the way that you and your staff have provided timely and helpful technical advice on the legislation.

I want to note that I am hearing complaints from folks about the fee system. I want to make a note that the only part of Food and Drug that seems to be working is that which functions under PDUFA and that and which has the advantage of having industry participate in the funding. I want to note that the industry seems to be prospering mightily under that particular section and be getting service from Food and Drug in a proper way. And that seems to be about the only place that the industry is getting protection or the American consumers are receiving necessary safety.

In 1938, the Congress comprehensively addressed the issue of food and safety. Seventy years later, Food and Drug Administration is still trying to protect the larger, increasingly global supply with outdated statutes and inadequate resources. As a result, the American consumer confidence in the Nation's food supply and the Food and Drug Administration and, quite frankly, in this body, the Congress, has declined. And American consumers are being forced to pay a heavy price, not only with recall after recall but also the fact that people are being sickened and killed by unsafe foods and also by pharmaceuticals.

And again I wish to hope that we will commence work on pharmaceuticals as soon as this business is attended to. The Food Safety Enhancement Act is a measured and effective response to the dire situation we are faced with today regarding food safety.

Mr. Chairman, the legislation is based on a bill you, Chairman Stupak, and I have introduced earlier this year and also on a bill that was introduced by me during the past Congress. It includes good technical advice from FDA and valued input from the minority and other stakeholders. And I want to make it clear that I am working with the minority to try and resolve their concerns, and that we are also working with the industry.

And I want to thank my friends in the industry for the goodwill which they have shown in working with us. And I also want to thank Chairman Waxman for his leadership on this point. I look forward to continued deliberations in the hope of producing speedily a bipartisan piece of legislation that will pass the committee and the House, as I have indicated, both in a correct and a speedy fashion.

Amongst other things, this bill will prevent safety problems before they occur. It will require manufacturers to implement food safety plans that identify and protect against food hazards. It will see that Food and Drug has the authority to see to it that good manufacturing practices are adhered to here in the United States

and elsewhere, especially in places like China which is in fact the Wild West in this particular matter.

It will advance the science of food safety, increase inspection frequency of food facilities, something which can happen more often on dog food manufacturers under the jurisdiction of the Department of Agriculture than it happens with regard to manufacturers who manufacture food products for the safety of our people.

It will enhance FDA's ability to trace the origin of tainted food in the event of an outbreak or food borne illness. And it should be noted that the Food and Drug Administration and the industry are totally incapable of providing speedy service in this particular.

It will enhance the safety of imported food. FDA will be allowed to require that certain foods be certified as meeting U.S. safety standards and again to trace. But also Food and Drug will be able to finally get enough people at the doors of this country to see to it that safety is properly enforced and that good manufacturing practices are adhered to around the world for the protection of our people.

It will provide strong enforcement tools including mandatory food recall authority, stronger criminal and civil penalties for bad actors, subpoena authority, and it will increase and strengthen Food and Drug's detention authority.

Finally, and I would argue more importantly, the legislation addresses the very important question of resources of the agency. We will give the agency the authorities it needs, and we would do them a grave disservice if we did not give them the resources they need.

The legislation includes the registration fee, which will fund food safety activities at FDA. The revenue from this fee, coupled with additional appropriations which we hope we can get out of those skinflints at the Appropriations Committee, the office of managing the budget, will ensure that Food and Drug can do its job.

For those who argue there is no benefit for the industry to pay a fee for safety activities at Food and Drug, I offer the following. U.S. peanut industry could lose $1 billion this year because of the outbreak of salmonella that forced the biggest food recall in history. That has just been replicated by other recalls in the food industry. Tomato industry lost $100 million in sales during the 2008 salmonella outbreak that ultimately was attributed to jalapeno peppers. Spinach growers took a $200 million hit to their industry during a 2006 bagged spinach recall.

And let us not forget that wonderful Chilean grape scare of 1989, which Food and Drug had neither the authority nor the competence to address. I ask unanimous consent to revise and extend my remarks. I have a few other things I would like to say that I know everybody will want to read. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Chairman Dingell. The gentleman from Illinois, Mr. Shimkus.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. Thank you, Mr. Chairman. Dr. Hamburg, welcome. I see Chairman Waxman has left the room. I appreciate his comments about there being some discussions. I do have to have admit that the discussions that we have had when we point out a point

that is correct, they accept. When there is a debatable point, Mr. Chairman, there does not seem to be any movement and compromise. So I would encourage more discussions on some of these issues if we really want this to be a bipartisan bill.

You know the other thing I have trouble with is draft hearings. If we are going to have a legislative hearing, let us have the legislation. This is the draft legislation, and if we had the great draft legislation hearing on climate change and then when the bill came before us, it had 300 additional pages in it. And there is fear on our part that this is a sneaky way to say yes, we had a legislative hearing, but you really don't have a legislation hearing if you don't have the legislation before you.

This is the Democratic majority operandi. We claim a crisis. Only government can be the savior. Government must get bigger, and the middle class pays. And that is the issue here. And I was on ONI in the last Congress with Bart Stupak, readily accepting the premise that we have to get inspectors into these facilities, and we are ready to address an issue that is thoughtful and respectful and pays for the inspectors and facilities where they are not going into.

And it is not like we haven't done anything. Congress, last Congress, approximately $57 million from the supplemental went to food safety. The House passed the 2009 omnibus appropriated an additional $325 million for the FDA with $140 million of the $325 million would go for food safety programs. In the President's 2010 budget, he included $1 billion additional to FDA for food safety.

So there is a huge commitment already for massive federal funds to go to food safety. Now we have, as our concern, a bill, a draft that has, what, $325 million for no explanation, no earmarking, no direction, and that is where a lot of our questions will be today is why that amount? What justifies that amount? How are we going to ensure that it is not going to be used for other purposes? And the like.

So I would ask the leadership on the other side that if they really want a bipartisan, let us get some bipartisan negotiations, sincere negotiations. I would be honored to yield.

Mr. DINGELL. I am very fond of the gentleman. He is very well noticed, and I have great respect for him. And I have been talking, as the gentleman well knows, to the leadership on the minority side both in the last Congress and this Congress. I want this legislation to be bipartisan. I don't want the gentleman to be surprised.

I would note to my good friend that we have been having hearings after hearings after hearings not only here but up in the Oversight Subcommittee. And during that time, I have been continually talking to my good friends on the minority side because I want you to be aboard. This should not be a partisan issue. And when we go to the next step in this process, I will assure the gentleman that most of the changes that will be made that will be changes that will be made as a result of discussions with my friends on the minority side. And I say that with respect.

And I thank my colleague, and I look forward to working with you. I yield back, Mr. Chairman.

Mr. PALLONE. Next is the gentlewoman from Colorado, Ms. DeGette.

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

Ms. DEGETTE. Thank you, Mr. Chairman. Mr. Chairman, this is the first step towards realizing a long-held dream, not just by me and other members of this committee but by the millions of Americans who have been concerned about the safety of our food, especially in light of the cascading litany of food borne illnesses that we have heard about from other members of this committee.

We have had a dozen Oversight hearings and also legislative hearings. We have had bills dropped by many members of Congress for many years, and I am so excited under your leadership and the leadership of Chairman Waxman and Chairman Dingell that we are finally on the verge of enacting comprehensive food legislation.

The most important thing about this bill is it would be a definitive statement by this committee and this Congress that food safety is a priority in the United States of America.

I want to highlight two of the sections of this bill, and I want to thank you and Mr. Dingell and others and Mr. Stupak for including the provisions of my two bills in this draft mark because they are critically important in the future to assuring safe food for everybody.

As you know, Mr. Chairman, I have been working on these traceability issues for many, many years. And when I first started, people said it couldn't be done. But then as we realized with time, not only can it be done and in slightly different ways in every industry, but if we want to assure this integrity of the food system, it has to be done. What I fondly call the salsa scare of last year is the perfect example of why.

We found people being sickened by salsa, and we couldn't figure out why. This destroyed pretty much the entire profit of the tomato crop for that whole year because everybody thought it was tomatoes that had the salmonella. As it turned out, after months and months and months of increased sickness, of increased scrutiny, we found out that no, it wasn't the tomatoes at all. It was jalapenos, and they were from Texas.

And what I found out is that we can go to this particular sector of the field and find those jalapenos, and we can do it quickly. So traceability is going to be essential. And I look forward to working with my friends on the other side of the aisle to make sure it is not onerous. But I will say this. It is not just in the interest of consumers. It is in the interest of businesses who want to protect their profits to have traceability.

Mandatory recall is a second provision of this bill that I have been working on for many years and I am so grateful has been included.

And I want to say finally, Mr. Chairman, all of this policy that we talk about, it is all well and good. But I can't help but think about young Jacob Hurley, who you might have seen. He was in our last ONI committee hearing.

Jacob is from Portland, Oregon, and he got sick from eating peanut butter crackers, his favorite food. When his parents took him to the doctor, they said they finally got him stabilized, and he wouldn't eat. So they told the parents have Jacob just eat what he

loves, the peanut butter crackers, the very food that had made him sick in the first place.

And the only way we found out about this was because the alert commissioner of Consumer Protection in Oregon showed up personally at his door and confiscated the peanut butter crackers. We need to fix this. We need to fix it now, and I am so grateful that we are. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Ms. DeGette. Next is the gentleman from Indiana, Mr. Buyer.

Mr. BUYER. Ma'am, welcome to the committee. Is it Hamburg or Hamburg?

Dr. HAMBURG. Hamburg.

OPENING STATEMENT OF HON. STEVE BUYER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. BUYER. Hamburg. Welcome, and my first reaction to the discussion draft is going to lead to some questions that I will have for you today. It appears that Congress a lot of times would like to pound our chest and then show the American people that we are doing something well.

But we really end up creating legislation within our own areas of jurisdiction, and we create problems. We create things that are multiplicious and redundancies. And if we really wanted to couple substance with the words that I have heard here from some of my colleagues today, we would be working with other committees of jurisdiction. We would have a very comprehensive bill. And so I am going to be asking you questions, ma'am, about clear lines of delineations and responsibilities between USDA and FDA, and who should really have what responsibility.

Or should we as a Nation put all food under one agency and work cooperatively with the Ag Committee to do something like that? What we have is a discussion draft that has been cleverly drafted only within the jurisdiction of our own committee, and so what we end up doing is are we exasperating a problem? And so I am interested in your leadership. You are representing an administration, and so I am interested in your best counsel to us and your willingness to work with leaders of other agencies to truly protect the American people.

And the other point I make is that Congress, as of late, has been beating up on FDA. I would say the FDA, the individuals that I have met and the ones that you have the privilege to lead are some pretty fine and capable and dedicated individuals.

In the last, gosh, 16 years, 17 years that I have been here, whether it has been Republicans in control or Democrats, we continue to pass legislation that heaps more and more responsibilities upon your core missions. And so here is your challenge to maintain the gold standards, not only with regard to pharmaceuticals but also in food, you know, we are about to send you legislation for a new mission on tobacco that is counter to your even cultural mission.

Yet we are going to continue to make you the whipping post, and so I am really concerned about the more responsibilities we give you, how much does that dilute your responsibilities? And so these

are some of the questions that I am going to be posing to you. And with that, I yield back.

Mr. PALLONE. Thank you. Gentleman from Georgia, Mr. Barrow.

OPENING STATEMENT OF HON. JOHN BARROW, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. BARROW. I thank the chair, and I appreciate the leadership you are showing on this issue. This is a matter of particular interest to me since, as Mr. Deal has already pointed out, two of the most egregious recent cases of tainted food in the food supply originate in my state of Georgia, and I think this bill represents a major step forward in trying to prevent this from happening again.

One of the things that is a particular bone of contention with me is that in the last outbreak, we got evidence in this committee that the manufacturer had test results which were showing positive presence of salmonella. The food that was sent out in the marketplace was tainted, and yet they didn't report that to the FDA.

Seems to me that we need to have, in addition to the good measures that have been incorporated in this bill, is an effective testing regime that has integrity in terms of sampling and integrity in terms of testing. And I think we have to make it easy for folks to be able to do this, to comply with this, and mandatory for them to report the results of any testing.

This way I think we can pick the bad actors out very early on and perhaps even do a better job of arresting trends at a very early stage, detecting problems before they become serious.

Above all, I want to make sure that we don't bring about the Sergeant Shultz syndrome. You know he was the comic characters in Hogan's Heroes, and he had a big, loud comic demonstration every now and then of not knowing what was inconvenient for him to know. So we want to make sure that folks don't have the option of opting out or have a disincentive to know what they need to know when they need to know it. And that we know what they know when they need to know it. So that is the balance I think we need to strike here. I look forward to working with my colleagues on this as we try and incorporate provisions like that in this bill. And with that, Mr. Chairman, I yield back. Thank you.

Mr. PALLONE. Thank you. Gentleman from Texas, Mr. Burgess.

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

Mr. BURGESS. Thank the chairman. Dr. Hamburg, Dr. Sharpstein, good to see you again. Spent some time yesterday out at the FDA's facility, and I will echo the comments of Mr. Buyer. You have a wonderful staff that you lead out there. They are obviously very, very dedicated individuals, sometimes working under the adverse conditions that we supply. But certainly I know you are very proud of the organization of which you lead, and I believe that pride is justified.

Mr. Chairman, I am going to stipulate to all of the difficulties that the Food and Drug Administration is encountering that have already been well-documented, and I would ask unanimous consent to insert my entire statement into the record. Let me just concentrate on the aspect that we are now finally, after I don't know

how many hearings on this, getting down to somewhat of the business of acting for the FDA and talking about legislation that would give the Food and Drug Administration some tools.

But we are also giving them a timeframe, which may prove to be a very difficult timeframe for implementation. And we are also putting some additional burden on businesses at a time that our economy is in some difficulty. The legislation proposed will mandate the largest change in food safety in at least two decades, and it will give the entire food industry a compressed time to do so. In a few short months, we will have to turn the current system of paper-based records into electronic form. Businesses will have to find the money to register as a food facility, and additional user fees, if we deem them appropriate in the future, and they will have to be able to fully trace the food to its place of origin.

All those may be laudable goals, but I am not certain that what we are proposing as a timeframe is adequate. And then the Food and Drug Administration itself, in that shortened compressed timeframe, will have to hire enough inspectors to meet the new inspection standards, create unique identifier numbers for every food facility, be they domestic or foreign, set up a new administrative law position for the new criminal and civil penalties, and make certain that each center has a food safety plan, all of this instantly demanded in one piece of legislation.

I would just point out when we did the Consumer Products Safety Improvement Act last year, H.R. 4040, we acted in good faith, and we acted with some dispatch. But we created some situations that are absolutely untenable. We have had to go back and try to amend some of those. We have driven some small businesses to the point of bankruptcy. We have created a situation where our resale shops, because they cannot measure the lead standard that we required, are in a position that they don't know whether they can sell the goods that have been donated or not.

So I urge us to take every due caution. The law of unintended consequences has a very short turnaround time in our current globalized world, and we need to be cognizant of that.

And then finally, let me just, you know, a word about bipartisanship. A bill is bipartisan if it is bipartisan at the beginning. And Chairman Dingell, I appreciate the courtesy that you showed me in the last Congress at involving me in at least some of the preliminary discussions of the draft that you were considering. But really when the draft comes to the committee for consideration, it really ought to have had input from both sides, and the fact that there are five or six Democrats on the bill and no Republican. Was there no Republican on this side of the dais with which you could sit down and talk and perhaps get to a point where there could be some general agreement?

We have done this before on other pieces of legislation. We did it on the Food and Drug Reauthorization Act in June of 2007. And I frankly do not understand why it is not worth the effort to make these pieces of legislation—we are not talking about points for the next election. We are talking about the regime that will be in place that will ensure the safety of the food for my grandson and Marsha's grandchildren. This is the legacy that we are going to be leaving, and it is too important to be left to partisan politics.

And I thank you for the additional time, Mr. Chairman, I will yield back.

[The prepared statement of Mr. Burgess follows:]

STATEMENT OF
CONGRESSMAN MICHAEL C. BURGESS, M.D.

BEFORE THE

SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE

June 3, 2009 HEARING
"Food Safety Enhancement Act of 2009 Discussion Draft"

In the past decade or so, the food marketplace has dramatically changed. Fifteen federal departments and agencies help regulate and oversee the food being consumed by our citizens, but none as high profile as the FDA.

Twenty-five percent of the products Americans use – food, drugs and devices – are regulated by the FDA, which has been unable to meet up to the demands of the emergent food marketplace.

They have been underfunded, under-resourced, understaffed and underappreciated. The FDA does not have enough food inspectors. They do not have enough food scientists. They do not have access to records of food facilities – and what access they have is records in paper form instead of electronic form.

Furthermore, they do not have enough controls in place should a foodborne outbreak occur to shut down imports of food, and they certainly do not have stronger civil and criminal penalties to punish bad actors who act in diametrically perverse actions to harm our nation.

In short, the tools the FDA currently has in place are insufficient to control the emergent food marketplace we participate in everyday.

Now, after several years of discussion, with various drafts of food safety legislation, we have this discussion draft to raise the performance metrics of the FDA and the food industry they oversee.

BUT as the scalding hot glare of the media – and our constituents – focus our attention on the unmet needs of the FDA to protect our food supply, in our desire to finally act ***FOR*** the FDA we have produced legislation which would give the FDA some tools but an impossible timeframe for implementation as well as a strong burden on small businesses.

This legislation proposed to mandate the largest change in food safety legislation in at least two decades, if not longer, and it would give the ENTIRE food industry a compressed time to do so, at times as short as a few months, to:

- turn the current system of paper based records into electronic form;
- to find $1,000 to register as a food facility;
- to find additional user fees if there is a failure to properly register; and.
- to be able to fully trace the food to the place of origin.

Then there is the burden on the FDA.

In no time at all, the FDA will need to

- hire enough inspectors to meet the new inspection standards;
- create unique identifier numbers for every food facility be they domestic or foreign;
- set up a new administrative law provision for the new criminal and civil penalties; and,
- make sure each facility has a food safety plan.

All of this action instantly demanded in one piece of legislation.

In our rush to action, we forget that we must give time for the industry to comply. Take for instance the CPSIA. We forever changed an industry with H.R. 4040, and the problems that have arisen with the implementation of H.R. 4040 has been too numerous to name. The timeframe given to them was impossible to meet. And that is just for makers of children's products.

We are now talking about food. EVERYONE eats food. Everyone. And we are telling an astronomically large industry to almost instanteously comply.

We need a realistic timeline for implementation.

Of course there is no excuse for comprising the safety of the American consumer, but food safety legislation has never been about compromising the safety of the American consumer. Bad actors will always be in existence no matter what Congress legislates.

What we are trying to do is to give the FDA the tools and other resources they need to meet the new marketplace for food. This legislation has some of the necessary tools we just need Congress to make sure they give both the FDA and the marketplace time to implement this.

Let's get it right the first time instead of having to revisit this issue post-passage like we have had to do with the CPSIA.

Mr. PALLONE. Thank you. The gentlewoman from California, Ms. Harman.

OPENING STATEMENT OF HON. JANE HARMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. HARMAN. Thank you, Mr. Chairman. I would like to welcome Peggy Hamburg, an old friend, a brilliant physician, and a superbly qualified person to this committee and to her new role as FDA commissioner. I think you bring a lot to this job and will help this committee which has worked on the issue of food safety for years and years and years come to a thoughtful, careful, healthful decision on the shape of this legislation. So welcome.

Mr. Chairman, I am very comfortable with the discussion draft, and I do know that it reflects many, many years of input from members. I thought that John Dingell's comment that it is almost old enough to vote was particularly apt. That applies to me too.

And I think that coming from a state like California, which is the largest agricultural producer in the country, we ignore food safety at our peril. The vice chairman, Diana DeGette was chronicling some of the recent outbreaks and how important it is to have traceability and mandatory recall. I agree. And we could have saved a lot of pain, a lot of cost, and a lot of health problems had we had those measures in place.

So I just want to conclude by saying that we have an able and willing partner facing us this morning. I think we have an able and willing committee on a bipartisan basis to engage with her, and I am very eager to see us make progress and to enact legislation close to the committee draft as soon as possible. It is in our national interest, and surely as we talk about grandchildren, it is in our grandchildren's interest. I yield back the balance of my time.

Mr. PALLONE. Thank you. Gentlewoman from Tennessee, Ms. Blackburn.

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

Ms. BLACKBURN. Thank you, Mr. Chairman, and I want to welcome Dr. Tim Jones who is going to be on our second panel. He is hiding over here in the back. He must be one of these Baptists from Tennessee. He is going to sit in the back row until time for him to come forward. But Dr. Jones is an epidemiologist with the Department of Health in our great state. Does a wonderful job for our state, and I am absolutely delighted that we are going to be able to hear from him today on the second panel. So, Dr. Jones, thank you for taking the time to come.

While the draft legislation before us today attempts to improve the safety and the efficacy of the Nation's food supply, it appears that there is still a lot of room for improvement. And I am appreciative that we are having the hearing, and I am hopeful that we are going to be able to work in a bipartisan way on this issue.

I appreciate the majority's attempt to improve the country's food safety system, but I think that we all know, especially those of us who are mothers, we know that you can't inspect your way to food safety. We know that this legislation is going to have to do more

than be reactive. This legislation broadly increases the FDA authority to make it one of the largest federal agencies in the existence.

My concern is the growth of bureaucracy, and what is going to happen as that bureaucracy grows. What I do think is necessary and I think it is necessary that our system be risk-based, that it be preventative, and take that approach, and that it effectively target bad actors.

It is imperative that resources are focused on issues of high risk and innovations that are most effective. However, this bill places undue burden on small businesses, and they would be harmed by burdensome and expensive provisions that are found in this current draft of this legislation.

The FDA has provided no evidence that it has improved its internal processes in order to improve the review of the Nation's food supply. This is something we have talked about endlessly in this committee and in hearings. So we are looking forward to having some questions on this.

There seems to be—and you haven't proven otherwise—that there are established protocols and lines of communication between different jurisdictions. You have not shown that there are best practices. Indeed, about 13 months ago, I asked for a list of best practices on intra-agency communication and how you are sharing this information, how you are working with your affiliates so that everyone can more easily pinpoint and get to the bottom of problems and bad actors and issues that are coming forward.

And yesterday, the FDA announced that they are studying ways to make the agency more transparent. This should have been done before we pass a bill that would give the agency millions of dollars in user fees. And I am going to yield my time back and submit my full statement for the record and look forward to the questions.

[The prepared statement of Ms. Blackburn follows:]

Congressman Marsha Blackburn
Opening Statement for Energy and Commerce
Health Subcommittee Legislative Hearing
"Food Safety Enhancement Act of 2009:
Discussion Draft Legislation"
June 3, 2009

It's nice to have Dr. Tim Jones from the Tennessee Department of Health with us today.

While the draft legislation before us today attempts to improve the safety and efficacy of the nation's food supply, it appears that there is still much room for improvement. I appreciate the Majority's attempt to improve the country's food safety system, but we cannot inspect our way into food safety. This legislation broadly increases FDA authority to make it one of the largest Federal agencies in existence – more growth of the bureaucracy.

What is necessary is a risk-based, preventative approach which effectively targets bad actors. It is imperative that resources are focused on issues of highest risk and interventions that are the most effective. However, this bill treats everyone equally, including small businesses that would be unnecessarily harmed by the burdensome and expensive provisions in this bill.

FDA has provided no evidence that it has improved its internal processes in order to improve the review of the nation's food supply. The lack of clearly established protocols and lines of communication between different jurisdictions and industry has continued to be very troubling to me.

Just yesterday, the FDA announced it is studying ways to make the agency more transparent. Such transparency should be in place before Congress passes a bill that would essentially give FDA millions of dollars in "user fees" – aka taxes – and additional workload – tobacco.

The FDA is saddled with so many unfunded mandates that placing additional stress on a "broken" federal bureaucracy will eventually lead to disaster.

As I have said in the past, FDA needs to shift its focus from reacting to food safety breaches, and instead implement policies to prevent food safety problems before they occur.

I look forward to continued work on this draft between the Majority and Minority to produce an improved, bipartisan food safety bill.

Mr. PALLONE. Thank you. Gentlewoman from the Virgin Islands, Ms. Christensen.

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

Ms. CHRISTENSEN. Thank you, Mr. Chairman, and welcome back, Dr. Hamburg. I know New York has suffered a great loss, but the Nation needs you more. I also think it is very fitting that as we have come back to Congress and begin to put the nuts and bolts on our health care reform legislation that the first hearing that this committee is having is with FDA because I believe we will begin that reform with an overhaul and a better resourcing of the Food and Drug Administration.

From the Food Safety Enhancement Act of 2009 that we are looking at in draft today and the Family Smoking Prevention and Control Act of 2009, we are looking at a new FDA, and you have the challenge as well as the opportunity to remake this important institution in ways that it better serves the health of the American public while also fostering, guiding, and supporting the bringing of new and better treatments to us as well.

I have confidence in a better resource FDA with more authority and one that is not overly prescriptive. I don't want to be overly prescriptive on what we tell the agency to do, but I hope that we will be able to allow the agency to do its job based on clear authority, adequate resources, and sound science.

In the case of food safety, in this my first few months on this committee, I have really been alarmed to find out what has happened that has put the public's health in jeopardy from salmonella to some questions about even the IRB process and several other areas. So we are here to help you create a better, stronger FDA, and this hearing is part of that process. And I thank you and all of the panelists for sharing their experience and expertise with us this morning.

Mr. PALLONE. Thank you. Gentleman from Pennsylvania, Mr. Murphy.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY OF PENNSYLVANIA. Thank you, Mr. Chairman, and welcome, Dr. Hamburg. Pennsylvania's number one industry is agriculture, and with that comes a lot of food processing. We are honored to have national companies located in Pennsylvania like Hershey's. We have companies like Welch's grows a lot of grapes there. And more locally in the Pittsburgh area, regional distributors of groceries like Giant Eagle, national distributors of olive products like Delalow's, and of course big names like Del Monte and the corporate headquarters of Heinz, and small companies like Sarah's Chocolates that sells around the country.

All of them have talked with us about concerns for this bill and certainly are very supportive of making sure we have a strong FDA, and we want to make sure that happens.

A few questions were raised, and I hope I will be able to remain for part of this hearing; although, I have to run to the floor, and

I apologize for that. I will miss some of this, but a number of issues: making sure that there is no unintended consequences of the bill that leads to increased price for consumers. Let us work on that, on the registration fee, particularly as it may affect some smaller businesses trying to work.

Also, with regard to the traceability, need to be clear what exactly the obligations are for both the processed and fresh food industry. Are we talking about traceability of final product or traceability of every ingredient that went into the product?

For example, if a local restaurant chain makes cookies or someone else makes cookies, trying to track every single ingredient that comes up with a specific food color dye may be a problem for them and would like to make sure we make that work for the safety of consumers but not in a way that impairs companies from doing their work.

And also unintended consequences of giving the FDA copies of all test results could be less testing. As companies go through lots and lots of test for products that never make it to market, would it be—to test the hundreds of samples each day have to be available or change to the testing of products that are in the marketplace?

With regard to the country of origin labeling and disclosure, to list every ingredient on a Web site could increase the costs and resources and not necessarily bring added value. Could there be some general labels such as some statement that this product may contain ingredients from one or more of the follow countries?

Also how about raising the importance of making sure that all enforcement officers and auditors are well-trained and calibrated to work to define audit standard? There is also concern of what happens with the family farm that may sell to local grocery stores. To what level would they have to comply? And would it be that the fees for them would be so high that they simply could not sell any products outside of their own farm store? And as that impairs some smaller distributors, how do we help them?

Another issue for grocery stores, what if they make packaged food at their stores such as some value-added ground beef products made in the meat departments? What happens if they mix in other foods at their store? How does the bill affect them in other ways?

So certainly in Pennsylvania we want strong food safety bills. We want ones that protect consumers. We want small businesses to be encouraged and large businesses to be supported but also encourage new startups. But more than anything else this week we want the Penguins to win the Stanley Cup, and I yield back.

Mr. PALLONE. Thank you. Gentleman from Texas, Mr. Green.

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

Mr. GREEN. Mr. Chairman, I want to thank you for holding the hearing today on the discussion draft of the food safety legislation. Over the past year or so, there have been several high profile food contamination incidents in the United States involving spinach, cantaloupes, peanut butter, and tomatoes. This committee has diligently investigated all of these incidents.

These hearings on the FDA have clearly shown us that the FDA simply does not have the resources, funding, or manpower and

technology it needs to protect the American food supply and fulfill its mission.

Chairman Dingell, Chairman Pallone, and Chairman Stupak have worked tirelessly on this proposed legislation. I would like to applaud them for their dedication on this issue. I am hopeful for this hearing and the discussion draft will bring us one step closer to passing food safety legislation out of the House.

I had a brief chance to review the legislation. I would like to briefly discuss a couple of issues that concern me. The discussion draft allows for food imported to be inspected by third-party accredited labs to conduct sample analysis. I support the provision, but I would like to see an investment in instruction in FDA labs.

The port of Houston is the largest port in the U.S. in terms of foreign tonnage, and a large portion of that is related to our energy industry. But the port imported 606,000 tons of imported food in 2007. The port of Houston does not have an FDA lab, and surprisingly there is no FDA lab in Texas even though we share the longest border with Mexico. I have yet to understand why Texas with its level of trade and southern border with Mexico does not have an FDA lab. In fact, there are over 300 ports of entry in the United States, and only 13 ports actually have FDA labs.

I hope my colleague from Arkansas will forgive me, but the closest FDA lab to Houston and the entire state of Texas is located in Arkansas.

Houston is not the only import area in Texas. Cities like Laredo, Texas that is one of the largest land-locked ports of entry in the world imports from Mexico literally thousands of trailers on a weekly basis. It seems unwise and frankly unsafe to have the FDA lab for the entire state of Texas located 100 miles away in another state.

The location of FDA labs throughout the U.S. needs to be evaluated and a report should be submitted to Congress on whether the FDA labs are located where they are most needed. The discussion draft allows FDA to assess current FDA lab locations and to relocate labs as necessary.

I would like to hear from the FDA on whether they have any plans to evaluate current lab, FDA lab locations. Congress also needs allocated funds to the building of more FDA labs. I was pleased to see the President's budget. The allocation of funds was three high-volume FDA labs. If we want FDA to truly ensure the safety of our food supply, we need to build more FDA labs in areas where food imports are arriving, such as Houston, so the FDA can quickly and accurately test our food imports and ensure food safety.

Again thank you, Mr. Chairman. Look forward to hearing our witnesses, and thank our new FDA director for appearing before the committee.

Mr. PALLONE. Thank you, Mr. Green. Our ranking member, Mr. Barton.

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

Mr. BARTON. Thank you, Mr. Chairman. I will be very brief. We support there being a legislative hearing and hearing on food safe-

ty. We think it is time to address this problem in a bipartisan fashion if at all possible. We do think it is important that we try to get it right if at all possible.

We understand that it is your wish and the full committee chairman's wish and former Chairman Dingell's wish to move with legislation sometime this month. Republicans are ready to help if we can agree on a bill that provides the FDA with the tools that it needs to ensure the safety of our food supply. But we will not support new blanket authorities that are designed merely to empower the bureaucracy.

Nearly everybody says that "we cannot inspect our way to foods safety." We need systems that reliably prevent sickness by applying resources in those places that are most susceptible to contamination. The draft before us proposes several areas to strengthen prevention of food illness outbreaks such as requiring all manufacturers to have food safety plans and also the creation of appropriate produce standards.

These ideas make sense and have near universal support. We are concerned however that parts of the draft add more weight than quality to the regulations and, in our opinion, provide too much discretion to the FDA without any corresponding food safety benefit.

For example, country of origin labeling is not about food safety. As a practical matter, it will simply increase the cost of groceries at the store. We know this because expert after expert has testified at the committee that this provision has absolutely no effect on safety.

There are several other specific concerns with the draft, including the level and the scope of the registration fees. I will say that the registration fees are less in this draft than they have been in some previous drafts so that I can at least say that we are moving in the right direction.

Having said that, it does appear that the majority simply wants $300 to $400 million in additional funds for the FDA, and we can't see that there is any clear purpose for that amount of funding.

Having said that, we look forward to the hearings, and if we can work on some of these problems, we are prepared to be positively engaged in the markup that comes after the hearings. With that, Mr. Chairman, I will yield back.

Mr. PALLONE. Thank you, Mr. Barton. The gentlewoman from Ohio, Ms. Sutton.

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

Ms. SUTTON. Thank you, Mr. Chairman. Thank you for holding this hearing on this extraordinarily important issue. I want to extend my appreciation to the sponsor of this bill and all of those who, for so long, have been fighting the fight to fix our food safety system and make sure that the food that is on the table to feed our families is safe for their consumption. And that which goes with them to school, they can fear not that it will be safe for their children to eat.

Chairman Emeritus Dingell, I thank you very much for your long effort in improving our food safety network, along with Representa-

tive Dingell, Representative Stupak and others on both sides of the aisle. And look forward to working with you.

As you may know, the very first bill that I introduced in the House, I believe, was a bill to call for mandatory recall authority for the FDA. And there is a reason for that. I mean we have seen these problems arise again and again and again within our food safety network. And the American people, I think, would have been shocked, as I was, to learn that our government did not have the authority to issue a mandatory recall when it became apparent that it was necessary.

Ohio has suffered the effects of problems with our food safety system. Most recently, the salmonella outbreak has claimed lives and harmed many throughout the Buckeye State, and it is critical that we are moving forward with a comprehensive bill to finally address and ensure the safety of America's tables and our system. Thank you so much. I yield back.

Mr. PALLONE. Thank you. Gentleman from Michigan, Mr. Rogers.

OPENING STATEMENT OF HON. MIKE ROGERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. ROGERS. Thank you, Mr. Chairman. Appreciate the hearing and congratulations, Commissioner, for your confirmation. I look forward to working with you. Some difficult issues ahead.

I am glad this committee is focused on food safety. I think we can all agree that the FDA needs more resources to protect our food supply and strengthen public health. I am concerned, however, that this might be a ready-shoot-aim event. We just passed a fairly onerous bill and added a lot of authority to the FDA that had a huge loophole in it that allowed tobacco regulation to be borrowed from the general fund of the FDA.

So you have this hole of millions and millions of dollars, of which you are going to have to try to apply to thousands and thousands of new regulators. At the same time, we are trying to improve food safety, and I can't think of anything more important than our food supply.

My hat is off to you, Commissioner, on the challenge of what you have just accepted. As we all know, the FDA is currently unable to inspect the majority of the Nation's food facilities. Worse, many high-risk facilities have gone without inspection and oversight at all. Over the last two years, we have seen the impact of this failure: numerous salmonella and E. coli outbreaks, which have sickened thousands and even led to death.

I hope that this bill could eventually be a bipartisan bill. However, many of the concerns that we have expressed have not been addressed, and we have not had the opportunity to sit down and have a discussion before this bill has come before the committee. And I think that is horribly unfortunate when you are talking about food safety and food safety issues.

The user fees in this draft are concerning to me. As written, the bill would require $1,000 in registration fee per food facility, but these funds totaling about $375 million which will be passed along to consumers, which are regular families trying to pay their bills already, there is nothing in there that dedicates this to new inspections.

So we have come up with a new tax regimen that doesn't benefit the FDA in getting it to the place where you need it most, which is inspectors for food facilities and food supply. Makes no sense to me, and that is something we absolutely have to change in this bill, or, Madam Commissioner, you are going to be looking at a very tough hole to fill again. There is nothing in here that tells the appropriators where to put that money so that you can best use it to accomplish the mission of which this bill will tell you it has to do without telling you where the money is coming from.

That is almost dangerous when you think about this plus the FDA tobacco regulation authority that allows them to take your money for food supply inspections and drug approval and use it for hiring new regulators for tobacco. That is a real problem that we need to fix not only in this bill, at least I hope we can.

If food producers are required to pay this new tax, they should absolutely have the certainty that the funds are going to be used for food safety inspections. I think that is common sense. I think we can all agree on it. I would hope to work with the majority to get that taken care of.

In addition, the draft's inspections schedule seems almost impossible to achieve. Today I hope, Commissioner, that you can shed some light on what a practical, risk-based inspection schedule should look like. And I hope you can cover that today in your statement and through questions.

I also have several other concerns: the new, broad recall authorities. Recall authority is important, but how it is done is incredibly important. An expansive new civil penalty regime, new labeling requirements that don't seem to have anything to do with food safety.

Again I think all of these issues we can address if we work together in a bipartisan manner and, I think, come around something that we all believe needs to happen. And that is more resources for food inspection and food safety regimes that the FDA has a primary responsibility for.

I look forward to working with you and thank you, Mr. Chairman, for this, I think, all important hearing.

Mr. PALLONE. Thank you, Mr. Rogers. Gentlewoman from Wisconsin, Ms. Baldwin.

OPENING STATEMENT OF HON. TAMMY BALDWIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Ms. BALDWIN. Thank you, Mr. Chairman. I appreciate the fact that you are holding today's hearing and also want to join my colleagues in commending you and Chairman Stupak and Chairman Emeritus Dingell and Chairman Waxman for putting this very important discussion draft before us that addresses very serious challenges that we face with respect to food safety.

Before I begin my remarks, I would like to submit for the record written testimony from the Secretary of the Department of Agriculture Trade and Consumer Protection in the state of Wisconsin.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Ms. BALDWIN. Thank you, Mr. Chairman. Food safety is an issue of great concern to me and my constituents. Approximately one in

four people in this country are affected or sickened by food-borne disease each year. As Americans, we rely on government to keep us safe, and as government, we have fallen down on the job.

As we consider this draft legislation, I know that our goal is to empower the FDA to prevent food contamination incidents before they occur. I hope that we do so with appropriate and sufficient resources, but also with precise coordination between other federal agencies, the states, and the private sector.

Currently with its limited resources, the FDA focuses its inspections on large manufacturers engaged in interstate commerce, and it leaves much of the front line work to the states. This bill creates a risk-based inspection system that significantly increases the frequency of inspections. I want to make sure that we are not duplicating efforts and that we can empower states to perform their work on the ground with logistical and financial support.

I urge the FDA to use this legislation to create a stronger, more integrated food safety system that leverages state and local resources.

As another result of limited resources, FDA relies on many private sector firms to conduct food safety testing on a contractual basis. I am pleased that the discussion draft includes a provision that would allow a laboratory accreditation process facilitating the FDA's use of third-party laboratories to perform testing.

And I want to make sure that the conflict of interest language in the bill does not prevent some of the most experienced laboratories from maintaining their strong partnership with the FDA moving forward.

I look forward to hearing your testimony, Dr. Hamburg, and that of the other witnesses today. And I thank you again, Mr. Chairman, for this hearing.

Mr. PALLONE. Thank you. Gentleman from Georgia, Mr. Gingrey.

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

Mr. GINGREY. Thank you, Mr. Chairman. Mr. Chairman, public health officials estimate that 76 million people become sick, 325,000 are actually hospitalized, and 5,000 die each year from food-borne illnesses caused by contamination. Incidents like those in my own home state of Georgia, where the actions of a few bad actors and a breakdown in effective government oversight sickened more than 677 people in 45 states and caused at least nine deaths underscores the need for action.

I agree with my colleagues that more needs to be done to ensure that the food products American consumers buy are safe. Additionally, I support the efforts of this committee as it reviews ways to streamline and improve the food inspection system in this country.

Mr. Chairman, I hope that these hearings will continue to allow us the opportunity to reflect on the breakdowns in our current system, as well as the appropriate solutions to safeguard the health and welfare of all Americans.

Madam Commissioner, I commend you for your recent appointment. Look forward to hearing from you and from the next panel of witnesses. And with that, Mr. Chairman, I yield back my time.

Mr. PALLONE. Thank you. Gentleman from Iowa, Mr. Braley.

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

Mr. BRALEY. Thank you, Mr. Chairman. Welcome, Dr. Hamburg. I don't think anyone sitting over here has anything but good wishes for you and the enormous challenges you face, and we wish you well and look forward to many fruitful and productive conversations with you. As vice chairman of the Oversight and Investigations Subcommittee, I have been very involved in the hearing that we have had up to this point on this important subject, and I am glad to see us finally getting to the point of considering legislation that is so critical to the health and safety of Americans.

Throughout this process, we have seen examples of both good and bad actors in the food industry. Some companies like Nestle USA set the standard with proactive food safety audits and showed us what can happen when companies do the right thing in reaching out and doing their own investigations.

On the other hand, we heard extensively about Peanut Corporation of America and its unsanitary and unsafe conditions and about its action to misrepresent the results of audits that were done, which put people at risk and cost people their lives.

That is why we are here today to talk about what we can do to improve the current state of the situation. This Food Safety Enhancement Act will solve many of the FDA's current limitations, and I am glad that it requires increased inspections of food facilities, tiered inspection systems that distinguish between high-risk facilities, low-risk facilities, and warehouses. And I also support the provisions to ensure the safety of imported foods, which is something I fought for since introduction of the Fresh Produce Safety Act last Congress.

Also very importantly I am very proud that this bill has strong whistle-blower protections. And I believe that it will help keep America's food supply safe. Many might consider some of the provisions in this bill burdensome. However it is important to look at opportunity costs of failing to take action to improve food safety.

In our March 19 Oversight hearing, I asked David Mackey, who is the CEO of Kellogg, how much the PCA Salmonella outbreak had cost his company, and he replied between $65 and $70 million. The legislation before us today might have prevented that outbreak and saved those costs.

Most important, however, is what we owe to the families of this country who have been injured or killed by unsafe foods and the desire to take real action to keep our food supply safe.

In 2006, a graduate of Dubuque Wallard High School in my district, a marathon runner named Jill Cole contracted E. coli from a spinach salad that she ate. After 17 days in the hospital, she was released with just eight percent of her kidney function, and she now has to see a doctor twice a year to monitor her kidneys. Jill and all other Americans should be able to have faith that their food is safe, and we are here today to try to restore that faith. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Gentleman from Maryland, Mr. Sarbanes.

OPENING STATEMENT OF HON. JOHN P. SARBANES, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MARYLAND

Mr. SARBANES. Thank you, Mr. Chairman. Welcome, Dr. Hamburg. We are so excited to see you in this position, and we look forward to your testimony on the proposed legislation. The comment has been made a couple of times that we can't inspect our way to food safety, and that may be true. But we can non-inspect our way to food danger, which I think has been unfortunately the hallmark of what has happened in recent past. And so this bill that is proposed is going to put so much more emphasis and inspection on the front end, which is going to make a tremendous difference.

When you look at the provisions that are contained in this proposed legislation, so many of them go under the heading of no-brainers. In other words, these are things that the average citizen would imagine are already in place and I think would be surprised to learn are not in place.

And so there is so much about this bill that represents some of the pent-up needs and concerns of the American public that we need to address. On the economics, and there has been a fair amount of discussion about that already just in the opening statements. The better we do on the front end, of course, with monitoring and inspection, the less cost we are going to have on the back end, both in terms of FDA needing to scramble to deal with outbreaks of food-borne illness, but also to save cost of businesses of not having to deal with the effects of that.

And I think that those saved costs will far outweigh the investment that we put in on the front end and certainly justify many of the measures that are contained in this bill. So we look forward to your testimony, welcome, and good luck to you. Yield back my time.

Mr. PALLONE. Gentleman from Connecticut, Mr. Murphy.

OPENING STATEMENT OF HON. CHRISTOPHER S. MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CONNECTICUT

Mr. MURPHY OF CONNECTICUT. Thank you, Mr. Chairman. I look forward to Dr. Hamburg's testimony and members of the other panel. I think what we are talking about here today is setting very high but very reasonable expectations for what we can do out of the FDA. And I think that if that is our goal, we can get a product that both parties can be proud of.

As the former chair of Connecticut's public health committee, I know I speak for a lot of state policymakers in our feeling of helplessness over the past 5 to 10 years especially, and I think you are going to find, as this committee will find, a lot of allies in state public health networks. They are going to be very supportive of this transformation that you are undergoing to try to assist in their efforts, which have been very difficult over the past several years.

Last thing, Mr. Chairman, I am very appreciative to you and to Mr. Dingell and others for including in this bill several aspects of the work that my colleague in Connecticut, chairwoman of the Agricultural Subcommittee of Appropriations Committee, Rosa Delauro. She has been working as a tireless advocate on this issue.

Parts of this bill relative to the inspection frequency for the riskiest foods out there, enforceable performance standards for food-borne standards are parts of her efforts incorporated into the underlying bill. And I appreciate you paying attention to her work here as well. Look forward to your testimony. Thank you for being here. Yield back.

Mr. PALLONE. Thank you. Gentlewoman from Florida, Ms. Castor.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Ms. CASTOR. Thank you, Mr. Chairman. And kudos as well to Rosa Delauro and Bart Stupak and John Dingell, our colleagues here that have worked for many years to improve food safety in America. And welcome to Dr. Hamburg. Based upon your background, obviously you enjoy a challenge, and food safety is an important challenge for our country.

Of all the issues we deal with in this subcommittee, food is the most ubiquitous. It is relevant to all Americans. I wanted to remind my colleagues that the Government Accountability Office—remember—keeps that very short list of major government problems that require broad transformation before they can ever hope to be effective. The list, called the high-risk series, includes notorious government failures such as the financial regulatory system, which failed to prevent the largest financial collapse in generations. It includes the implementation of the Homeland Security Department, which has been plagued from the beginning by cost overruns. And no surprise, it also include federal oversight of food safety.

And here is an example from last year that really hurt in my home state of Florida. Tomatoes last year from Florida were blamed for a nationwide salmonella outbreak that was eventually traced to jalapeno and Serrano peppers from Mexico. In the meantime, FDA intimated at the time not to consume Florida tomatoes, and that cost our state and agricultural producers and hard working folks over $100 million. All of the time and effort spent hinting and suggesting that Florida tomatoes were the problem only served to delay the solution to the real problem and allow more Americans to get sick.

Our committee understands the problem. This committee has held several hearings, and we understand that we must act expeditiously. Part of the problem lies in the lack of federal authority to effectively respond to a crisis. When FDA does not have incontrovertible proof of a specific food contamination, it cannot today issue a mandatory recall. Instead it must rely on corporations to voluntarily choose to pull inventory from the shelves.

The FDA does not even have the ability to assess civil penalties. This legislation before us gives the FDA that long overdue enforcement authority. The problems facing food safety and oversight are legion, and they are difficult. But they are not insurmountable, and I am confident that we will move the Food Safety Enhancement Act of 2009 quickly and provide American consumers with a safe, transparent and reliable food supply. I yield back my time.

Mr. PALLONE. Thank you. Gentlewoman from California, Ms. Eshoo.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. ESHOO. Thank you, Mr. Chairman, for having this important hearing on the Food Safety Enhancement Act of 2009, and I want to extend the warmest welcome and congratulations to Dr. Hamburg. She is a woman of exceptional talent, high intellect, a person with great character, and someone that has given much to their country already and comes from one of the most outstanding families, I think, in our country. You can tell how elated I am that the President chose so wisely in appointing you as FDA commissioner. We all look forward to working with you. To the extent that you succeed, the country is going to succeed.

I also think that your tenure can be and will be the mark where the FDA returns to being the gold standard in terms of a public agency. The American people believe in the FDA. They want the FDA to succeed because what you do they can't do for themselves. And the decisions that are taken can be the difference between life and death. That is how profound the decisions are.

So I can't tell you how thrilled I am that you are the one. I am pleased that the legislation that we are considering is going to improve the traceability of food because when tainted food is discovered, it is critical that we know where it has come from, where it has gone and what stores it is sold in. If sales are limited to a certain area, targeted recall could take place, which would be more effective for consumers and businesses.

And I am also pleased to see the mandatory country of origin labeling for food is included in the bill. I think in today's environment, this is really essential information for consumers to know where their food comes from. This is a long and complex bill, and I too, along with my colleague Mr. Murphy from Connecticut, really want to salute those that have worked on this issue.

Rosa Delauro has just been tireless, and you know that she brings passion and intellect to what she does. And so some of the ideas from her legislation are embedded in this. I look forward to our conversation. I hope that what we are asking the FDA to do that you are really up to it.

I think we have lived on fees for a long time, and I still have questions and would like to know directly from you whether you really think you are going to have the resources that are necessary to do this. Because if you don't, then the print of the legislation or law would be wonderful to read like some constitutions around the world that are absolutely magnificent, but they are not worth the paper they are written on.

We have fallen off the edge of a cliff in terms of what is coming into the country and what has happened to the American people. We have to get this right this time. And some think that there should be a stand-alone food inspection agency. Can the FDA actually do all of this? Do you have the resources for it?

I mean if there is pizza that has pepperoni on it versus pizza that doesn't have any meat on it, should there be a split jurisdiction between agriculture and the FDA in terms of inspection? I think the more splits there are, that there is more of an oppor-

tunity for things to fall between the cracks. I may be entirely wrong, but I still have some questions.

I don't think this is a perfect piece of legislation, but I am sure glad that we are considering the issue. So I wish you nothing but the best. I have great, great confidence and respect for you, and I am very proud that the President chose to pick the best in the country for this job. Thank you.

[The prepared statement of Ms. Eshoo follows:]

Statement of the Honorable Anna G. Eshoo
House Committee on Energy and Commerce
Hearing on the *Food Safety Enhancement Act of 2009*
June 3, 2009

Thank you Mr. Chairman, for holding today's hearing on the *Food Safety Enhancement Act of 2009.* I want to welcome Dr. Margaret Hamburg and congratulate her on becoming the FDA Commissioner. She is brilliant and effective and I believe the President has chosen the right person for these critical times. Over the past few years we've seen increasing outbreaks of food-borne illnesses from spinach to tomatoes, and peanut butter to pistachios. The American people expect the food that comes to market to be safe to eat and to share with their families. If we continue to look to the FDA as the gold standard for ensuring safety, we must arm them with the proper resources to do their job.

I'm pleased that the legislation we're considering today will improve the traceability of food. When tainted food is discovered it's critical that we know where it came from, where it's gone, and what stores it was sold in. If sales are limited to a certain area, a targeted recall could take place which would be more effective for consumers and businesses.

I'm also pleased to the see that the mandatory 'country of origin' labeling for food is included in the bill. In today's environment, this is essential information for consumers to know where their food comes from.

I look forward to hearing from our witnesses and what suggestions they have to improve the legislation.

Mr. PALLONE. Thank you. Gentlewoman from Illinois, Ms. Schakowsky.

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

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, and congratulations, Dr. Hamburg. I come to this issue with a lot of history and also this particular issue with a lot of emotion. My good friend Nancy Donnelly whose only child Alex was lost because of eating hamburger with E. coli and then dedicated her life to creating an organization, Safe Tables are Priority, has worked tirelessly for food safety.

And year after year, we have people coming before us telling these devastating stories, and every time we say we are going to do something so it never happens again. And yet it does.

In February, we heard testimony from Peter Hurley whose young son was made ill by eating Austin peanut butter crackers. They were found in millions of homes, and we were all shocked by documents presented at that hearing that showed that the Peanut Corporation of America knew that their products were tainted and yet released them into the food supply anyway.

So the discussion draft that is before us includes provisions that will seriously fill many of the gaps in our current food system. I wanted to just mention a couple of things that I think ought to be considered for review. There is just a brief mention in the bill dealing with the issue of antibiotic-resistant pathogens and the extent to which antibiotics that are used in livestock contributes to this resistance. We don't always think about this as food safety, but I think it is a truly important issue with H1N1. I know it was a virus, but nonetheless everybody is waiting for that kind of a plague that we don't have the care for partly because of antibiotic resistance.

Second, I believe the companies who have positive test results for possibly dangerous contaminants should be required to report those results to the FDA. We heard how PCA, nobody knew about it, and I think there are many other examples. It is a question on how the FDA effectively can ensure the safety of our food if we don't even know where there might be a problem.

And finally I believe the collecting and disseminating of information about food safety and food-borne illness to consumers is a critical component of any food safety plan. I am encouraged by the provisions of the bill, but I think there may be more that we can do to ensure that Americans are adequately informed. Thank you so much.

Mr. PALLONE. Thank you, and I believe that completes our members' opening statements. So we will now turn to our witness. And let me say, Dr. Hamburg, I appreciate your being here. I want to welcome you. We have, as you know, five-minute opening statements that become part of the record, and then you may get some questions afterwards from members of the committee. So thank you and if you would begin.

STATEMENT OF MARGARET HAMBURG, COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Dr. HAMBURG. Chairman Pallone and members of the subcommittee, I am Dr. Margaret Hamburg, commissioner of the Food and Drug Administration. Thank you for the opportunity to appear before you today to discuss the urgent need for reform of our Nation's food safety system. I commend you, Chairman Waxman, Chairman Stupak, Chairman Emeritus Dingell, and other members of the committee and your staffs for your leadership and hard work in developing this draft legislation.

The food safety bill under consideration represents significant reforms needed to modernize our food safety system. I am honored to have been chosen by President Obama to lead this great agency, and I am inspired by the President's personal commitment to improving food safety, including the progress being made by his food safety working group.

The President has backed up his commitment with resources, proposing historic increases in funding for FDA's food safety efforts. I also appreciate the support of Secretary Kathleen Sebelius and the Department of Health and Human Services and of Secretary Tom Vilsac and the U.S. Department of Agriculture for major progress on food safety.

In addition, a coalition of consumer groups is fighting for improvement in the food safety system so that more families do not have to suffer tragic consequences from food-borne disease. Major sectors in the food industry also support and are advocating for fundamental change, but even with all this support and momentum, our efforts will fall short unless Congress modernizes food safety laws to deal with the challenges of the 21st century. That is why this hearing is so important.

From the perspective of FDA, there are three key questions to ask about food safety legislation. First, does the legislation support a new system focused on prevention? Second, does the legislation provide FDA the legal tools necessary to match its existing and new food safety responsibilities? And third, does the legislation provide or anticipate resources for the agency to match its responsibilities?

To comment on the discussion draft, let me address each of these issues in turn. The first, does the legislation support a new food safety system focused on prevention? The draft legislation would indeed transform our Nation's approach to food safety from responding to outbreaks to preventing them. It would do so by requiring and then holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination.

Does the legislation provide FDA the legal tools necessary to match its existing and new responsibilities? In a new food safety system, FDA has the fundamental responsibility of overseeing and verifying the implementation of preventive measures by hundreds of thousands of companies. The agency also retains the existing critical role of protecting the public during an outbreak. FDA needs new legal authorities to be able to succeed in these roles and protect the public health. This legislation would provide these critical tools.

My written testimony provides several examples, but I would like to highlight one of the most important new authorities now. Section 106 provides FDA with explicit authority to access food records during routine inspections, thereby addressing one of the most significant gaps in FDA's existing authority. The authority provided in this provision is essential to enable FDA to identify problems and require corrections before people become ill.

It also enables the agency to verify, during routine inspections, that firms are maintaining proper distribution records. Records access and record keeping by all persons in the distribution chain are the key mechanisms of providing regulators with information on plant operations, product safety, and product distribution. Such information is necessary to verify compliance and to identify problems.

Lastly, does the legislation provide or anticipate resources for the agency to match its existing and new responsibilities? The draft legislation makes an important investment in the resources needed for major progress. After all, FDA must have the resources necessary to meet its responsibilities. Otherwise, the public will not benefit from the promise of a modern food safety system, and the agency will fail to meet the expectations of the President, Congress, and the public.

The bill authorizes three fees that are also requested in the President's fiscal year 2010 budget. One of these is in Section 101, which provides for a registration fee. This fee is of critical importance to enable the agency to improve and expand its food safety activities, including to increase its inspection coverage of the approximately 378,000 registered facilities and to enhance its other food safety activities.

Section 105 proposes a rigorous inspection schedule for food facilities. These requirements start 18 months after the enactment. To meet these requirements, Section 105 allows the agency to use inspections conducted by inspectors from recognized state, local, other federal agencies, and foreign government officials.

FDA would like to raise three issues about Section 105. First, the amount of resources required to achieve these inspection goals would far exceed even the historic increases in the President's fiscal year 2010 budget. Moreover, it would be difficult, if not impossible, for FDA to hire and train thousands of additional staff so quickly, even while relying on inspections by state, local and other federal and foreign government officials.

As a result, FDA encourages the committee to modify this section to take into account the operational and resource challenges involved.

Second, as we develop a new food safety system, FDA will gain better information to guide the agency's approach to inspection and oversight. We will understand where we must inspect more frequently because of the high risk of certain foods, facilities, and processes, and understand where we can protect public health without conducting inspections as frequently.

As a result, FDA would support flexibility to modify the inspection requirements based on the best available data on risk.

Third, Section 105 could do more to provide flexibility to FDA in meeting the inspection challenge. The draft legislation allows the

agency to rely on inspections by other federal agencies as well as by state, local, and foreign governments. An additional promising mechanism for international inspections is certification by accredited third parties. FDA would like the flexibility to explore the use of such an accreditation system and audit the performance of accredited third parties. With strong standards and robust oversight by FDA, this approach could help address the oversight challenge posed by the more than 220,000 registered foreign facilities exporting to the United States.

This is a historic moment for food safety in the United States, a moment for FDA and its sister agencies in the federal government to rise to the challenge of the 21st century. Success means fewer hospitalizations and deaths, fewer devastating recalls, and greater health for the American people.

The draft legislation is a major step in the right direction. I commend the committee for its leadership, and on behalf of the hundreds of dedicated staff devoted to food safety at FDA, I look forward to assisting with the legislative process. I welcome any questions you may have.

[The prepared statement of Dr. Hamburg follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TESTIMONY OF

MARGARET A. HAMBURG, M.D.

COMMISSIONER OF FOOD AND DRUGS

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

JUNE 3, 2009

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Pallone and Members of the Subcommittee. I am Dr. Margaret Hamburg, Commissioner of Food and Drugs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss the urgent need for reform of our nation's food safety system. I commend you and Chairman Waxman, and other Members of the Committee, and your staffs, for your leadership and hard work in developing this draft legislation.

This is my first testimony as FDA's Commissioner. And it is fitting that my first testimony focus on food safety.

I have devoted my career to advancing the public health. I served as the New York City Health Commissioner for six years in the 1990s, and then served as the Assistant Secretary for Planning and Evaluation at HHS. I have served on numerous committees related to public health as a member of the Institute of Medicine.

Food safety is a core public health issue. Every year, millions of our friends and neighbors in the United States suffer from foodborne illness, hundreds of thousands are hospitalized, and thousands die. Public health has been defined by the Institute of Medicine as "fulfilling society's interest in assuring the conditions in which people can be healthy." A precondition for health is having access to safe food.

It is a tremendous honor to have been chosen by President Obama to lead this great Agency. I am aware of the President's personal commitment to improving food safety and of the progress being made by his Food Safety Working Group. The President has backed up his commitment with resources, proposing historic increases in funding for FDA's food safety efforts (see appendix).

I am also aware of the support of Secretary Kathleen Sebelius and HHS, and of Secretary Tom Vilsack and the U.S. Department of Agriculture (USDA), for progress on food safety.

A coalition of consumer groups is fighting for improvements in the food safety system so that more families do not have to suffer tragic consequences from foodborne disease. I am impressed that major sectors in the food industry also support and are advocating for fundamental change.

But even with the President's support … even with the full efforts of HHS and USDA and other Federal, state, local, tribal, and territorial food safety partners… and even with the backing of consumer groups and industry … our efforts will fall short unless Congress modernizes food safety laws to deal with the challenges of the 21st century.

That's why this hearing is so important.

FOOD SAFETY LEGISLATION

From FDA's perspective, there are three key questions to ask about food safety legislation:

- First, does the legislation support a new system focused on prevention?
- Second, does the legislation provide FDA the legal tools necessary to match its existing and new food safety responsibilities?
- Third, does the legislation provide or anticipate resources for the Agency to match its responsibilities?

To comment on the discussion draft, let me address each of these three questions in turn. I will highlight a few of the many important new authorities in this bill.

Does the legislation support a new food safety system focused on prevention?

The draft legislation would indeed transform our nation's approach to food safety from responding to outbreaks to preventing them. It would do so by requiring and then holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination.

FDA is eager to further the development of this modern system. Working with industry, consumers, states, localities, and other key partners, we will establish basic standards for preventive controls. We will then join with states and localities to create an integrated national system of inspection, verification, and enforcement.

Key relevant provisions in the legislation include section 102, which requires facilities to conduct hazard analyses and implement preventive controls. It also requires companies to have a comprehensive food safety plan. Section 104 requires adherence to science-based safety standards issued by the Secretary for fresh produce and certain other raw agricultural commodities to prevent contamination. Section 112 improves FDA's ability to share key information on food safety between levels of government. These, and other provisions, are critical to modernizing our nation's food safety system.

Does the legislation provide FDA the legal tools necessary to match its existing and new responsibilities?

In a new food safety system, FDA has the fundamental responsibility of overseeing and verifying the implementation of preventive measures by hundreds of thousands of companies. The Agency also retains the existing critical role of protecting the public during an outbreak. FDA needs new legal authorities to be able to succeed in these roles and protect the public health. This legislation would provide these critical tools.

The draft legislation recognizes the importance of modernizing FDA's efforts to protect the safety of the food supply. Sections 102, 103, and 104 provide that the failure to comply with preventive controls, the food safety plan requirement, performance standards, or safety standards for produce would deem the food adulterated. An adulterated food is subject to seizure, condemnation, and forfeiture, and also may be refused admission when offered for import into the United States. Section 132 makes the Agency's administrative detention authority more useful by expanding the circumstances under which the Agency can detain a food, thereby

preventing its movement or distribution while the Agency takes appropriate regulatory action. Section 134 increases the criminal penalties for certain "knowing" violations, including distributing violative food, and section 135 provides the Agency with civil penalties when a person violates the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). Together, these authorities underscore the responsibilities of firms to only market safe food and give the Agency essential tools to enforce these requirements to protect American consumers.

The draft bill also recognizes the importance of providing FDA with improved access to information. Section 101 requires facilities to register annually, deems products of non-registered facilities misbranded and consequently prohibits their sale, and allows FDA to modify the food categories that firms provide during registration. These measures will help ensure that the Agency has accurate information about who is making food for American consumers.

Section 201 will provide FDA with important information about commercial importers and require that they comply with good importer practices as a condition of maintaining the registration. This section also prohibits importing a product without being properly registered, and deems a product misbranded if it is imported by an unregistered broker or importer.

The requirements in this section of the bill represent significant enhancements to FDA's authorities with respect to imported products. At present, importers and brokers are not required to register with FDA. These changes will reduce risks to consumers from potentially harmful products by requiring importers to take appropriate steps to protect product safety, and by

allowing FDA to take action against importers who do not implement appropriate measures to ensure the safety of the products they import.

Section 106 provides FDA with explicit authority to access food records during routine inspections, thereby addressing one of the most significant gaps in FDA's existing authority. The authority provided in this provision is essential to enable FDA to identify problems and require corrections before people become ill. It also enables the Agency to verify during routine inspections that firms are maintaining proper records.

Although FDA has routine records access for certain other FDA-regulated products, and USDA has similar authority for the food products it regulates, FDA does not have explicit authority for the vast majority of foods under its jurisdiction. This provision provides FDA with access to critical information to identify problems before an emergency occurs. Under current limited authority, FDA generally only has access to required records during an emergency situation involving serious threats to health or life. Records access and recordkeeping by all persons in the distribution chain are the key mechanisms of providing regulators with information on plant operations, product safety, and product distribution. Such information is necessary to verify compliance and to identify problems.

The requirement in section 107 to implement a product tracing system for food will also provide FDA with enhanced information that will help the Agency trace foods more quickly during an outbreak. The current requirement to keep records for the immediate previous source and immediate subsequent recipient (one up / one back) requires the Agency to go to each point in

the distribution chain during an outbreak to trace the source and distribution of the contaminated product, which is not a sufficiently expedient process when trying to prevent more people from becoming ill. The ability to trace the path of any food, including tomatoes, other fresh produce, and peanut butter, back through every point in the supply chain or forward through the supply chain, is crucial for limiting foodborne illness in an outbreak, for preventing future outbreaks, and for reducing the impact on the segments of the industry whose products were not associated with the illnesses.

Does the legislation provide or anticipate resources for the Agency to match its new responsibilities?

The draft legislation makes an important investment in the resources needed for major progress. After all, FDA must have the resources necessary to meet its responsibilities. Otherwise, the public will not benefit from the promise of a modern food safety system, and the Agency will fail to meet the expectations of the President, Congress, and the public.

The bill authorizes three fees that are also requested in the President's FY 2010 budget. For example, section 101 provides for a registration fee. This fee is of critical importance to enable the Agency to increase its inspection coverage of the approximately 378,000 registered facilities and to enhance its other food safety activities. Section 108 provides for a reinspection fee for a food facility that commits a violation that requires additional inspections by FDA. This will help cover the costs of reinspecting FDA-regulated facilities that fail to meet current Good Manufacturing Practices (cGMPs) or other FDA requirements. Section 144 authorizes the Secretary to charge and collect a fee for the issuance of export certificates for food and animal

feed which would facilitate trade. This fee will help cover the cost of this program, which is necessary for firms to do business with countries that require such certificates.

Section 105 proposes a rigorous inspection schedule for food facilities, ranging from at least every six to 18 months for high-risk processing facilities, every 18 months to three years for low-risk processing facilities and food labelers and packers, to every three to four years for warehouses. These requirements start 18 months after enactment. To meet these requirements, section 105 allows the Agency to use inspections conducted by inspectors from recognized State, local, other Federal, and foreign government officials.

FDA would like to raise three issues about section 105.

First, the amount of resources required to achieve these inspection goals would far exceed even the historic increases in the President's FY 2010 budget. It would be difficult, if not impossible, for FDA to hire and train thousands of additional staff so quickly—even while relying on inspections by state, local, and other federal and foreign government officials. As a result, FDA would support modification of these provisions to take into account the operational challenges involved, such as by changing these inspection frequencies.

Second, as we develop a new food safety system, FDA will have better information to guide the Agency's approach to inspection and oversight. We will understand where we must inspect more frequently because of the high risk of certain foods, facilities, and processes. We will also understand where we can protect public health without conducting inspections as frequently. As

a result, FDA would support flexibility to modify the inspection requirements based on the best available data on risk.

Third, section 105 could do more to provide flexibility to FDA in meeting the inspection challenge. The draft legislation allows the Agency to rely on inspections by other Federal agencies as well as by state, local, and foreign governments. An additional promising mechanism for international inspections is certification by accredited third parties. FDA would like the flexibility to explore the use of such an accreditation system and audit the performance of accredited third parties. With strong standards and robust oversight by FDA, this approach could help address the oversight challenge posed by the more than 200,000 registered foreign facilities exporting to the United States.

CONCLUSION

This is a historic moment for food safety in the United States – a moment for FDA and its sister agencies in the Federal government to rise to the challenge of the 21st century. Success means fewer hospitalizations and deaths, fewer devastating recalls, and greater health for the American people. As Secretary Sebelius recently noted at the Food Safety Working Group listening session, "with the leadership and commitment by our President and so many Members of Congress, and this renewed partnership across HHS, USDA, and our sister Federal agencies, I know that this is the time when we will finally make real progress and strengthen our nation's food safety system."

The draft legislation is a major step in the right direction, and I look forward to working with you to address both the issues raised here today and any other matters of concern. I commend the Committee for its determination and leadership on this legislation. On behalf of the hundreds of dedicated staff devoted to food safety at FDA, I look forward to assisting with the legislative process.

I will be happy to answer any questions.

Appendix to FDA Testimony

Food Safety Highlights of the President's FY 2010 Budget

FDA will conduct a broad range of food safety activities with the new FY 2010 resources. For example, during FY 2010:

- FDA will hire 678 additional full-time equivalent staff to expand programs and activities that protect America's food supply.

- FDA will fund the cost-of-living pay adjustment for FDA professionals who conduct food product program activities.

- FDA will increase domestic and foreign risk-based inspections, conduct more audits of controls designed to prevent contamination, establish three additional high volume laboratories, and conduct more food safety intervention, sampling, and surveillance through our Office of Regulatory Affairs. The FY 2010 budget increase will allow FDA to hire more than 220 additional investigators. When fully trained and deployed, the new investigators will enable FDA to conduct the following additional field activities, based on the FY 2010 increases in budget authority and user fees proposed in this initiative:

  -4,000 additional domestic food safety inspections
  -100 additional foreign food and feed inspections
  -20,000 additional import food and feed field exams
  -3,000 additional samples for analysis in FDA laboratories.

- FDA will begin to implement a new strategic framework for an integrated national food safety system. Under this framework, FDA will build and expand existing programs and relationships with its regulatory partners: our federal, state, local, tribal, and territorial partners. This will allow FDA to increase information sharing and improve the quantity and quality of food safety data that FDA receives from its food safety partners.

- FDA will work with all stakeholders to better ensure that food protection is built into the complete life cycle, from food production to food consumption.

- FDA will improve its understanding of food and feed vulnerabilities and risks. This will include improving FDA's ability to use baseline data to measure the impact of food safety efforts and to track the status of foodborne illnesses in the United States. Achieving a better understanding of vulnerabilities and risks will allow FDA to adjust food and feed safety priorities and ensure that food programs achieve the best health benefit for the American public.

- FDA will improve its ability to detect signals of contamination and also improve its ability to collect and analyze adverse events for food and feed.

- FDA will respond more quickly to foodborne outbreaks and will improve its ability to quickly trace contamination to its source.

- FDA will improve risk communication during a food safety event so that the public can respond promptly to FDA alerts and protect themselves from harm.

- FDA will increase the capacity of the Food Emergency Response Network by establishing three new laboratories for chemical analysis.

- FDA will further develop an integrated genomic data base for *Salmonella* and conduct research to reduce knowledge gaps.

- FDA will charge fees to cover the cost of reinspecting FDA-regulated facilities that fail to meet current Good Manufacturing Practices or other FDA requirements.

- FDA will charge fees to cover the cost of issuing export certificates for food and feed.

- FDA will upgrade and integrate information technology systems, including systems that we use to screen, sample, detain, and take enforcement actions against imported food and feed products that violate FDA safety standards.

Mr. PALLONE. Thank you, Dr. Hamburg. We will have a series of questions now from the members. Each of them gets five minutes, and I will start with myself. Under the bill, all facilities, both domestic and foreign, seeking to market food in the U.S. must register each year and provide certain information about the facility to the FDA. If the facility is not registered, it is illegal to market food from that facility in the U.S. And in order to register, each facility would be required to pay $1,000 per year as a registration fee.

Now, my understanding is in 2002, there was bioterrorism legislation, and under that legislation, food facilities were required to register, but there was no requirement to update that registration. So my questions reference that registration under the 2002 bill. Has that system resulted in problems in terms of FDA's ability to accurately account for all facilities selling food in the U.S.? And maybe you can tell us what problems exist.

And then the second part is do you believe that linking a fee to the requirement to register would help address whatever problems exist under this system that dates back to that 2002 bioterrorism legislation?

Dr. HAMBURG. Thank you. I think it is clear, based on the experience since the bioterrorism act in 2002, that we do need the extended authorities that would be offered in this bill. We know that when a facility registers once but doesn't have to register again, that it does create problems in terms of our ability to fully understand the nature of the food-related activities in that facility.

The Peanut Corporation of America, I think, is one good example. When they first registered, they weren't actually making peanut butter, and then they added that to their activities. With annual registration, we would have a much better record and understanding of the activities. And it would provide us with the tools to be more responsible in our oversight and in our inspections.

With respect to the issue of fees, I think it is a very important component of any food safety plan that Congress would enact. We absolutely need to have the resources to do our job. I understand that fees represent a burden on companies, and I wish that we were not dependent on that mechanism in all cases. But I do think that that fee is an investment in a robust and effective food safety system. That fee will go to enable the FDA to provide certain specific services and put in place the board and modernized food safety system that American consumers expect and need.

Mr. PALLONE. All right, let me go back to this fee because in the President's budget, he asked for $75 million in registration and reinspection fees. So obviously the administration has already shown support for the concept of a registration fee for food facilities in the budget.

However in our bill, with its $1,000 per facility fee, we would generate much more than the $75 million that is in the President's budget. So I want you to explain, if you could, what was contemplated in the President's budget request of the $75 million. Did that request seek to address the new authorities provided in this bill?

Dr. HAMBURG. Well, the President's budget request was, of course, put together before the specifics of this proposed legislation

was put forward. So it wasn't addressing all of the specific requirements laid out in this bill, importantly including the inspection schedule.

In my written testimony, there is an appendix that actually lays out some of the food safety highlights in the President's bill and some of the targeted areas for that $75 million increase in the budget.

It was to include many elements that are a part of this legislation, increased inspections but not to the degree that this legislation would call for, the implementation of preventive controls, strengthened laboratory testing, a stronger integration of FDA and federal food safety efforts with the state and local activities which is ultimately very, very essential to the——

Mr. PALLONE. Well, I know that the bill allows these fees to be applied towards a broad array of FDA's food safety activities. You know, in other words, it allows the fees to be used to boost FDA's ability to develop standards like performance standards and preventive controls. Do you agree that the fees should be applied towards all these activities that we mention in the bill?

Dr. HAMBURG. I think we want a robust, comprehensive program, and those fees should be applied to putting in place that suite of activities. The preventive controls are directly related to what companies must do under the new legislation, and I think it is very appropriate that the fees cover that aspect. For example, the inspections obviously are directly related. Very important that the fees cover that aspect and many other aspects of the portfolio of activities outlined in the legislation really are essential to what needs to be done to protect consumers and ultimately to protect the food industry. So that the public and consumers can be assured that the products are safe.

Mr. PALLONE. Thank you. Thank you very much. Mr. Deal. I am sorry. Mr. Whitfield.

Mr. WHITFIELD. Thank you. Mr. Deal had to leave. Dr. Hamburg, as you probably know, Senator Kennedy and Durbin and Burr and Greg have introduced a food safety bill on the Senate side. And has the administration endorsed that bill, or has it endorsed this bill, or has it endorsed any bill?

Dr. HAMBURG. You know I have to be honest that I have not—I have only been on the job seven days, and I have been focused on your piece of legislation.

Mr. WHITFIELD. OK.

Dr. HAMBURG. And so I would be happy at a later time to discuss in more detail the bill on the Senate side.

Mr. WHITFIELD. But as far as you know, the administration has not endorsed either bill?

Dr. HAMBURG. I don't believe so.

Mr. WHITFIELD. OK. Well, the reason I brought that up, there are some significant differences in this Senate bill and the House bill. And one area of difference relates to recall authority of the FDA. And under this bill, the FDA would have the authority for recall if an article of food may cause adverse health consequences. That would be the legal standard, may cause. But in the Senate bill, it says that there must be a reasonable probability of serious adverse health consequences or death. So those standards are sig-

nificantly different, and I would just ask you, since you are now going to be responsible for this. That first standard that is in this bill seems so general and so nebulous in a way. Does that bother you? Don't you think it would be better to have a more precise identified standard for recall?

Dr. HAMBURG. Well, I certainly understand the concern that you are raising, and I think there may be some opportunities for some wordsmithing. Certainly we would never seek to recall a product without, you know, some reasonable expectation that there was serious adverse consequences and harm related to that product. A recall is no small issue both in terms of resources and efforts on the part of the FDA and also its implications on industry and consumers who want access to those products.

So I think it is an area that we would like to work with you on for language. We wouldn't want it to be too overwhelmingly prescriptive because you want to have the flexibility in that kind of potentially emergency situation to move forward.

Mr. WHITFIELD. Well, I agree. I mean I think this is an area that we should look at because we know the ramifications of a recall, the expense involved, and certainly we want to have a balancing of protecting the public versus preventing undue expenses to companies as well. So I am glad to see that that is at least an area that you would be willing to talk about.

I might also say the same thing would apply to the access of records. There really is no standard at all in this bill, but in the Senate bill, it says that if FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death, FDA would have access to and be able to copy all records and so forth and so forth. But under this bill, it appears that FDA would just have blanket authority to request any records at any time without any sort of standard being met.

Dr. HAMBURG. Well, here I would like to stress that I think access to routine records is extremely important to assuring a safe food supply. It is very important that when inspectors go into a facility, they can examine certain aspects of what has been the procedure during a preceding period of time and not just inspect what is happening at that moment. Had we been able to better access routine records in the case of PCA, which has been talked about already this morning, we would have been able to see that there was documentation of contamination several years earlier, which had not been adequately addressed.

Mr. WHITFIELD. My time has about expired, but I would like to ask just one additional question. It relates to Jan Schakowsky's comment in her opening statement about the use of antibiotics in the agricultural community and the fact that more and more people seem to be establishing immunity to certain antibiotics. Is that a concern of yours?

Dr. HAMBURG. It is a huge concern of mine in terms of the growing problem of antibiotic resistance in this country and around the world and the implications that it has for our armamentarium of antibiotics to address serious and life-threatening diseases. I think it is an area that merits a lot of attention by the FDA, working in partnership with others. It is a topic I would be happy to come

back and discuss in more detail with you. And it is very high priority for me in terms of overall goals to improve public health.

Mr. PALLONE. Thank you. Chairman Dingell.

Mr. DINGELL. Mr. Chairman, thank you. Welcome again, Dr. Hamburg. Congratulations. My first question, it will be a yes or no—well, inspections are an important part of finding and addressing food safety problems. Isn't this correct?

Dr. HAMBURG. Yes.

Mr. DINGELL. Your agency does not have a good record when it comes to inspecting food facilities. Last year, you inspected 6,562 food facilities in the United States, 152 foreign facilities in the same time. Was that enough inspections? How many should you have? And what resources would you need to do the job?

Dr. HAMBURG. I think we can do better. With respect to the question of exactly how many, you know, I cannot tell you that now. But——

Mr. DINGELL. I will submit you a letter asking these questions in greater detail.

Dr. HAMBURG. I was warned that you would do that.

Mr. DINGELL. And I ask unanimous consent that the record remain open to include both my letter and the response of the administrator.

Mr. PALLONE. So ordered.

Mr. DINGELL. Would you support an increased frequency requirement?

Dr. HAMBURG. We clearly need to do more frequent inspections. We also need to do smarter inspections, and we need not to rely simply on inspections as our tool for a safer food supply.

Mr. DINGELL. We agree on that. I am keenly aware that there is a substantial cost associated with conducting foreign and domestic facility inspections. How much do you need to do this properly in terms of personnel and money? If you can't give it now, I will ask the record be kept open to receive that.

Dr. HAMBURG. All right, well it is a complicated answer, and there are some unknowables, but we need a lot more money.

Mr. DINGELL. Mr. Chairman, I ask unanimous consent that the record remain open so that this can be inserted at the appropriate time.

Mr. PALLONE. Mr. Chairman, the record will remain open. You don't have to keep saying it.

Mr. DINGELL. Thank you. And it is clear with new inspection requirements, FDA is going to need new additional resources to meet that requirement. Is it not?

Dr. HAMBURG. That is absolutely true.

Mr. DINGELL. The President has asked for additional resources for food safety activities at the agency. He requested, I am told, about $259 million in additional money. Is that correct?

Dr. HAMBURG. Yes.

Mr. DINGELL. It was the President's intent that these additional dollars, amounting to $164.8 million in new budget authority and $94.4 million in new fees, registrations, re-inspection and export certification would be used for increasing the number of food facility inspections conducted by your agency. Is that not correct?

Dr. HAMBURG. It would be used for that as well as other components of a more comprehensive modernized food safety system.

Mr. DINGELL. Thank you. It is correct that the President's budget request for food safety activity did not include any new requirements that may come with the food safety legislation that we are considering here. Is that correct?

Dr. HAMBURG. I am sorry, but could you repeat the question?

Mr. DINGELL. The President's request for new monies did not include monies to address the questions that you will be compelled to face under the new legislation. Is that correct?

Dr. HAMBURG. It addressed some components but not the full——

Mr. DINGELL. But not all?

Dr. HAMBURG [continuing]. Panoply of requirements that are outlined in this legislation.

Mr. DINGELL. There are many who have resisted new money for improving food inspection frequency by the agency. They ask that the use of these dollars for such activity be prohibited. Would you agree with that or disagree?

Dr. HAMBURG. I hate to do this, but this style of questioning——

Mr. DINGELL. I am sorry. I have limited time.

Dr. HAMBURG. I know.

Mr. DINGELL. I have 12 seconds left.

Dr. HAMBURG. Could you just repeat the question?

Mr. DINGELL. Question: Do you agree with the idea that we should prohibit the use of registration fees for inspection?

Dr. HAMBURG. I think we need registration fees to enable the agency to do its inspectional activities and other components of a food safety plan.

Mr. DINGELL. As a matter of fact, one of the few successful activities of Food and Drug at this particular time is what you do under PDUFA, which is supported by fees. Is that not correct?

Dr. HAMBURG. That is correct.

Mr. DINGELL. And you are starving in almost every other place. Isn't that so?

Dr. HAMBURG. Correct.

Mr. DINGELL. Can you state with any certainty the number of people, importers, customs brokers, filers, who import products under FDA's jurisdiction to the United States in any year? I believe the answer to that question is no.

Dr. HAMBURG. Is no, and this legislation would enable us to get a much better handle on who is out there producing and distributing food for U.S. consumption.

Mr. DINGELL. And the reason is that they are not currently required to register with FDA. Isn't that the reason?

Dr. HAMBURG. That is a large part of the reason, yes.

Mr. DINGELL. Isn't it important to FDA to have an accurate, up-to-date accounting of who these people are?

Dr. HAMBURG. Very important.

Mr. DINGELL. Now, these individuals are not required to comply with certain requirements to ensure the safety of these products that they import. They can handle any type of FDA-related products and are not required to have any specific training to do so. Is that not correct?

Dr. HAMBURG. That is correct. We would like to make sure that individuals importing food into the United States followed standards and guidelines that we expect with domestic food production.

Mr. DINGELL. Good. The discussion draft establishes a program to require importers, U.S. custom brokers of foods, drugs, and devices and others to register with the FDA and require that good importer practices are maintained as a condition for maintaining registration. Do you agree with that requirement?

Dr. HAMBURG. We would like importers to be registered.

Mr. DINGELL. Now, one more question, and then—well, I tell you what. I note my time is up. Madam Administrator, I will be submitting you a letter. Mr. Chairman, thank you for your patience, and I would thank my colleagues. I would note that the changes in the draft that we have before us today are those which have been largely done in consultation with FDA and in consultation with my minority colleagues. The next changes that you see will originate in about the same way. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Chairman Dingell. Next is the gentleman from Indiana, Mr. Buyer.

Mr. BUYER. Thank you. In your statement, you support the FDA's ability to trace foods more quickly during an outbreak, so you would support a track and trace system with regard to food. Is that correct?

Dr. HAMBURG. I would. I think it is very important to our ability to respond quickly to outbreaks of concern.

Mr. BUYER. And since you appear to be endorsing the bill, this draft discussion bill in front of us, you also support then the FDA's ability to increase inspections of food processing facilities. Is that correct?

Dr. HAMBURG. I think we need to do more inspections, but as I said earlier, I think we also need to recognize that it isn't simply increasing the number of inspections that will get us to the food safety system that we need. But it is also instituting the preventive controls and really shifting the way we think about food safety and also, you know, stronger partnerships with the locals and foreign government.

Mr. BUYER. Ma'am, when you discover a contaminated food, you believe it is your responsibility then to prevent the distribution of that contaminated food into the marketplace. Am I correct?

Dr. HAMBURG. Yes.

Mr. BUYER. So you are asking for that ability to do a recall. Would that be correct?

Dr. HAMBURG. Yes.

Mr. BUYER. And that once that contaminated food has been discovered, do you believe that you should have the ability to order the destruction of the contaminated food?

Dr. HAMBURG. It depends on the specific circumstance. Sometimes with a contaminated food, it might be possible to reprocess it and make it available in a safe way. But it is contaminated and putting consumers at risk and such an option does not exist, then that food should not be allowed to be provided to consumers.

Mr. BUYER. Since you support a federal tracking system for food, would you also be willing to support an electronic pedigree system for an interoperable tracking system for pharmaceuticals?

Dr. HAMBURG. You know I think that in both realms, it is very important to know where things came from——

Mr. BUYER. Is this yes?

Dr. HAMBURG [continuing]. And where they are going.

Mr. BUYER. Is this a yes?

Dr. HAMBURG. Well, you know, I am reluctant to——

Mr. BUYER. You are going to choose contaminated lettuce over adulterated drugs? I don't think so.

Dr. HAMBURG. No, I am not. I didn't think your question was either/or. I thought it was——

Mr. BUYER. My question is if you are going to support a pedigree system for the tracking and tracing of contaminated food, don't you also believe that it is important for us to have an electronic pedigree for the tracking and tracing of pharmaceuticals?

Dr. HAMBURG. In concept, I think, as I said, that traceability is very important to assure that what consumers get is——

Mr. BUYER. All right, let me get to this. We have 11 international mail facilities. Add three other mail facilities, DHL, UPS, and FedEx, of which 30,000 to 35,000 pharmaceutical packages come into those mail facilities every day. So do the math. When you do your inspections about 80 percent of them are either adulterated or they are counterfeit knockoffs. Yet FDA claims they do not have the ability to destroy.

So you are sitting here before this committee today saying that you know believe that you should have increased ability to inspect and to go after this contaminated food. I want to make sure that you also believe that you should have the ability to destroy these counterfeit, knockoff drugs. Because if you just do the math, that has got to be in excess of 350,000 counterfeit adulterate, knockoff drug packages per day. That is millions of packages per year that are harming people. So let me go right to you. Do you believe that FDA should have the authority, equal authority, to destroy these counterfeit adulterated drugs?

Dr. HAMBURG. As I indicated earlier, this is my seventh day on the job, and I haven't been briefed in full on all these issues. The problem of counterfeit drugs is huge concern, and I am eager to work with you since you clearly care very much about it.

Mr. BUYER. All right, you know what is happening right now? Here is customs, and right over here is FDA. There is not even a wall, yet customs has the ability to destroy. But you claim you don't have the ability to destroy. Please don't come before this committee and tell our country that you think we ought to be able to protect you with regard to food, but with regard to drugs, I can't believe as a doctor you would say——

Dr. HAMBURG. And I am not telling you that, sir, but I am——

Mr. BUYER. Well, then be clear.

Dr. HAMBURG [continuing]. Telling you that these are issues that are at the heart of the FDA mission and as a physician, extremely important to me. They are issues that I am determined to work on, determined to work with members of Congress to find appropriate solutions. But I am not comfortable at this time discussing the specifics of that program which I haven't been fully briefed on.

Mr. BUYER. All right, ma'am, I will be willing to work with you because I can't believe that this would be an issue that you would equivocate on. I yield back.

Mr. PALLONE. Gentlewoman from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you very much, Mr. Chairman and Dr. Hamburg. I want to add my welcome to that of my colleagues to your appointment. I know you are going to be working with this committee on a lot of different issues.

I want to talk to you about the trace back system because we have worked very closely over the years and most particularly on this latest iteration of the legislation on setting forth mandatory characteristics that would be contained in the tracing system that the FDA sets up through the regulatory process.

For example, the bill requires that the origin and previous distribution history of food must be maintained, and that history must be linked with the subsequent distribution history of the food. And it also requires—to me this is a really key component—that the system be interoperable. So for different types of food, they can figure it out.

Some people question whether it will ever be feasible to implement this type of system, and I am wondering if you can give your opinion on the feasibility of this type of a trace back provision.

Dr. HAMBURG. Well, as you indicated, it is very, very important and key to our success in being able to respond swiftly to outbreaks and make the appropriate interventions to protect the American public. Interoperability is absolutely key because it involves a whole range of different players along the full life cycle of the product, and that is one of the great challenges.

I think as we move forward in developing and implementing a traceability program, we need to work very carefully with industry and with the different components of the food production system. We need to do it in the context of public meetings and open exchange, but that should be our goal absolutely.

Ms. DEGETTE. And in the draft legislation, that is exactly what we do is we give the FDA the authority to work with industry and consumer groups to develop both the specific types of traceability technology and also the interoperability, correct?

Dr. HAMBURG. Yes.

Ms. DEGETTE. In other words, we are not saying—different sectors of the food industry have different types of traceability requirements, and we are not saying that we have a one-size-fits-all, correct?

Dr. HAMBURG. Correct.

Ms. DEGETTE. Do you think that there is an economic case to be made to the industry for better traceability?

Dr. HAMBURG. I think absolutely because with the opportunity to really do adequate trace back, we can really target what are the components of a food or the specific food products that are causing the problem and remove those or put in place the interventions to decrease the risk to that particular component of the food life cycle. In that way, we can both save lives and reduce illness.

But I think also reduce the cost to companies who, as we have heard about this morning, you know, have occasionally been inappropriately targeted when the trace back was inadequate and we

didn't identify the correct product. And also when there is a whole industry, but there is only one processor or manufacturer that is the problem, then we can protect the rest of the industry by really honing in on the particular product at risk.

Ms. DEGETTE. And once we develop this system, it should also make identification and removal of the specific contaminated food much more speedy than it has been——

Dr. HAMBURG. Absolutely.

Ms. DEGETTE [continuing]. Which again benefits consumer health, and it benefits the economic interests of that sector. Just one last question. The draft legislation that we have prepared exempts farms that sell directly to consumers or to restaurants from the traceability requirements, the farmers markets and so on. Do you think that that is an appropriate carveout for them?

Dr. HAMBURG. I think that we have to recognize the burdens on smaller businesses, but we also, from a public health point of view, have to assure that when there is a problem we can get access to the information that is needed to identify the source of a contaminated food. So we need to work very closely with——

Ms. DEGETTE. You know one thing is that these farmers markets, for example, they are not broadly distributing their food. It is just local. So if someone did get sick, the state health department could easily trace it back.

Dr. HAMBURG. It certainly makes it easier to do the outbreak investigation.

Ms. DEGETTE. Right. Thank you very much.

Mr. PALLONE. Thank you. Gentleman from Illinois is ready?

Mr. SHIMKUS. Thank you, Mr. Chairman. Mr. Chairman, can I ask you a process question first?

Mr. PALLONE. Sure.

Mr. SHIMKUS. Is there a possibility that the subcommittee may consider this legislation next week?

Mr. PALLONE. Yes.

Mr. SHIMKUS. And if so, I would ask then if members who could submit questions for the record by the close of business tomorrow, could we have witnesses respond to those questions by the close of business Monday?

Mr. PALLONE. Sounds like a good idea to me since we are likely to mark up next week. You have no problem with that?

Dr. HAMBURG. I think that is very appropriate approach.

Mr. PALLONE. OK.

Mr. SHIMKUS. And we do know——

Mr. PALLONE. Without objection, that is what we will do.

Mr. SHIMKUS. We know that is challenging, but, of course, this is a draft as I said in the opening statement. So we appreciate that. And again we do appreciate your testimony and welcome on board and we are all working for really on the same team trying to get responsible legislation that protects human health while ensuring that fees go to where fees need to go. So I just have two.

One, and this goes back in history. Two decades ago when Congress was deliberating on how to improve the state clinical laboratory testing—and I have been in the lab tech issue a lot—this committee under the leadership of now Chairman Emeritus Mr. Dingell, Mr. Waxman, and my own former colleague Mr. Madigan

issued a conference report stating that proficiency testing is considered one of the best measures of laboratory performance and arguably the most important measure since it reviews actual test results rather than merely gauging the potential for good results.

As we examine the discussion draft and its call for accreditation standards for laboratories to perform analytical testing on food, in your opinion, should proficiency testing be explicitly included here too?

Dr. HAMBURG. I think that we would only want to work with accredited labs, and the accreditation process addresses those kinds of concerns. The accuracy of the testing is key to making the right decisions, and, you know, I think that as we move forward, laboratory testing needs to be a strong component of what we do. And so efforts to ensure the accuracy of testing results is absolutely key to protect businesses and to provide the public health system with the information it needs to take action on.

Mr. SHIMKUS. And I would agree with that. I think that is as close to a yes as I will get, and that is fine. But I think that is a critical component if we are going to do this, that the proficiency test be a process by which we, you know, test the tester so we have some certainty.

Let me go back, and I know we have talked about this $75 million in the President's budget and $375 million in revenue. I mentioned this in my opening statement before some of the discussion, and I understand that, you know, this legislation offers more authority. And so that is why there may be a differing number than what the President proposed.

But I think a lot of us are going to be challenged by the fact—and what would be helpful before we move to markup is, you know, show us the money. Show us where we came up with this amount. As I have said also, there has already been millions of dollars put into food safety over the past six months.

A lot of us are trying to understand where $375 million came out. We understand that there was $1,000 per facility, and you add up the facilities, you get $375 million. But that doesn't answer the question as to where is that money? Is that money going to go to an inspection regime? And what does it cost to do an inspection regime?

I have been really a strong spokesperson for a risk-based system. Now, the risk-based system promoted in this draft legislation in nowhere near what I believe a risk-based system should be. I think you should go after risky individuals. And facilities that in essence offer no risk, you ought to incentivize them, and this has been statements that I have made for a long time. So I think even this risk-based approach that we are saying can be modified somewhat.

So is there a way to get up a better handle, or do you have better numbers that support this discussion draft that $375 million actually means $374 million more dollars worth of ability to inspect?

Dr. HAMBURG. Well, regrettably, I don't believe that the $375 million will cover the costs of inspecting on the schedule outlined in the bill. We actually would need considerably more resources to do that. We know, you know, based on—estimates vary, but that domestic inspections cost a little over $9,000. International inspections are probably threefold higher, and the number of facilities re-

quiring inspection are very, very large, numbering in the hundreds of thousands. The numbers add up quickly.

Mr. SHIMKUS. And my time has expired, and I apologize. I would just say that there is going to be skeptics that say OK, we have $375 million on a fee schedule, and it is not going to go for inspection.

Dr. HAMBURG. It will go for inspection.

Mr. SHIMKUS. It will go to other aspects of the FDA, and it would help provide some clarity. And, Mr. Chairman, if I could just end on this because the chairman emeritus mentioned this once again that there has been negotiation with his Republican colleagues. I would call them information positions of the answer of no. Not really negotiations on addresses of the bill, and I would encourage, maybe this is going to be a member-member discussion. But if we want a bipartisan bill, we ought to have some just not dictates, this is what we are going to do, but this is where we need to work together. And I yield back my time.

Mr. PALLONE. Thank you. Let me just reiterate again what Mr. Shimkus suggested in terms of the questions. We are going to ask the witnesses, including you in the next panel, and I will not remind the next panel that they submit their questions—the members submit question by the end of tomorrow night, which would be Thursday night and that we have responses by the end of business day on Monday, OK. I will mention that again. I mean I don't know. It may be difficult to meet that schedule.

Mr. SHIMKUS. Yes, would the chairman yield? And we understand that is a lot to ask, but for us to move, I think it——

Mr. PALLONE. Yes, that is fine and——

Dr. HAMBURG. No, we are happy to comply with that. We appreciate that you are taking this——

Mr. PALLONE. OK.

Dr. HAMBURG [continuing]. So seriously and wanting to move it forward swiftly.

Mr. PALLONE. All right, thank you. Gentlewoman from California, Ms. Harman.

Ms. HARMAN. Thank you, Mr. Chairman. I have sat here for a few hours listening to this hearing, and I think the content is very important. And I do think this committee has developed an enormous record on this subject. This is not new information for members of this committee, and I do think we will be able to move legislation next week. And I hope it will be bipartisan, and I agree with Mr. Shimkus that there should be opportunity for the other side to participate.

I wanted to acknowledge a comment that Mr. Buyer made before he left the hearing room. He was in some fashion implying that Dr. Hamburg is not focused on drug safety. My response to that is of course she is. She has been here for 10 minutes and the first topic up is food safety, so let us give her and this committee time to focus on that subject in the near future and not be accusing each other in some way of perhaps inadequate attention.

On the subject of food safety, which is what we are talking about, there is a section in the legislation about testing by accredited labs. Last year, I recall a huge worry about whether the prior administration was going to cut back on the number of accredited labs and

the impact that that would have on major ports of entry like the ports of Los Angeles and Long Beach. My district happens to be there. That are the place where enormous amounts of imported food enter the country.

So I just want to give you a chance, Dr. Hamburg, not in terms of a yes-and-no answer session, but could you assure us that lab capacity is a priority of yours and assure us that there will be adequate lab capacity for the anticipated importation of food and for the standards in this legislation to work?

Dr. HAMBURG. Absolutely. Laboratory testing is an essential component of a strong, science-based food safety system. And we do not have any plans to restrict our laboratory capacity. And I think, you know, as we move forward, we will want to make sure that we are applying the best possible science, including laboratory science, to our testing and screening activities. I hope that there will be advances in laboratory science and technology that will enable us to do our inspections in a more efficient and cost-effective way. But it is a pillar of what we do, and we will continue to support it. And we may, as resources become available and needs suggest, actually expand our capacity.

Ms. HARMAN. Well, I appreciate that, and I am not suggesting that our current lab structure be frozen in time. Obviously if there are improvements either in location or in function, we ought to embrace that.

But another one of the concerns that has been expressed is the ability to get the results from the lab to the FDA in a timely manner. Do you think the current system is adequate in that respect, and are you thinking about improvements to that?

Dr. HAMBURG. Well, we are eager to implement a system for reportable foods that will include laboratories reporting positive tests to FDA, and I think that will be a very important additional element to our activities.

Ms. HARMAN. Good. Well, I appreciate that too. Obviously in light of some of the recent outbreaks and their devastating impact on human life and health, it is important to get that information out and accurate as soon as possible.

Mr. Chairman, I don't have further questions of the witness. I am just thrilled that she is here. I yield back.

Mr. PALLONE. Thank you. Gentlewoman from the Virgin Islands, Ms. Christensen.

Ms. CHRISTENSEN. Thank you, Mr. Chairman, and I think your time is almost up. Thank you for your patience with all of the questions and listening to all of our opening statements.

In your testimony, you reference Section 106 that provides the more explicit authority for FDA to access food records during inspections. Do you think that that is enough, or should we go further in the legislation to mandate that those records be forwarded to FDA?

Dr. HAMBURG. You know I think what is outlined in the legislation is certainly a very good starting point. We don't want to be inundated with information. We don't want to put too much of a burden on industry, but we do need that access to records. We need companies to keep appropriate records, and we need to be able to have it to be able to inform our routine inspectional activities, to

be able to work with the companies to make sure that they have adequate preventive controls in place. And we need it certainly in the event of a serious outbreak of public health concern to enable us to swiftly get the information we need for action.

Ms. CHRISTENSEN. So you think that requiring them to have their plans and to have their plans audited in conjunction with your authority to have access to the records should be sufficient?

Dr. HAMBURG. You know I think we would want this to be a dynamic process as we learn more, putting in place the programs and policies and then learning from experience. But I think the bill lays out a very sensible and doable approach.

Ms. CHRISTENSEN. OK, and you also talk about the huge task of hiring and training inspectors. And if I understand correctly, you are asking for some more flexibility in the legislation to be able to do that. Are you asking for general flexibility, or would a transitional timetable with times certain in the legislation work just as well?

Dr. HAMBURG. Well, I think we just have to recognize that this would be an enormous scale-up of activity and that we need the timeframe to enable us to do it right, to recruit the people and train the people to work with industry to develop the systems that work. So we like flexibility in that way, and we would like more general flexibility so that we can learn as we go in terms of the inspection schedule and some of the requirements in that regard.

Ms. CHRISTENSEN. OK, my last question is kind of a general one. I don't think it was asked before, but even as late as yesterday, someone asked the secretary the question about one single entity to secure food safety with the authority over the food safety program for the country.

I don't think the secretary supported it. I am sure you don't support it, but what can you say about, if you have had a chance to look at how FDA and USDA work together or don't work as well together as they should? What can you say about addressing the concerns that give rise to the legislation that would put it in a single entity?

Dr. HAMBURG. Well, a couple of responses to your important question. One is that clearly as the new FDA commissioner, I have a first and urgent priority to strengthen food safety within the FDA and I think that there are many things that we can do to strengthen our program to improve accountability, to raise the issue as high priority. Part of strengthening food safety within FDA is strengthening coordination with critical partners as well, and that certainly means with USDA, and I look forward to a working relationship with them.

It also means strengthening the working partnerships with state and local public health organizations, and it very importantly also involves working with other international agencies and foreign governments because I think we are going to see the percentage of food coming in from overseas increasing in the years to come. And the globalization has a profound impact on the work of the FDA.

And I also do think that the authorities and tools that this new draft legislation could potentially provide to the FDA will be extremely important in moving the federal government and the FDA

in the direction that we need to for robust and modernized food safety system.

Ms. CHRISTENSEN. Thank you for your answers. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Gentlewoman from Ohio, Ms. Sutton.

Ms. SUTTON. Thank you, Mr. Chairman, and thank you very much, Dr. Hamburg, for your service and for all that I am confident you are going to do to improve food safety in this country.

As I mentioned in my opening statement, Ohio has been hit hard by issues arising from food safety. In the past year, there have been 105 cases of salmonella reported in Ohio and sadly three deaths resulting from the most recent peanut-based strain.

Nellie Napier was a constituent of mine who unfortunately died from salmonella poisoning that she contracted in a nursing facility, and just in April of this year, in Cuyahoga County there were three incidences of illness from E. coli and another death, this time a seven-year-old girl. So this is an urgent issue for the people that I am so honored to represent.

I mentioned that I introduced the Protect Consumers Act, which was a bill that would give the FDA mandatory recall authority, and I am happy to see that it is a part of this comprehensive bill. And I would just like to get a little bit more of your opinion about the need for recall authority. And this bill, of course, seeks to remedy the situation of the FDA not having the mandatory recall authority by laying out two different types of recall authorities.

First if the FDA believes that a certain food may cause adverse health consequences or death, the FDA can require a recall. But in that scenario, FDA must first give the company an opportunity to voluntarily recall its own products. And if that doesn't work, then the FDA can order a mandatory recall.

And then, of course, the second type of recall is an emergency recall if the FDA finds that a certain food presents a threat of serious adverse health consequences or death. You may do that immediately.

Can you just tell me about whether you think that the need and the approach, the two-tiered approach, is addressed in a good way in this bill and why it makes sense?

Dr. HAMBURG. Well, I think the history is that voluntary recall is often effective in getting those potentially harmful products off the shelves and protecting consumers but that you do need that emergency mandatory recall function as a backup. There certainly have been cases where the mandatory recall of a dangerous product has been delayed because of a reluctance on the part of the company to pull that product, and there has been a back-and-forth and lawyers involved and delays of weeks, putting consumers at risk.

So I think that to have the mandatory recall as a emergency measure is very, very important. And sadly in a world where we might also need to address intentional contamination of food, that emergency mandatory recall becomes a very, very important tool. You know I think the reality is that having that as an enforcement tool probably makes it easier to also work with companies on the voluntary recall.

So I think it is a continuum that we need. We need both.

Mr. SHIMKUS. Will the gentlelady yield just on this same point, just a follow up on this?

Ms. SUTTON. I have very little time, but I will yield.

Mr. SHIMKUS. Yes, just to follow up. One of the issues would be may cause. That is kind of a low standard. I think there is going to be concern about the may cause language in here and how do you define that.

Dr. HAMBURG. Yes, well we discussed that earlier, and I think perhaps there is some wordsmithing that could be done on that point.

Mr. SHIMKUS. Thank you. I thank my colleague.

Ms. SUTTON. Sure, and if I could just follow up on the suggestion that has been made and some have argued that because mandatory recall is such a strong tool that only the commissioner should be able to exercise the authority to order a recall with no further delegation. And I just wanted to know about your thoughts on the approach of having only the commissioner order a recall and how that would work for the FDA. And frankly, while I am at it, would such an approach work with regard to suspensions and subpoenas, and what are your thoughts about those subjects?

Dr. HAMBURG. Well, these are important and powerful authorities that shouldn't be used lightly. However, I think that experience shows that senior level officials can be entrusted with these authorities along with the commissioner, but it is certainly something that we would want to work with Congress on in order to put in place the system that people have the most confidence in.

Ms. SUTTON. I thank you, and I am certain that we share concerns about expediency and making sure things happen in a quick time. And I think that your answer on the way that the recall authority would work, you having the mandatory authority would give you an opportunity to encourage even more strongly—or they would be necessarily encouraged, the companies, to comply on their own as well. So thank you very much.

Mr. PALLONE. Thank you. Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman, and again, Dr. Hamburg, appreciate your patience today in—but if you think this is tough, you have FDA to work on, which is—and I laugh because in '07 we spent a great deal of our time, both in the subcommittee and the full committee, in reforming FDA. And then last year with all the food safety issues that came up, it seemed like we are back at it again, and I am glad you are there.

In my opening statement, I mentioned my concerns about the location and number of FDA labs, and I know my colleague from southern California, Congressman Harman, mentioned the same thing. Texas does have the longest running border with Mexico, and the port of Houston is right behind the port of LA/Long Beach in imported tons of food, yet we don't have an FDA lab. And I have had the honor of meeting my FDA inspectors on the docks of the port of Houston, but they are detailed out of Laredo, Texas.

And I guess because it is such a large state and the need for a lab somewhere, I am glad the bill does include the ability to contract with labs because we want the inspections done as quick as possible. Does the FDA tend to evaluate the current locations of the 13 labs and whether these locations are meeting the inspections de-

mands? But also in the President's budget, talks about three high-volume FDA labs, and how would the FDA decide where to place these labs? And what consideration would be placing in a place like Texas or even southern California? I didn't know southern California didn't have a lab with LA/Long Beach. And that is my only question. So thank you, Mr. Chairman.

Dr. HAMBURG. Well, you know, I am fascinated that the laboratory issue comes up so much here because it is such a key issue. And in my past experience as a public health official, it is often the laboratory that is the underappreciated component of public health needs. So this is very encouraging to me.

At the present time, we don't have any plans to expand that basic, you know, network——

Mr. GREEN. Thirteen labs.

Dr. HAMBURG [continuing]. Of laboratories that you mentioned. Although, as I said to Congresswoman Harman, you know, with additional resources and expanding need, that might be a possibility. We will be creating some additional high throughput laboratories. And in all honesty, I am not certain about the process by which those laboratories are being developed and cited. It is something I need to go back as a very new FDA commissioner and learn more about. But the laboratory issue is one that is essential as we have discussed.

Mr. GREEN. I guess the reason it comes up so often is it, over the last three years actually, our committee has spent so much time on, you know, pharmaceutical safety, food safety, and the concern is that we are importing so much of our food. Like I said, Laredo, Texas is probably the biggest land-based port in the world. And so much food comes from Mexico we need the inspections as timely as possible to move the produce or whatever the products, the foodstuffs particularly. But we also need to make sure that it is—and the problem is it is not paid for. But with this fee that is going to be assessed, hopefully that will generate the resources, both for the personnel and also for the facilities.

And I guess if you are having to contract with private labs, that may be great, but there are times that a public lab would be faster and ultimately cheaper to the folks who pay the bills. And so that is why I just ask FDA to look at that. I am glad we are going to contract because we want the commerce to flow. But if there is a need to have a lab that would be more economical and just as fast to contract with the private labs, then I would hope this funding source—I guess over the last three years, our hearings have said FDA is—the staff, we don't have the staff, we don't have the resources. Well, we are going to try to give you the resources in this bill and hopefully to hire the staff and to have the facilities.

Dr. HAMBURG. And let me just assure you that your constituents are not being compromised in terms of the laboratory testing that is needed to protect their food supply because samples can be shipped to labs. In the modern era, it can be done in a timely and safe way. So the coverage in terms of laboratory testing is still available, but I hear and understand your concern about the gap in terms of an onsite facility in your region.

Mr. GREEN. Well, and I think the fear that some of us had is that we don't want to play favorites. These ports compete for cargo, and

we don't want it to be based on that there is not an FDA lab or it is slower to get this through one port as compared to the other port. And I know I have run out of time but appreciate the responsibility you are taking on. And hopefully we will provide you with the tools that you need. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Green. Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman, and thank you, Commissioner, for being here. As chair of Oversight and Investigations and one of the authors of the Food Safety Enhancement Act, I have done about nine hearings in the last two years just on food safety and certainly is a major problem. One of the problems I found every time we had a hearing, there is always lack of information that the FDA did not have from either the manufacturer of the food or the producer of that food. And it was always difficult to get information.

The Safety Enhancement Act authorizes the FDA to issue subpoenas for records and other things relevant to any hearing investigation or proceeding or relative to any other matter within the FDA's jurisdiction, including matters under the Public Health Service Act and the Federal Anti-Tampering Act.

Do you believe subpoena power would be beneficial to the FDA?

Dr. HAMBURG. It is very important for us to get access in a timely way to the information that we need, and I think that that authority will enable us to act more swiftly and effectively, yes.

Mr. STUPAK. Well, I hope you would because I think we are still waiting for information from the 2007 salmonella outbreak and peanut butter and from the Georgia plant, Blakely, Georgia. I don't think we got all that information yet.

Some in the food industry though appear to be concerned that the FDA will abuse its subpoena power. Their concerns center around the subpoena provision that authorizes the FDA to issue subpoenas in matters under FDA's jurisdiction that are not part of a particular hearing or investigation of a specific violation of the act.

There seems to be a fear that FDA will go on fishing expeditions, constantly sending out burdensome unnecessary requests for documents. How would you address these concerns?

Dr. HAMBURG. Well, I think that we have enough work to do without going on fishing expeditions. We would be seeking information that would be of vital importance to addressing the tasks at hand. It would be of great value to have the ability to access critical information, to inform the inspection process as well as to inform outbreak investigations. And I think that if we are going to be able to really move forward to ensure the safety of the food supply, this is one of a number of tools that will enable us to really do what needs to be done.

Mr. STUPAK. That is refreshing to hear because I have been pushing subpoena power for the FDA for 10 years, and get a witness to agree from the FDA. But by the time I got back to my office, the FDA had called me and say that is not the official position of the FDA. We are against subpoenas. So it is refreshing to hear that, and I am sure you won't use it for a fishing expedition.

Let me ask you this. Chairman Waxman and I wrote to you to review this phenyl A BPA. While previous FDA commissioner

found no problem with it, FDA's own science review found there was room for concern. And we wrote to you, and you wrote back indicating that you have agreed to review the safety of BPA. So let me just say thank you on that point.

I think it is important that we look at all the documents and all the evidence and all the studies, not just two studies when there are over 100 other studies that raise concern on this phenyl A.

Also on food safety, on the lab situation, it has been my concern the last FDA commissioner thought food safety was to close six or seven of the 13 field labs, which I thought was the wrong idea. So we have always fought reorganization or closing of these labs. And we actually had to put in legislation to make sure these field people, critical work for the FDA and for the safety of the American people, stay on their jobs.

And you recently wrote back to me, myself and Chairman Waxman, indicating that there are no current or future plans to close or consolidate any of these 13 field laboratories. And you also went on and said that you are actually hoping you will be able to hire at least 70 new analysts for the 13 labs to replace staff losses over the last few fiscal years. So thank you for that, and without objection, I would like to place the record from the commissioner in the record, this letter in the record.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. STUPAK. Let me ask you one more question if I may. Risk-based inspection schedule. One of the important new requirements in the new food safety bill will be to put in place is a risk-based inspection schedule for food facilities. Under current law, even risky facilities can go years between FDA inspections, but our legislation has strict requirements to make sure FDA inspectors actually get into the riskiest facilities as frequently as possible. The riskiest facilities must be inspected at least every 6 to 18 months. No food production or storage facility will go more than four years between inspections.

Under current law, there is not any requirement regarding how frequently these facilities must be inspected, is there?

Dr. HAMBURG. There is not, and I think that your desire to see a risk-based strategy be put in place is absolutely key so that we can target resources on the highest risk.

Mr. STUPAK. Does this bill give you the flexibility you need to modify the inspection goals based on available resources and the best available evidence on risk?

Dr. HAMBURG. Well, as I said in my testimony, I am concerned about the requirements for inspection outstripping available resources, and that has been a chronic problem for the FDA in terms of being able to fulfill its important mission.

I think that the inspectional strategy outlined in the draft legislation is a wonderful aspirational goal. I would love to be able to sit here and say that FDA could take it on and fully achieve it, but there is a reality of limited resources, both dollar and human. And I think that is where we need some flexibility to really look at the numbers and really also begin to move swiftly in the direction outlined in this bill but also try to learn as we go so that we can find ways to do our inspections in a more efficient targeted way and

really focus on the highest risk and really try to leverage other resources to achieve the goals as well through partnership with state and locals, partnership with foreign governments and potentially with third parties that are certified and overseen by the FDA to help us particularly with respect to the burgeoning number of foreign sites for inspection.

Mr. STUPAK. Well, the——

Mr. PALLONE. I am sorry, Mr. Stupak, but we are——

Mr. STUPAK. I just want to mention about the registration fee for——

Mr. PALLONE. I am sorry. No more questions though. We are done with questions. Go ahead. You had a comment?

Mr. STUPAK. Yes, I was just going to say hopefully the registration fee that we would be putting in place with up to 400,000 facilities would provide enough resources to do the inspection and other work that the FDA sorely needs to the resources and the personnel to do it. We understand that. Hopefully that will be part of the bill.

And thank you, Mr. Chairman, and thanks for your help on this bill.

Mr. PALLONE. Thank you. Mr. Deal.

Mr. DEAL. Yield briefly to Mr. Shimkus for a follow up.

Mr. SHIMKUS. And I thank my ranking member, and I am glad my colleagues here because I want to follow up on this wordsmithing that we talked about on the may cause. That is why we still have the same problem on the subpoena power issue because in the subsection three, it says "any other matter relative to the commissioner's jurisdiction under this act." I would like there to be a "may cause."

I have a problem with the "may cause" in the other part of the bill or the draft. We should at least have a "may cause" for offering a subpoena to someone. And so I would hope that that would be something else we would look at. So I think there is some issues.

We want subpoena power, but we want it for a reason. We just don't want it to be at the whim, with all due respect, Dr. Hamburg. And I will yield back to the ranking member.

Mr. DEAL. Let me ask you a question with regard to another area, and that is the registration and fees collected from commercial importers, and there has been a change in this draft from previous drafts that we have seen. Specifically, why should drug and device manufacturers who currently already pay an annual establishment fee be required to pay a duplicative fee? And what entities are really encompassed within this commercial importation fee schedule?

Dr. HAMBURG. Well, the importer fee refers to fees on the individuals or the companies that are serving as the link between foods that are grown, processed, manufactured overseas and being brought into the United States to be distributed to consumers here. And so they are not necessarily representing a given manufacturer, but it is a very important function because it is that bridge between what is happening on the international scene and what is coming into this country for use.

Mr. DEAL. Specifically with regard to the drug and device manufacturers who currently already register and already pay a fee, would you envision that they are going to have to pay an additional

registration fee in addition to what FDA already collects from? And if so, why?

Dr. HAMBURG. In terms of the importer function, I need to go back and look at this issue with respect to devices because I don't know how that system is set up, whether it is the manufacturer that is serving in that role or not. So I will go back and learn more about that.

Mr. DEAL. Would you take a look at that? I think that is one that we really seriously need to look at. I don't think we ought to be duplicating what you are already doing because you have jurisdiction there. I think that would be unfair.

Let me ask you also quickly with regard to the tracing of food, the tracing system that is put in place for you to issue regulations. It appears that that would include the restaurants to be able to have traceability, and I am told that 7 out of every 10 eating establishments are not part of chain operations. They are just independent, separate food operations. I am just curious as to whether or not you think that this would have a serious impact on these small business owners. And do you think we ought to do a cost/benefit analysis before we impose that kind of cost on these individuals?

Dr. HAMBURG. Well, I think clearly we want to work with restaurant owners and small businesses in order to make sure that the systems are not too cumbersome, but it is very important that they keep records because if there is a tainted food that is in their facility, the implications for the health of their business as well as for the health of their consumers is very significant indeed. And I think that they would want to be able to assist in sharing their information about where the foods came from so that the traceback can occur and we can identify the source of an outbreak and control it.

So I think they are a very important link in the food supply chain and, you know, protecting health really depends on them keeping records.

Mr. DEAL. Let me ask you what has FDA done to implement the current, what I think is called the one-up-one-back traceability requirements? What has been done to implement that?

Dr. HAMBURG. Well, the one-up-one-back has been in place, as I understand it, for a while now. But it has proven not to be adequate to really capture the full lifecycle of a product and that we really need, as we mentioned earlier, the full supply chain to be documented and integrated. Interoperability, not just fragments, you know, is really key to a successful and swift investigation of outbreaks and the ability to control a problem and prevent future exposures to a contaminated food product.

Mr. PALLONE. Thank you. Just the way we are proceeding, Mr. Markey is going to go now, and he is our last——

Dr. HAMBURG. OK.

Mr. PALLONE [continuing]. Questioner for you, Dr. Hamburg. We have one vote, but we will be right back after that. And then we will start with the second panel. So, Mr. Markey.

Mr. MARKEY. Thank you, Mr. Chairman, very much. Congratulations, Dr. Hamburg.

Dr. HAMBURG. Thank you.

Mr. MARKEY. You may know that I have a bill that calls for BPA to be banned from being used in food and beverage containers because of the risks that have been identified. We have also recently learned the food and chemical industries have launched a public relations campaign opposing any efforts to deal with this issue.

Is the FDA concerned about BPA? And what does the FDA plan to do about those concerns?

Dr. HAMBURG. Well, we are concerned. Certainly I am aware of, you know, some of the studies that have raised issues in animal populations and some of the information about BPA. In many components of the food supply, we are starting to see activities at the local and the state level in terms of action with respect to BPA. And I would hope that FDA could really be providing leadership on some of these issues of assessing and analyzing risk.

We are taking another look at the BPA issue. The acting chief scientist at the FDA has been asked to take the lead on this because, of course, this is a decision where we have to bring the best available scientific data to bear. We need to look at all of the studies and examine them. But it is an issue of great consequence for Americans. As a mother as well as a physician, it is an issue that I think we need to look at seriously.

And I look forward to being able to come back with some report from this serious look that is being taken. And we expect that it is going to be a task for him over the summer to lead this review, and by the end of the summer, beginning of fall, we hope to be able to put forward a fresh look at the BPA issue.

Mr. MARKEY. Do you have any advice for parents who are concerned about their children ingesting this chemical?

Dr. HAMBURG. Well, I think of course parents that are concerned can find alternatives that don't have BPA, and I think that for the most part, I think that those alternatives are pretty clearly labeled and pretty available. And I think anyone with concerns, you know, should do so.

Mr. MARKEY. OK, thank you for your work on this. If you could keep us posted on the progress you are making on——

Dr. HAMBURG. Absolutely.

Mr. MARKEY [continuing]. The evaluation of it. Thank you so much. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, and thank you very much, Dr. Hamburg. As we have said, you know, we do intend to move forward on this bill next week, and we appreciate your input and whatever else comments you may give us by next Monday. We have one vote. We will come back, and then we will hear from our second panel. Thank you.

Dr. HAMBURG. Thank you. Thank you for your leadership on this important issue.

[Recess.]

Mr. PALLONE. The subcommittee will reconvene, and I see our second panel is already seated. Let me introduce each of you. On my left is Mr. Michael Ambrosio, who is representing the Food Marketing Institute, and he is the vice president for Quality Assurance Division at Wakefern Food Corporation. Next we have Ms. Pamela G. Bailey, who is president and chief executive officer of the Grocery Manufacturers Association. And then we have Ms.

Caroline Smith DeWaal, who is the Safe Food Coalition food safety director of the Center for Science in the Public Interest. Dr. Tim F. Jones, who is a state epidemiologist from the Tennessee Department of Health. And last is Mr. Thomas E. Stenzel who is president and CEO of United Fresh Produce Association.

Welcome. You know it is five minutes, and obviously your statements become part of the record if you want to include material more than the five minutes. And we all heard before—I know some of you are wondering if you can meet the deadline, but since we do intend to go to markup next week, I agreed with what Mr. Shimkus said about we will give you any additional written questions by the end of business tomorrow, and we would like them back by Monday at the end of business.

So we will start with Mike Ambrosio. Thank you for being here again.

STATEMENTS OF MICHAEL AMBROSIO, FOOD MARKETING INSTITUTE, VICE PRESIDENT, QUALITY ASSURANCE DIVISION, WAKEFERN FOOD CORPORATION; PAMELA G. BAILEY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, GROCERY MANUFACTURERS ASSOCIATION; CAROLINE SMITH DEWAAL, SAFE FOOD COALITION, FOOD SAFETY DIRECTOR, CENTER FOR SCIENCE IN THE PUBLIC INTEREST; TIM F. JONES, STATE EPIDEMIOLOGIST, TENNESSEE DEPARTMENT OF HEALTH; AND THOMAS E. STENZEL, PRESIDENT AND CEO, UNITED FRESH PRODUCE ASSOCIATION

STATEMENT OF MICHAEL AMBROSIO

Mr. AMBROSIO. Thank you. Chairman Pallone, Ranking Member Deal, and members of the Health Subcommittee, I am honored to appear before you today on behalf of the Food Marketing Institute to present our views and suggestions on the Food Safety Enhancement Act Discussion Draft.

FMI and its member company share the common goal of enacting legislation this year that would genuinely improve the safety of the food supply. Steps that actually prevent the presence of adulterance in the food supply are the only true way to improve the safety of our food.

I am Mike Ambrosio, vice president of quality assurance, Wakefern Food Corporation. I have been in charge of food safety programs at Wakefern for 30 years. Founded in 1946, Wakefern has grown from a small struggling cooperative into the Nation's largest retailer-owned, non-farm cooperative in the United States. We are headquartered in Keasbey, New Jersey. Wakefern, along with its Shop Rite Stores, employs over 47,000 individuals in New Jersey, New York, Pennsylvania, Delaware, Connecticut, Massachusetts, Rhode Island, and Maryland.

Today I am also representing FMI, a national trade association that has 1,500 member companies made up of food retailers and wholesalers in the United States and around the world.

FMI members operate approximately 26,000 retail food stores with combined annual sales of roughly $400 billion representing three-quarters of all retain food store sales in the United States.

FMI's retail membership is composed of national and regional chains as well as independent grocery stores.

This morning I will present several of FMI's recommendations for revising the bill, but I ask that my entire statement be included in the record.

In April of 2008, I testified before this subcommittee on legislation that would have modernized and overhauled the food safety systems at the Food and Drug Administration. Since that time, high-profile food safety outbreaks and recalls involving tomatoes, jalapenos, peanuts, and pistachios have not only made headlines but regrettably have caused illness and in some cases even death.

Many of the themes and ideas that I share today will be similar to those that I shared in 2008, but there are differences that reflect lessons learned and new weaknesses in the existing food safety system identified from these latest recalls.

As the purchasing agent for the consumer and the final link in the supply chain, our industry understands that it is vital to ensure that the FDA has the necessary authority, credibility, and resources to meet the challenges of today's global marketplace.

Consumer confidence remains an essential factor in this debate. Food safety issues can be extremely complex and consumer vary greatly in their knowledge of the science and other issues affecting the safety of our food supply. However as food safety issues draw national headlines, consumer awareness has a well concern about the safety of commercially prepared food and products purchased at the supermarket heightens.

Mr. Chairman, I applaud you, Mr. Dingell, Chairman Waxman, and all members of the committee for your efforts to address changes that are needed to improve our food safety system. We support many of the proposals in the draft by emphasizing the need to have preventative measures be the foundation on which the food safety system should be built. The draft also recognizes that we need to focus on the majority of resources on facilities and products that pose the greatest risk of contamination that could result in food-borne illness or injury. We must continue to be sure that any changes meet certain criteria, be supported by science, have measurable benefits, be affordable, be realistic and be implemented without unintended consequences.

First we applaud you for not only designating an entire section of the bill solely to prevention, but also putting this first in the most extensive section of the bill. From our perspective, this is the appropriate emphasis.

In addition, I would like to specifically comment on certain sections of the draft. FMI recognizes that a strong public/private partnership is needed to help ensure safety of the food supply. Although every penny counts in this tough economic times, there is nothing more important than improving and ensuring the safety of our food supply. We are willing to support a fair registration or user fee provided that it is utilized by the FDA in a transparent and accountable manner to improve the safety of our food supply through means such as conducting research and consumer education programs.

We look forward to working with the committee to address our concerns about how the FDA may utilize any fees collected. We

support the requirement that every registered food facility conduct a risk assessment and implement and maintain a validated food safety plan and identify potential resources of contamination and appropriate food safety controls and document those controls that would prevent, eliminate, and reduce potential hazards.

Adherence to food safety plans goes a long way towards developing a culture within a company that is critical to ensuring food safety. Mr. Chairman, thank you for the opportunity to testify. We appreciate the work that has gone into the development of the Food Safety Enhancement Act discussion draft with the goal of improving food safety and the food supply and helping to restore consumer confidence in the food safety system. I look forward to your questions and remain available to the subcommittee. Thank you.

[The prepared statement of Mr. Ambrosio follows:]

FOOD MARKETING INSTITUTE

Testimony of Mike Ambrosio

Vice President, Quality Assurance
Wakefern Food Corporation
On Behalf of the Food Marketing Institute

The Food Safety Enhancement Act
The United States House of Representatives

Subcommittee on Health
Energy and Commerce Committee
June 3, 2009

Chairman Pallone, Ranking Member Deal and Members of the Health Subcommittee, I am honored to appear before you today on behalf of the Food Marketing Institute (FMI) to present our views and suggestions on the Food Safety Enhancement Act discussion draft. FMI and its member companies share the common goal of enacting legislation this year that will genuinely improve the safety of the food supply. Steps that actually prevent the presence of adulterants in the food supply are the only true way to improve the safety of our food.

I am Mike Ambrosio, Vice President, Quality Assurance, Wakefern Food Corporation. I have been in charge of food safety programs at Wakefern for almost 30 years. Founded in 1946, Wakefern Food Corporation has grown from a small struggling cooperative into the nation's largest retailer-owned (non-farm) cooperative in the United States. Headquartered in Keasbey, New Jersey, Wakefern, along with ShopRite stores, employs over 47,000 individuals throughout New Jersey, New York, Pennsylvania, Delaware, Connecticut, Massachusetts, Rhode Island and Maryland. In 2008, retail sales totaled over $10 billion for our company.

Today I am also representing FMI, a national trade association that has 1,500 member companies made up of food retailers and wholesalers in the United States and around the world. FMI members operate approximately 26,000 retail food stores with combined annual sales of roughly $400 billion, representing three quarters of all retail food store sales in the United States. FMI's retail membership is composed of national and regional chains as well as independent grocery stores.

The American consumer has access to a selection of products in today's grocery store that is unmatched. Our customers have products available to them everyday that are grown and made not only in the United States, but also throughout the world. As a result, fresh fruits and vegetables are available for purchase year round and fresh seafood can be found in the middle of our country far from any ocean. The average grocery store has over 50,000 individual items on their shelves with large supermarkets having over 100,000 different items for sale. Regardless of the number of items in a store though, the most important goal of food retailers and wholesaler is to ensure that the food we sell is as safe and of the highest quality possible.

In April 2008, I testified before this Subcommittee on legislation that would have modernized and overhauled food safety systems at the Food and Drug Administration (FDA). Since that time high profile food safety outbreaks and recalls involving tomatoes, jalapenos, peanuts and pistachios have not only made headlines, but regrettably have caused illness and in some cases even death.

Many of the themes and ideas that I share today will be similar to those that I shared in 2008, but there are differences that reflect lessons learned and new weaknesses in the existing food safety system identified from these latest recalls. As the purchasing agent for the consumer and the final link in the supply chain, our industry understands that it is vital to ensure that the FDA has the necessary authority, credibility and resources to meet the challenges of today's global marketplace.

Consumer confidence remains an essential factor in this debate. Food safety issues can be extremely complex and consumers vary greatly in their knowledge of the science and other issues affecting the safety of our food supply. However, as food safety issues draw national headlines, consumer awareness as well as concern about the safety of commercially prepared foods and products purchased at the supermarket heightens. As a result, shoppers may quickly alter purchasing decisions and will even go as far as avoiding an entire product category if they are not confident of its safety.

In FMI's annual survey of consumers, presented in the annual U.S. Grocery Shopper Trends report (Trends), 83 percent of shoppers say that they are either somewhat or very confident in safety of food in the supermarket. However, the vulnerability of consumer confidence is illustrated by the high percentage of shoppers who are only "somewhat" confident at 72 percent compared to those that are "very" confident at 11 percent. We believe that strengthening consumer confidence is the responsibility of both private industry and the government working together.

At the retail level, supermarkets have many prevention programs in place to protect our customers, including consumer education campaigns, employee food safety training, extensive sanitation programs, food safety management systems, and programs that involve working closely with our suppliers, especially those beyond our borders. I would like to share with the Committee some programs utilized by Wakefern, and many other companies in the food retail industry to help ensure the safety of the products on our shelves.

Wakefern is committed to working with the supplier community to constantly improve the safety of the food they manufacture and process, and to this end participates in the Safe Quality Food (SQF) Program. SQF provides independent certification that Wakefern's suppliers' food safety and quality management systems comply with international and domestic food safety laws and regulations. Recognized by the Global Food Safety Initiative (GFSI), the SQF certification program relies on highly qualified, accredited, third party certification entities to provide objective, independent assessments of a supplier's ability to produce, process, prepare and handle food according to the highest possible standards, which meet or exceed the standards set by the U.S. government. Wakefern has chosen to use accredited third party certification programs like SQF because they represent the cultural change that is needed in our food safety system. Such programs adhere to rigid requirements to avoid conflict of interest and ensure that only trained, qualified auditors perform the safety performance assessments. Accredited certification provides an additional layer of review above anything that is required by the local, state or federal government and helps ensure our brand integrity and the protection of our consumer.

Within the domestic retail setting, training store managers and workers in food safety is an important tool for protecting public health. Currently, Wakefern makes extensive use of the SuperSafeMark program to train and certify our store-level managers and associates. SuperSafeMark is the most comprehensive food safety and sanitation training

program designed specifically for food retail employees, and through the National Registry of Food Safety Professionals, offers accredited food handler certification to store associates. This instruction emphasizes methods for combating foodborne illness with time and temperature controls, measures to prevent cross contamination, and programs for personal hygiene, and cleaning and sanitizing best practices.

Along with these prevention-based programs, we have in place rapid response systems to ensure that when a problem is identified, we take immediate action to remove recalled product from the distribution chain and retail shelves as quickly as possible. A new resource developed by the food industry to improve the speed and accuracy of recall notifications is the recently introduced FMI Product Recall Portal. This electronic notification system allows suppliers to send a secure, automated alert directly to retailers and wholesalers about products that must be recalled, providing information about the recalled product in a standardized form 24 hours a day, seven days a week.

The final link in the supply chain is the consumer. Wakefern has long provided consumers with practical, science-based guidance on safe food handling at home through the Partnership for Food Safety Education. The Partnership brings together consumer advocacy groups, the FDA, U.S. Department of Agriculture, Centers for Disease Control and Prevention, national industry associations and health and scientific groups.
The Partnership created the award-winning "Fight BAC!" education program to teach children about food safety as part of their school curriculum. The Partnership's "BAC Down!" program urges consumers to use thermometers to ensure their refrigerators remain at safe temperature levels – no higher than 40 F. Most recently, the Partnership launched the "Be Food Safe" campaign in cooperation with USDA to provide retailers with a wide range of resources to educate their customers about safe food practices. The campaign encourages the use of colorful, modular icons and photography to illustrate the basic and most important safe food-handling practices:

- Clean — Wash hands and surfaces often.
- Separate — Do not cross-contaminate foods.
- Cook — Heat foods to proper temperatures.
- Chill — Refrigerate foods promptly.

All of these food safety initiatives at the retail level cannot ensure that we deliver safe food to our customers if the food coming into our stores isn't already produced and processed to the highest standards. While the entire food industry continues to work together in developing stronger and innovative food safety programs, FMI and its members recognize the crucial and evolving role for government to play in assuring the safety of our food supply.

Mr. Chairman, I applaud you, Mr. Dingell, Chairman Waxman and all the members of the Committee for your efforts to address changes that are needed to improve our food safety system in the latest draft legislation. We support many of the proposals in the discussion draft by emphasizing the need have preventive measures be the foundation on which any food safety system should be built. The draft also recognizes that we need to focus the majority of our resources on facilities and products that pose the greatest risk of

contamination that could result in food-borne illness or injury. We must continue to be sure that any changes meet certain criteria:

- Be supported by science;
- Have measurable benefits;
- Be affordable;
- Be realistic; and
- Be implemented without unintended consequences.

Preventing food safety problems from occurring by mitigating risk must be the guiding principle for changes. Our focus must be on actions that will have the greatest impact on improving food safety. We support many policy initiatives in the draft legislation because they are clearly intended to prevent the presence of adulterants in the food supply.

Prevention:
First, we applaud you for not only designating an entire section of the bill solely to prevention, but also putting this first and the most extensive section of the bill. From our perspective, this is the appropriate emphasis. In addition I would like to specifically comment on certain sections in the draft.

Changes in registration of food facilities (Sec. 101):
FMI recognizes that a strong public-private partnership is needed to help ensure the safety of the food supply. Although every penny counts in these tough economic times, there is nothing more important than improving and ensuring the safety of our food supply. We are willing to support a fair registration or user fee provided that it is utilized by FDA in a transparent and accountable manner to improve the safety of our food supply through means such as conducting research and consumer education programs. We look forward to working with the Committee to address our concerns about how the FDA may utilize any fees collected.

Food Safety Plans (Sec. 102):
We support the requirement that every registered food facility conduct a risk assessment, and implement and maintain a validated food safety plan that identifies potential sources of contamination and appropriate food safety controls, and documents those controls that will prevent, eliminate or reduce potential hazards. Adherence to a food safety plan goes a long way toward developing a culture within the company that is critical to ensuring food safety.

Risk-Based Inspection Schedule (Sec. 105):
We are pleased to see that Section 105 directs FDA to target its inspection resources based on the risks associated with different types of facilities. For prevention to have the greatest chance of success, particularly with limited resources, resources should be deployed using a risk-based model. In terms of factors to consider for assessing the risk presented by the facility, we are pleased to see that the FDA will be considering whether a facility importing food has been certified in accordance with Section 801 (p). Certification by a qualified certification body can also be used as a factor to assess the

risk of domestic food producers and would further assist FDA in targeting its resources based on risk.

Traceability (Sec. 107):
We recognize that collaboration with FDA is necessary to ensure that industry initiatives will better assist in the event of a foodborne illness outbreak. We support the draft's provisions requiring the Secretary to gather information to identify technologies for tracing and to assess the costs and benefits associated with the adoption of such systems, hold public meetings for input and conduct pilot projects when writing regulations. However, we would recommend that the Secretary be allowed to design systems based on the information gathered and not be mandated to develop a specific type of system prior to those efforts.

Current traceability systems do not uniformly meet the needs of industry, the consumer, or government. Enhancing systems that will help minimize the time required to identify, isolate and remove product that may cause injury, illness or adverse health consequences is the most important goal of a traceability system. Development of a stronger food traceability system is not a static process. Technology improvements are being made everyday that improve both information transfer and food processing. Improving traceability is a long term commitment. A number of strong pilot projects addressing the unique needs of a particular product or industry are ongoing and are already resulting in improvements in best practices. One challenge that has been identified that we are working to alleviate is the need to develop consistent industry standards for messaging of data related to product that ensures interoperability among data capture and transfer systems, so that all elements of the supply chain can receive information about the product or commodity in a consistent, timely manner

We also recommend including retailers in the section allowing direct sales by farms to be exempt from the requirements of the section. Wakefern and many other retailers support local farms in their communities by featuring locally grown produce in their stores in the same manner a local restaurant would make it available to its customers. We would like to be able to continue supporting our local economies and small farmers while also giving the consumer the opportunity to purchase fresh produce grown locally.

Certification (Sec. 109):
FMI supports the draft's recognition that certain qualified third parties can provide valuable support to FDA by helping to ensure that the food being imported into our country is meeting all U.S. food safety requirements. We look forward to working with the Committee to provide FDA with further guidance on the definition of a "qualified certified entity" and incorporate the added oversight of accreditation to help ensure that certifications are administered only by recognized certification programs and audits are being performed by third party certification companies that have demonstrated that the processes and standards used in the auditing and certification program are sufficient to verify compliance of food producers and processors with federal food safety standards.

Safe and Secure Food Import Program (Sec. 113):
We are also pleased to see that the discussion draft includes provision for a "fast lane" for imported foods that meet certain standards. We believe that this will encourage more producers abroad to utilize heightened food safety programs. The bill's "Guidelines" section provides factors that FDA should consider in developing the program. We strongly recommend that you add certification by a "qualified certified entity" in accordance with the standard set forth for certification.

Reportable Food Registry (Sec. 112):
The bill would significantly revise the standards for the reportable food registry that FDA was required to develop under the Food and Drug Administration Amendments Act of 2007, but that has not yet been finalized. Since the agency has been delayed in implementing the reportable food registry, we are concerned that the additional provisions in this bill may further delay development of the registry. We look forward to working with the Committee on this issue.

New Recall Authority (Sec. 111):
We believe that FDA should be given the authority to mandate a recall in only those cases where a company responsible for adulterated food does not act promptly to recall a food that presents a reasonable probability of causing serious health problems or death. This authority would allow FDA to act when a firm refuses to recall product or when a company is no longer in business and is not able to conduct the recall. Penalties and other punitive measures should also be limited to those responsible for the adulteration.

We are however concerned with the proposal to give FDA the authority to issue a "cease distribution" order as a result of its impact on retail operations. Stores have very little room to hold foods for an extended period of time, particularly frozen or perishable foods. If FDA issues a "cease distribution" order for a product, retailers will treat that order as if the product had been recalled. Stores would immediately remove the product from the shelf and implement other measures to ensure the consumer could not purchase the specific item. We need to be able to transport these items out of the store both for space reasons and because we would not want to hold food subject to a "cease distribution" order near food that will be sold to the consumer.

New Enforcement Measures (Secs. 131-136):
The draft bill grants FDA extraordinary new powers to suspend or halt the production and distribution process of food products for a variety of reasons while also increasing the ability of FDA to assess fines for all infractions. New powers and penalties must be complemented by a hearing and appeals process that is fair, reasonable and quick. Penalties and enforcement measures should be available to deter and punish those that knowingly violate our food safety laws.

Although we certainly want the government to have all tools necessary to pull adulterated product out of the market, unless FDA has some degree of certainty regarding the cause or location of the adulterated foods, we could well end up in another situation like the one we all experienced when tomatoes from Florida were believed to be the cause of an

outbreak but ultimately FDA determined that the cause was jalapeno peppers. New enforcement measures must appropriately balance the need for the agency to act quickly in a public health emergency, but to act accurately with respect to the cause or element of concern. Inaccurate response will erode the confidence of consumers.

Country of Origin Labeling for Ingredients (Sec. 143):
Retail food stores are already required by statute to identify the country of origin of certain food products including produce, seafood and meat. This provision was never intended to improve food safety. Focusing on prevention systems that help ensure the safety of imports is a far better utilization of resources than attempting to put in place a system that will only attempt to identify all of the countries associated with any final food product.

Whistleblower Protections (Sec. 208):
The discussion draft includes "whistleblower protections" that have not previously been part of the Federal Food, Drug & Cosmetic Act. We are concerned about how alleged violations of whistleblower protections would be investigated by the Secretary of Labor, specifically the Occupational Safety and Health Administration (OSHA) and OSHA's ability to investigate alleged violations of the FD&C Act.

* * *

Mr. Chairman, thank you for the opportunity to testify. We appreciate the work that has gone into the development of the Food Safety Enhancement Act discussion draft with the goal of improving the safety of the food supply and to helping to restore consumer confidence in our food safety system. I look forward to your questions and remain available to the subcommittee for further discussion and information should you need it.

Mr. PALLONE. Thank you. Ms. Bailey.

STATEMENT OF PAMELA BAILEY

Ms. BAILEY. Thank you, Mr. Chairman. Good afternoon.

Mr. PALLONE. I don't know if that is on, the mike. You don't have a mike.

Ms. BAILEY. Thank you. I am Pam Bailey, and I am president and CEO of the Grocery Manufacturers Association which represents more than 300 food, beverage, and consumer products companies.

Americans enjoy one of the safest food supplies in the world, but we recognize that steps can and must be taken to make our food supplies even safer. We applaud Chairman Waxman, Chairman Emeritus Dingell, Chairman Stupak, and Chairman Pallone for developing the discussion draft of the Food Safety Enhancement Act of 2009.

Product safety is the foundation of consumer trust. We look forward to working with the committee to quickly enact food safety reforms that will restore consumer confidence and will continually improve the safety of our food supply.

Although the food industry is ultimately responsible for the safety of our products, strong government oversight is a critical part of our foods safety system. That is why GMA supports much in the discussion draft, including your proposal to set safety standards for fruit and vegetables, your proposals to improve the safety of imported food and food ingredients and your proposals to give FDA strong enforcement powers to deal with bad actors, including mandatory recall authority.

In particular, we strongly support proposals to require all food manufacturers to conduct a hazard analysis to identify potential sources of contamination, identify appropriate preventive controls and to document those preventive controls in a food safety plan.

We believe that food safety plans are the cornerstone of prevention and that they will help ensure that safety is built in from the very beginning. We have proposed certain modifications to some of these provisions to your staff, and we look forward to working with you.

In particular, we look forward to working with you to address your concerns about traceability. We recognize that the discussion draft instructs FDA to assess the costs, benefits, and feasibility of traceability technologies and gives FDA the power to exempt certain foods. Furthermore, we recognize that the discussion draft instructs FDA to conduct pilot projects and public meetings. However, we believe these studies, meetings, and pilot projects should be completed before FDA decides whether and how to assign the food industry the responsibility for tracking a food product and which coding and identification systems may be best suited to this task.

As you anticipate in the draft, the cost and feasibility of requiring every manufacturer to maintain the full pedigree of every ingredient in every food may outweigh the public health benefits. To address concerns raised during the peanut product recall, we urge you to consider whether intermediate distributors and brokers

should include on the labeling of their bulk ingredients the identity of the ingredient supplier.

In general, we support proposals to give FDA stronger enforcement powers, including the power to order a recall. We believe that certain enforcement provisions of the discussion draft, such as mandatory recall and suspension of registration, should only be exercised by senior agency officials when there is a risk of serious adverse health consequences and should ensure that companies are afforded certain due process protections, such as an administrative hearing.

As we saw during the recent recalls of tomatoes and jalapeno peppers, recalls can have a devastating financial impact, and they need to reflect the best science and wisest agency judgment.

Finally, we strongly support efforts to provide FDA with additional resources. GMA helped create the alliance for a stronger FDA, and we have worked with other consumer and industry groups to increase FDA spending. If Congress enacts the FY 2010 request of the FDA and the Obama administration, we will have seen food safety spending at FDA increase by nearly 80 percent since F& 2006.

More funding is needed. We look forward to working with the committee to identifying appropriate role for industry. Our industry is significantly increasing our own investments in food safety, and we are prepared to make additional investments to continually improve the safety of our food supply and to comply with many of the new mandates that are envisioned in the discussion draft. We are not opposed to all fees, and I am confident that the committee can reach a bipartisan consensus on the agency's resource needs and an appropriate role for industry.

Let me close by saying again that the food and beverage industry is committed to working with you to quickly enact food safety legislation which makes the prevention of contamination the foundation of our food safety system. Thank you.

[The prepared statement of Ms. Bailey follows:]

Written Testimony of Pamela G. Bailey
President and CEO
Grocery Manufacturers Association

before

House Energy and Commerce Subcommittee on Health
"'Food Safety Enhancement Act of 2009 Discussion Draft Legislation"

June 3, 2009

Good morning. My name is Pamela Bailey and I am President and CEO of the Grocery Manufacturers Association, which represents more than 300 food, beverage and consumer product companies.

Food safety and consumer confidence are top priorities for the food and beverage industry. Americans enjoy one of the safest food supplies in the world, but food and beverage companies recognize that steps can and must be taken make our food supplies even safer. We applaud Chairman Waxman, Chairman Emeritus Dingell, Congressman Stupak and Congressman Pallone for developing the discussion draft of the Food Safety Enhancement Act of 2009, which will provide the U.S. Food and Drug Administration (FDA) with the resources and authorities it needs to help make prevention the foundation of our food safety approach and bolster consumer confidence in the safety and security of the food supply. We also applaud Congresswoman DeGette, Congressman Costa, Congressman Putnam and Congresswoman DeLauro for their leadership on this important issue.

There are two important elements to our food safety system. First, because consumer confidence is the foundation of everything we do, manufacturers take food safety very seriously and invest their reputations and resources in producing safe products. Ultimately, the food industry is responsible for the safety of its products. We take that responsibility very seriously and want our consumers and policymakers to know that we are vigilant when it comes to product safety. To address the challenges posed by a complex and global food supply, GMA and its member companies have expanded their

efforts to continually improve the safety of food and to respond quickly to address contaminated food in the marketplace.

Second, strong government oversight is a critical and necessary part of our nation's food safety net, and we look forward to working with the Committee to quickly enact food safety reforms that will restore consumer confidence and will continually improve the safety of our food supply.

We strongly support in concept many of the proposals in the draft, including those that require food companies to have a food safety plan; proposals for FDA to set safety standards for fruit and vegetables; proposals to improve the safety of imported food and food ingredients; a risk-based approach to inspection that recognizes the important role played by states and competent foreign authorities; and proposals to give FDA strong enforcement powers to deal with companies that have violated food safety laws, including mandatory recall authority when needed. Together, these reforms will prevent contamination, raise the bar for the entire food industry and deter bad actors. In addition, we have also offered important modifications to the draft to committee staff and will continue to work with them on a bipartisan basis to address those provisions.

In particular, we believe that food safety plans are the cornerstone of prevention, and that they will help ensure that safety is "built in" from the very beginning. We strongly support proposals to require all food manufacturers to conduct a hazard analysis to identify potential sources of contamination, identify appropriate preventive controls, document preventive controls in a food safety plan, monitor the effectiveness of preventive controls, take corrective actions when warranted, and make records related to a food safety plan available to FDA during an inspection.

The principles of food safety hazard analysis and prevention are well established in guidance documents, including those issued by Codex, the International Organization for Standardization, and the National Advisory Committee on Microbiological Criteria for Foods, and we look forward to working with the Committee to align the discussion

draft with these nationally and internationally-recognized standards, and to ensure that every food manufacturer has a food safety system based on a scientifically and technically solid foundation. The role of FDA should be to ensure that a facility's hazard analysis is scientifically and technically sound and that a facility's preventive controls are being implemented. FDA should be given the authority to modify the requirements of a food safety plan to exempt some facilities, such as warehouses where the food itself is not exposed to the environment.

We look forward to continuing to work with the Committee and staff to address your concerns about traceability. We recognize that Section 107 of the discussion draft instructs FDA to assess the costs, benefits and feasibility of traceability technologies and gives FDA the power to exempt foods when FDA determines that a tracing system for such food is not necessary to protect public health. Furthermore, we recognize that the discussion draft instructs FDA to conduct pilot projects and public meetings. We believe these studies, public meetings, and pilot projects should be completed *before* FDA decides whether and how to assign the food industry the responsibility for tracking a food product and which coding and identification systems may be best suited for this task. Because many raw ingredients are commingled and blended to smooth out natural farm-to-farm variability, traceability will not always add value as we trace the origin of raw ingredients back to the farm, as the discussion draft implies. As you anticipate in Section 107(c)(4)(B), the cost and feasibility of requiring every manufacturer to maintain the full pedigree of every ingredient in every food may outweigh the benefits.

To address concerns raised during the peanut product recall, we propose two important improvements while FDA and the food industry work together to identify additional improvements to our traceability systems. To ensure that food manufacturers know their ingredient suppliers, we suggest that the Committee explore whether to propose that intermediate distributors and brokers include in the labeling of their bulk ingredients the identity of the ingredient supplier. Distributors and brokers can create "blind spots" in the value chain when they fail to pass the identity of an ingredient supplier to their customers. A simple change in labeling rules for bulk ingredients could

eliminate these "blind spots" by identifying ingredient suppliers on the label or sending identifying information in a form that accompanies the product, whichever is most practical. In addition, enforcement of the current "one step forward, one step back" systems created by the Bioterrorism Act can be improved in two ways: one, by working with FDA to better communicate industry responsibilities under the Act; and two, by making traceability records available during a routine inspection.

We also look forward to working with the Committee to give FDA stronger enforcement powers, including the power to order a recall when a company has been given the opportunity and has declined or refused to recall food that poses the risk of serious adverse health consequences. We believe that certain enforcement provisions of the discussion draft, such as mandatory recall and suspension of registration, should only be exercised by senior agency officials, should only be exercised when there is a risk of serious adverse health consequences, and that companies should be afforded certain due process protections, such as an administrative hearing.

As we saw during the recent recalls of tomatoes, jalapeno peppers, spinach, and other food products, recalls can have devastating financial impacts. FDA, CDC and others must be given new tools and resources to understand the source of contamination before taking action, and we applaud the Committee for expanding our existing surveillance systems and research to better determine the sources of contamination. We believe that new powers created in the discussion draft can be improved to ensure that enforcement actions, such as mandatory recalls and suspension of registration, reflect the best science and agency judgment.

We look forward to working with the Committee to ensure that the infant formula provisions of the discussion draft meet the nutritional needs of infants. As you know, infant formula is already the nation's most highly regulated food product.

We strongly support efforts to provide FDA with additional resources. In 2006, GMA helped create the Alliance for a Stronger FDA, and we have worked with other

industry and consumer groups to seek unprecedented increases in food safety spending. If Congress enacts the FY 2010 request proposed by FDA and the Obama Administration, FDA food safety spending will have increased by nearly 80 percent since FY 2006.

More funding is needed, and we look forward to working with the Committee to identify an appropriate role for industry. Our industry is significantly increasing our investments in food safety and is prepared to make additional investments to continually improve the safety of our food supply. In particular, we are expanding an electronic recall portal that facilitates rapid flow of information between manufacturers and retailers during product recalls, and we are expanding efforts to train food safety scientists and managers globally to implement new safety systems. Our industry is also prepared to make a substantial investment to comply with many of the new mandates included in the discussion draft. However, we are concerned about provisions that would increase the cost of food without improving the safety of our food supplies, such as identifying the country-of-origin for all ingredients.

We are not opposed to all fees, and I am confident that the Committee can reach a bipartisan consensus on the agency's resource needs and an appropriate role for industry. We are concerned about the size and purpose of the significant new fees proposed in the discussion draft in spite of historic increases in federal food safety spending. If enacted, the fees proposed would provide roughly 40 percent of FDA food-related spending – an unprecedented increase in industry financing of a public health agency that has been financed through general revenue for more than a century. As FDA's science advisory board has noted, a combination of fees and inspection mandates could drain critically needed resources from science and standard-setting functions. In particular, we are concerned that a broadly applied fee to finance basic FDA functions, including inspections and enforcement, creates an inherent conflict of interest that will erode, rather than improve, consumer confidence in our food supplies. Our industry is ultimately responsible for the safety of its products, but securing the safety of the food supply is a government function which should be largely financed with government resources. As

legendary consumer advocate Carol Tucker Foreman has said, food safety "inspectors should protect public health the same way police officers protect public safety."

Let me close by saying that the food and beverage industry is committed to working with you to quickly enact food safety legislation which makes the prevention of contamination the foundation of our food safety system. We look forward to working with the Committee to enact food safety legislation that boosts consumer confidence and addresses the challenges posed by today's 21st century food supply.

Mr. Chairman, I would like to reiterate that we are not opposed to all fees, and we have a historic opportunity to ensure the FDA has the appropriate resources and authorities it needs to provide Americans with a safe and secure food supply.

Thank you.

Mr. PALLONE. Thank you. Ms. DeWaal.

STATEMENT OF CAROLINE SMITH DeWAAL

Ms. DEWAAL. Thank you very much. Thank you for your leadership, Chairman Pallone, and also the leadership from many other members of this subcommittee and committee. And also thank you to you, Ranking Member Deal, for the many hearings that we have sat through. We have listened to the witnesses. This work has been going on before this committee for a long time, and I think hopefully we are nearing an end.

My name is Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest, but today I am representing 10 consumer, public health, and victims' advocacy organizations that are members of the Safe Food Coalition.

Let me begin by saying that we believe this is a strong bill that will improve food safety. It requires food companies to build into their processes the conduct of regular hazard analysis, and they have the institute preventive controls to prevent problems from occurring. It provides a modern framework for food safety oversight to replace the antiquated food safety laws that have hamstrung the Food and Drug Administration. It gives FDA essential new authority to carry out the mission of preventing illnesses and outbreaks and to inspect food plants much more frequently, and it addresses the funding issues urgently needed to institute the program improvements, doing this with a modest registration fee.

The heart of any effective reform effort lies in prevention, which is in the bill's hazard analysis and preventive control section. The bill provides FDA with new tools like written plans and access to processing records that will allow government inspectors to review the conditions in plants over time, not just when inspectors are in the facility.

We recommend additional strengthening of the bill by requiring companies or labs to report pathogen on final product samples to FDA whenever they are encountered in a facility. This would give FDA an early warning of problems and might prevent another tragedy, like the outbreak linked to the Peanut Corporation of America.

It is a common adage that you cannot detect what you don't inspect. Random and frequent inspection by public officials is a necessary component of an effective food safety system. This legislation divides food companies into three categories based on risk and directs FDA to inspect the facilities every six months to four years.

While this is a vast improvement over FDA's existing program, we continue to believe that more frequent inspections are needed, particularly of high risk facilities. Risk-based inspection is a concept that expands across the entire spectrum of food products not just those regulated by FDA.

The registration fee, as proposed, is quite modest. And at $1,000 per facility, it should provide somewhere between $300 and $400 million in new revenue for food safety activities. Let us put this fee into context. In the Peter Pan outbreak, the average cost per victim reporting an illness was $2,650. And this is based on an estimate using the Economic Research Service Cost calculator. So when there is an outbreak, consumers who are affected may pay over

$2,500 or more. These are individuals. So clearly $1,000 fee on each facility to avoid these problems is more than reasonable, especially when compared to the cost of individuals and families that you have had here before this committee, testifying on the severe impact of food-borne illness.

In addition, I would just like to note that companies themselves can run advertising campaigns to promote their products that run into the tens and even hundreds of millions of dollars.

To conclude, I just want to say that polling has shown that the public has lost confidence in the safety of food. The percentage of consumers confident in food safety fell to about 22 percent according to the University of Minnesota's Food Industry Center. This legislation provides a modern framework for FDA's regulation of the food supply that will deliver many benefits to consumers though it does stop short of structural reforms that we also think are essential.

We appreciate your leadership, and we believe that these new authorities that you are proposing will over time prevent the outbreaks and illnesses and help restore consumer confidence.

Earlier this year, members of the Energy and Commerce Committee made commitments to the victims of the Peanut Corporation of America outbreak that change would come to FDA. President Obama said at a bare minimum, we should be able to count on our government, keeping our kids safe when they eat peanut butter.

We urge you, Chairman, to act swiftly to finalize this legislation and to enact it. Thank you.

[The prepared statement of Ms. DeWaal follows:]

Testimony of Caroline Smith DeWaal
Representing the Safe Food Coalition
before the
Subcommittee on Health of the
House Committee on Energy and Commerce

Washington, DC
June 3, 2009

Good morning Mr. Chairman, Ranking Member Deal and Members of the Subcommittee. My name is Caroline Smith DeWaal, and I am the Director of Food Safety at the Center for Science in the Public Interest (CSPI). My testimony today is offered on behalf of the consumer, public health and victim advocacy organizations listed below that are members of the Safe Food Coalition.[1]

Thank you for this opportunity to talk to you about the consumer community's views on the Food Safety Enhancement Act. Let me begin by saying that we believe this is a strong bill that will improve public safety.

- It requires food companies to build safety into their processes by conducting a regular hazard analysis and instituting preventive controls;
- It provides a modern framework for food safety oversight to replace the antiquated and unworkable food safety laws that have hamstrung the Food and Drug Administration (FDA);
- It gives FDA essential new authorities and resources to carry out a new mission focused on preventing food-borne illnesses and outbreaks, including a requirement that FDA inspect food processors much more frequently than at present; and
- It addresses the issue of funding urgently needed program improvements with a modest registration fee.

Consumers want Congress to pass meaningful food safety legislation this year. Polling shows the public has lost confidence in the safety of the food supply. The percentage of consumers confident in the safety of the food supply fell to 22.5 percent earlier this year, according to The

[1] The Safe Food Coalition members endorsing this testimony are: Center for Foodborne Illness, Research and Prevention, Center for Science in the Public Interest, Consumer Federation of America, Consumers Union, Food & Water Watch, Government Accountability Project, National Consumers League, The Pew Charitable Trusts, Safe Tables Our Priority, and Trust for America's Health.

Food Industry Center.[2] CSPI's polling of its members confirms this, finding a majority are very concerned about food safety. With the public's trust in both government and industry in the disaster zone, consumers are demanding change.

Each year 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from food-borne disease, according to the Centers for Disease Control and Prevention (CDC). People like Ashley Armstrong, who at three years of age suffered acute kidney failure and months of dialysis after eating *E. coli*-tainted spinach, and Shirley Almer, who overcame cancer only to be felled by *Salmonella*-contaminated peanut butter. These are just two of the many victims who personally or represented by family members have testified before Congressional committees and visited your offices to tell personal stories about the tragedy of food-borne disease.

With responsibility for 80 percent of food supply, FDA's food program is a critical element in reducing this public health burden. But when foods that consumers think of as "safe", like spinach or peanut butter, become deadly, it sets off alarms for consumers. They become concerned that they can't rely on either the government or industry programs to protect their families. Two hundred illnesses and several deaths from spinach contaminated with a deadly strain of *E. coli*; two outbreaks with 1,200 illnesses and nine deaths from peanut butter tainted with *Salmonella*; pet food adulterated with toxic chemicals; imported peppers identified with almost 1,500 illnesses in 43 states – each of these tragedies has demonstrated different weaknesses in our ability to manage food safety. More importantly, these issues have confirmed for consumers and the Congress that the federal food safety system is broken. As President Obama has emphasized, "At a bare minimum, we should be able to count on our government keeping our kids safe when they eat peanut butter.... I don't want to worry about whether [Sasha's] going to get sick as a consequence of eating her lunch."

The Committee Has Built the Record for the Food Safety Enhancement Act

Since 2007, Congress has conducted 24 oversight and legislative hearings on food safety. Today's hearing is the fourth held by the Health Subcommittee on specific legislation to reform FDA. Along with being informed by extensive hearings into food safety problems and potential solutions, the bill rests on a foundation of over a decade of legislative development by its lead sponsors. Chairman Frank Pallone first introduced the Consumer Food Safety Act of 1998 in the 105th Congress. In that same term of Congress, Chairman Emeritus John Dingell introduced his Imported Food Safety Act of 1998, which eventually became the FDA Globalization Act of 2009. Those bills became the basis for the draft legislation we are discussing today, each of which have been fully vetted through hearings in this Subcommittee since 2007.

The legislation before us is also a product of Chairman Henry Waxman's leadership and concern for improving food safety. As Ranking Member and then-Chairman of the Oversight and Government Reform Committee, he investigated weaknesses in FDA's inspection system and regulatory failures in its regulation of fresh produce safety. To address problems documented in those reports, the bill provides new resources for hiring additional inspectors,

[2] Press Release, *Consumer Confidence in Food Safety Plunges in Wake of Peanut Butter Contamination, University of Minnesota Study Finds*, UMNews, Feb. 23, 2009, at http://www1.umn.edu/news/news-releases/2009/UR_RELEASE_MIG_5325.html.

gives FDA clear authority to set produce safety standards, and sets inspection frequencies of six to 18 months for the highest risk foods. This recognition of varying inspection frequencies reflects new recognition of the complex job that FDA is assigned, and the fact that when it comes to food, the agency can not take a "one size fits all" approach.

Beginning in 2007, Chairman Bart Stupak led a series of hearings in the Oversight and Investigations Subcommittee that investigated failures in FDA's oversight of the food supply. Those hearings focused on major outbreaks such as melamine in pet food; *E. coli* in bagged spinach; *Salmonella* in peppers; and botulism in canned foods and identified systemic failures in our food safety laws. To name of few of the findings the hearings disclosed:

- The ability of facility managers to deny inspectors access to company records that showed contamination problems at the plant (addressed in section 106 on records access);
- The fact that facilities don't have to report tests that are positive for pathogenic contamination (partially addressed in section 112 on the reportable food registry); and
- Questionable testing practices that allow companies to shop for a lab that is most likely to provide favorable tests (addressed in section 110 on accrediting laboratories).

Other members of the Energy and Commerce Committee, Republican and Democrat, have contributed to the bill through their insightful questioning of witnesses, willingness to negotiate agreements, and desire to ensure the safety of the American public. Certainly, we thank the Committee leadership for reaching out to take advantage of the long-standing expertise and interest of non-committee members like Rep. Rosa DeLauro in crafting this legislation. Her support is also vital to ensure that the agency is fully funded to implement its new authorities. The purpose of this too brief history is to highlight that the Food Safety Enhancement Act is a well-vetted, mature bill backed by a strong record of oversight and legislative hearings.

The bill builds on current industry practices, refocuses FDA's role on preventing outbreaks and meets the reform criteria of consumers. We are not so naïve in our outlook as to say this legislation alone will end outbreaks, but it gets the authorities right, gives the watchdog some teeth, and puts in place a modern food safety system that will reduce the number of illnesses linked to tainted foods.

The Food Safety Enhancement Act Aligns with Consumer Goals

The strength of the bill is also measured through how it addresses specific areas of weakness at FDA. In 2007, CSPI released a white paper, "Building a Modern Food Safety System for FDA Regulated Foods." It described 11 areas of reform that are essential to improve FDA's ability to prevent contaminated food from sickening the public. Below, the Food Safety Enhancement Act is compared to each area identified in the white paper.

Preventive Controls: the Heart of a Modern Food Safety System

The heart of any effective reform effort lies in prevention, and fittingly the heart of the Food Safety Enhancement Act is its hazard analysis and preventive controls section. Section 102 requires every registered food plant to build safety into its processes by conducting an analysis of

biological, chemical or other hazards that may enter food it is processing. This analysis serves as a basis for implementing preventive controls. Validating, monitoring, verifying and documenting the effectiveness of the controls complete the prevention system. The system described in the legislation is built on the framework of the industry-designed Hazard Analysis and Critical Control Points (HACCP) program. It is embraced by the food industry and implemented in many food processing plants already (although not always adequately). Notably however, the bill provides important new mechanisms, like written plans and access to processing records that will allow government inspectors to review conditions in the plant over time, not just on the day when inspectors are in the facility.

The access to plant records is essential and it sets the Food Safety Enhancement Act apart from other bills by giving FDA much greater access to monitoring and verification records. It also provides FDA with authority to evaluate safety plans and direct changes where needed to protect public health. Additionally, when a company becomes aware that contaminated food has left its control, it must report that to the Reportable Food Registry along with any product or environmental sampling and testing it has done. The Committee needs to preserve and strengthen these important provisions.

Record access is a passive approach, however. Mandatory reporting of positives would permit FDA to identify potential risks, and through inspection and oversight, to avoid illnesses and deaths linked to contamination problems known to the facilities. Section 112 has helpful – but limited – authority that requires positive reporting of test results if there is a direct threat of severe adverse health consequences or death. Reporting of positives whenever they are encountered in a facility would alert FDA to potential problems. This could prevent another Peanut Corporation of America by giving FDA an early warning that problems may exist within the facility before contaminated food is put on the market. The tragedy of the recent outbreak linked to the Peanut Corporation of America clearly illustrates why the groups endorsing this testimony support the addition of a provision requiring facilities to conduct testing as part of its preventive control plan and report positives directly to FDA. Such a system of mandatory reporting is used by the Environmental Protection Agency to monitor the safety of drinking water, and it would be appropriate as a protection in the food supply as well.

As we saw in both the 2007 and 2009 outbreaks linked to peanut products, facility operators knew from internal testing that *Salmonella* was present. Yet, in neither case did they report this finding to FDA or state inspectors. With this information, inspectors would have been in a much better position to identify to potential problems and inquire about steps each facility had taken to resolve those problems.

Mandatory reporting could also alert FDA to emerging risks. Little was known of *Salmonella's* ability to survive in peanut butter prior to the 2007 outbreak. Perhaps if FDA served as a centralized repository for this information across the food industry, the agency could identify problems before an outbreak occurs. We look forward to working with the Committee on refinements that will ensure that a company like the Peanut Corporation of America will test its products and report its findings promptly to FDA.

Enforceable Performance Standards

FDA's ability to set performance standards for the most serious hazards and to require food processors to meet those standards is essential to ensure that food is produced in a sanitary manner that limits the likelihood of disease-causing contamination. When I talk to safety experts from industry, I am frequently told the biggest challenge is deciding what the best measures to evaluate a HACCP system are. But an FDA-established performance standard helps eliminate the guess work for the companies and provides a level playing field for similar products. Section 103 addresses this need by requiring FDA to review epidemiological data, identify significant contaminants, and issue performance standards that minimize, prevent or eliminate the hazard. While we would like to see a more structured program at FDA for reviewing and issuing performance standards, we believe the language in the bill is the minimum necessary and we urge the committee not to weaken it.

Inspections: Essential to Compliance

It is a common adage that you can't detect what you don't inspect. Random and frequent risk-based inspection by public officials sworn to protect public health is a necessary component of an effective food safety system. It is not surprising that with FDA's current average inspection frequency of one visit in 10 years,[3] misconduct at Peanut Corporation of America (inspected by FDA once in eight years) went undetected.

This legislation, in Section 105, divides food companies into three categories based on risk, and directs FDA to inspect high-risk facilities no less than once every six to 18 months, low-risk facilities every 18 months to 3 years and warehouses at least every three to four years. These inspection rates are far lower than the monthly inspections that two-thirds of the American public, when polled on the issue by Consumers Union, believe is appropriate.[4] While this is a vast improvement over FDA's existing program, we continue to believe that more frequent inspections than called for in this bill are needed—particularly of high-risk facilities. We understand that, though not perfect, the bill attempts to strike a reasonable balance between the realistic budget and workforce constraints at FDA, and an ideal inspection system.

However, we think it is important for the Committee to understand the need to look at the concept of risk-based inspection across the entire spectrum of food products, not just those regulated by FDA. Thus, any definition of high risk must start with the understanding that slaughter and processing raw meat and poultry are exceptionally high-risk activities. Most meat and poultry slaughter fall under USDA's responsibility and that Department is required to inspect these functions on a continuous basis. The Food Safety and Inspection Service (FSIS) is present in every plant every day. That is appropriate for meat and even seafood processing because of the risk of zoonotic disease and pathogens. FDA's responsibility with regard to meat or poultry is limited to slaughter and processing of animals and birds not specifically itemized in the FMIA and PPIA. Oversight of processing game birds and animals is FDA's primary activity in this area.

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[3] House Comm. on Gov't Reform, *Fact Sheet: Weaknesses in FDA's Food Safety System*, Oct. 30, 2006.
[4] Food-Labeling Poll 2008, available online at http://www.consumersunion.org/pub/core_food_safety/006298.html.

The USDA system of continuous inspection of these high risk products provides important protection that is not in the discussion draft, and we urge the committee to address it. First the bill should explicitly recognize the need for continuous inspection of very high risk raw animal products, and second it should authorize FDA to contract with USDA to have the Agriculture Department's inspectors provide continuous inspection for the very limited number of such plants currently under FDA's jurisdiction. Such authority could be used if FDA determines that it does not have a sufficient number of inspectors to allow for continuous inspection of the small number of plants that slaughter so-called "non-amenable species" of animals, or that process raw meat from such animals for sale to the public (such as plants grinding fresh venison).

Import Certification

Imported foods make up approximately 13 percent of a typical consumer's total diet each year, and during certain seasons, the majority or virtually all of certain foods (such as some types of fresh fruits) are imported. Although USDA regulated foods are subject to certification as meeting our safety standards, no such system exists for FDA-regulated foods. Instead the agency relies on a border inspection program that captures only one in 100 shipments. As a result, imported berries, melons, peppers, even green onions, coming from areas with substandard hygiene practices, have sickened thousands of Americans.

We believe that all imported food should be produced under conditions and meet standards that apply to domestically produced foods and the bill gives FDA many new tools to meet that objective. For the first time, foreign suppliers as well as domestic ones would be required to comply with the hazard analysis and preventive controls and agricultural standards in the bill. Section 109 establishes a system for requiring certification of certain incoming products, such as high-risk foods, and foods from countries or regions with weak government controls. Such certification provides assurance from a foreign government or agent approved by FDA that the food complies with U.S. standards. Section 204 creates a dedicated corps of foreign inspectors charged with inspecting foreign facilities for compliance. Finally, under section 203, FDA can refuse to admit food from a facility or country that obstructs an inspection.

Research and Education

FDA, as a science-based agency, must have a vigorous program for research that includes a system for conducting public health assessments through improved surveillance and through improved data sharing across agencies to provide a more accurate picture of the trends, sources, demographic distribution and outcomes of foodborne disease. Section 121 requires the Secretary of Health and Human Services to conduct a public health assessment, building on existing surveillance networks that will be capable of integrating and linking multiple diverse data sources within the Department of Health and Human Services (HHS). Included with the assessment are provisions for creating a public education and advisory system (section 122) that will better define the potential impact and risk of foodborne illness. In Section 123, the agency will be required to conduct research into ways to improve food protection by investigating important food safety topics, such as multi-drug resistant pathogen strains, and by developing important research tools, such as a foodborne illness health registry. We believe the Secretary

should have clear direction to also coordinate with other Federal and State agencies on development of the surveillance system, and conduct of the health assessment, educational outreach and research.

Protecting our Produce

Since 1998, fresh fruits and vegetables have been linked to an increasing number of outbreaks. Given the central role of fresh produce consumption in a healthy diet, consumers need to be confident that raw agricultural products are safe to eat. Outbreaks from spinach, lettuce, tomatoes, peppers and sprouts in recent years have shaken that confidence. Section 104 requires FDA to write safety standards for raw agricultural products that will minimize the risk of serious adverse health consequences or death. We support these safety standards and believe they can assist farmers in managing safety to protect their customers from preventable illnesses. However, as appropriate, Congress should make clear that when setting standards, FDA should take into account the needs of small organic and small diversified farms selling to local markets.

Enforcement Tools

The bill greatly improves FDA's ability to address system failures when they occur with a variety of enforcement tools:

Mandatory Recall. Section 111 establishes authority, sought by FDA and consumer organizations, that permits the agency to order a recall of food that may cause adverse health consequences or death. It also adds additional authority to issue an emergency recall order in the case of a food item that may cause serious adverse health consequences or death.

Traceback. The current traceability system based on one-up/one-down recordkeeping has proven inadequate. Section 107 fixes gaps in the one-up/one-down system by requiring FDA to develop a system for tracing the full pedigree of a food item, with an appropriate exemption for farmers selling directly to local consumers.

Detention. The current detention provision has proven unworkable. Detention is an important precautionary authority that allows inspectors to apply their knowledge and experience to identify and prevent potentially unsafe food from entering commerce. Section 132 replaces the evidence standard that has hampered inspectors in exercising this authority with a reasonable belief standard that is more appropriate to a precautionary detention, the purpose of which is to allow time to develop evidence.

It also gives FDA needed new authorities to punish companies, like the Peanut Corporation of America, that may choose to disregard the law.

Criminal Penalties. FDA needs a greater range of penalties to punish violators. The punishment for committing a prohibited act under the Food, Drug and Cosmetic Act is one year in jail and/or fine, a Class A misdemeanor.[5] As demonstrated by the recent case

[5] 21 U.S.C. § 333(a)(1).

involving Peanut Corporation of America, which had annual revenues of $17.5 million,[6] the threat of a misdemeanor sentence and fine did not serve as a deterrent to alleged misconduct. Section 134 raises the crime of knowingly committing certain prohibited acts to a felony punishable by up to 10 years in prison and a fine.

Civil Penalties. FDA is severely restricted in the food area in its use of civil fines.[7] Civil fines provide a flexible response to corporate misconduct that can be tailored to the violation and are available to address violations by drug and device manufacturers. These remedies are not the food side except for illegal pesticide residue. Section 135 fixes this deficiency and will permit FDA to address problems found during inspections before they fester into criminal violations.

Whistleblower Protections. Interviews with Peanut Corporation of America employees revealed they witnessed dangerous practices at the plant but did not come forward because in a small town with few employers they could not risk being fired.[8] Personal job security should not trump protecting public health and whistleblower protections can be critical to finding and preventing an outbreak. Section 208 ensures that employees who do the right thing are protected from the threat of being fired, demoted, suspended or harassed for helping in the investigation of a violation of a food safety law.

Other Critical Considerations

A number of provisions need to be especially mentioned because they represent areas where the bill may be weakened if amended, or – conversely – could be strengthened to better protect public health.

Adulteration Standard

We agree with basing enforcement actions on the adulteration and misbranding provisions in sections 402 and 403 of the Food, Drug, and Cosmetic Act. Many of the food safety bills currently being discussed rely on the prohibited acts section, which would limit the use of enforcement tools discussed above such as detention, seizure, and mandatory recall. Importantly, using the prohibited acts section – rather than adulteration or misbranding – would provide FDA with little ability to respond to unsafe imports. We urge the committee to resist changes that would weaken enforcement of sections 101, 102, 103, 104, and 109.

Registration Fees

Registration fees should not be allowed to supplant appropriations for FDA as the principle support for food safety activities. The registration fee, as proposed in section 101 is appropriate, and at $1,000 per facility should provide FDA with an additional $325 million in resources for food safety activities.[9] Consumers greatly prefer registration fees over inspection

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

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

[8] Dahleen Glanton, *Inside 'Nasty' Nut Processor: Ex-employees Say Rodents, Roaches and Mold Commonplace*, Chicagotribute.com, Feb. 3, 2009.

[9] Based on a reported 325,000 domestic and foreign facilities currently registered with FDA.

fees and the food industry should as well.[10] If the prevention efforts and government oversight reduced the likelihood of an outbreak, it would pay off for any company producing an impacted product – for example, all spinach or peanut butter processors – that are saved from losses at the time of a recall and, most importantly, consumers who experience the medical costs, lost work and suffering of an illness.

Let's put the $1,000 registration fee into context. To promote their brands, Kraft General Foods spent $1.5 billion, General Mills spent $955 million, and ConAgra foods spent $384 million on advertising in 2007. That same year, the outbreak of *Salmonella* Tennessee in Peter Pan peanut butter cost ConAgra in excess of $140 million.[11] Meanwhile, in the Peter Pan outbreak, the Economic Research Service estimates that the average cost per victim reporting an illness was $2,650.[12] Clearly, a $1,000 fee on each facility is more than reasonable, and hardly sufficient to cover the costs of the food safety activities of FDA. As structured, the registration fee provides the government with resources equal to much less than the advertising budget of a single major food processor and yet cost each facility less than half of the average cost borne by a single victim.

Moreover, claims that food safety activities are a public good for which the industry receives little benefit are wrong. As Congressional investigations and hearings have documented, when resources fall short of needs at FDA, broad segments of the food industry suffer collaterally from outbreaks and recalls. Weak oversight results in an uneven playing field for good processors when bad actors – realizing the risk of detection is slight – scrimp on safety and undercut their more responsible rivals.[13] To the extent registration fees support additional food safety activities, industry will benefit from better safety oversight.

Improving Oversight of Antibiotic Resistance in Agriculture

The food safety challenge in the United States is compounded by the growing crisis of antibiotic resistance. Many antibiotic-resistant strains of bacteria include those that cause common food-borne illness. For example, nearly 1.4 million people in the U.S. contract *Salmonella* infections annually, and of those, roughly one-fifth (272,000) of the infections are antibiotic-resistant. There are about 2.4 million *Campylobacter* infections in the U.S. annually, and roughly half (more than 1.2 million) of those are resistant to at least one antibiotic. The World Health Organization, American Medical Association, American Public Health

[10] Among the organizations endorsing this testimony, there were diverse opinions on the appropriateness of a flat fee for registration. Several groups, including Food & Water Watch and Safe Tables Our Priority, support a sliding scale based on the production volume of a facility.

[11] Mike Hughlett, *E. coli Outbreak Kills Meat Company: Huge Costs Seen in Fixing Problems*, The Chicago Trib., Oct. 6, 2007, http://www.chicagotribune.com/features/lifestyle/health/chi-sat_toppsoct06,1,4231570.story.

[12] Estimated using the USDA Economic Research Service cost calculator and accounting for the hospitalization of 20 percent of the 628 reported illnesses, as reported by the Center for Disease Control and Prevention. The cost calculator may be accessed at http://www.ers.usda.gov/Data/FoodBorneIllness/salm_intro.asp.

[13] The outbreak caused by lax safety at Peanut Corporation of America is estimated to have cost peanut producers $1 billion in lost profits and sales. Elizabeth Weise, *Salmonella Outbreaks Lead to Food-safety Changes*, USA Today, April 2, 2009, at http://www.usatoday.com/news/health/2009-04-01-nuts-salmonella-food-safety_N.htm. Other segments of the peanut industry also suffered with sales of peanut butter reportedly falling 13 percent in the four week period ending Feb. 21 relative to the same period in 2008. *Consumers Still Shun Peanut Butter*, Wall Street Journal, March 11, 2009.

Association, Pew Commission on Industrial Farm Animal Production, and others point to the overuse of human antibiotics in food animal production as one important contributing factor in the rise of antibiotic resistance, and call for limits on non-therapeutic, or non-disease-treating, uses of human antimicrobials in farm animals. We therefore urge the Committee to include language in the food safety bill that would help to address this serious problem.

GRAS

We are grateful for the effort at improving the transparency and reporting of generally regarded as safe (GRAS) determinations. GRAS substances are a special class of food additives that do not require prior approval by FDA. Instead, food processors may self-affirm that they are safe for the intended use or can apply to FDA for a determination. Under section 142, FDA is required to post the notice and scientific justification for declaring a proposed substance as GRAS on its website. This is a positive first step, but we believe the section as drafted falls short of protecting the public from largely unregulated and potentially dangerous substances. A better approach would be to define safety in terms of health consequences (such as obesity, heart disease, and allergic reaction), require companies to submit a petition for a GRAS determination at least 180 days before using the substance in food, and make the notice and supporting data available for public review. This brief allowance for a reasonable review of a GRAS determination would not slow innovation or prevent use of genuinely safe additives. Failing to make these changes, however, will leave open a door for exposing the public to increased risk for preventable diseases from the food it consumes.

Preemption

Changes made to section 4 make the section unclear and should be reversed. As currently written, it may have an unintended consequence of permitting industry to argue in court that more protective state food safety laws are preempted by FDA actions. A preemption argument was used in *People v. Tri-Union Seafoods* to overturn California's labeling law with regard to methylmercury in canned tuna. While the decision appears anomalous, we are nonetheless concerned it represents a wakeup call for consumers that preemption arguments may become more prevalent in state food safety litigation. Moreover, the language will apply to all areas of FDA regulation, such as drug litigation where preemption continues to generate controversy. Since the preemption issue is controversial and presents an area of special concern to consumers, we urge that you return to the clearly stated non-preemption language that appeared as section 4 of the FDA Globalization Act.

Conclusion

The new legislation provides a new framework for FDA's regulation of the food supply that will deliver many benefits to consumers. We believe that these new authorities will help reduce the incidence of outbreaks and recalls, and over time will help to increase consumer confidence in the food supply.

But in terms of modernizing our antiquated government approach to food safety, Congress and the Obama Administration will need to go beyond giving FDA more authority and funding. Structural reforms are also essential. Although FDA is responsible for the safety of 80

percent of the food supply, the FDA's commissioner must divide her attention among drugs, medical devices, foods and cosmetics – and food issues frequently fall to the bottom of the pile. Food responsibilities are divided among at least three centers within FDA, and there is no single food safety expert in charge of the policies, budget and enforcement staff. This means there is no single credible voice communicating to the public and the industry what can be done to prevent outbreaks. Food safety monitoring within HHS should be separated from drug and device approvals. The agency needs to be divided in two, with a new Commissioner of Food and Nutrition Policy who reports directly to the HHS Secretary. Food safety functions under the Department of Agriculture have this sort of direct reporting, leading to greater involvement by the Secretary of Agriculture when problems arise in the meat area.

But, we understand and respect the Chairman's decision to address the immediate problems in FDA and leave structural changes for later legislation. The Chairman's vision, embodied in the Food Safety Enhancement Act is clear, precise and effective. Earlier this year, members of the Energy and Commerce Committee made commitments to the victims of the Peanut Corporation of America outbreak that change would come to FDA. It is time to move forward with strong legislation that will prevent outbreaks by requiring safety to be built into the processing of food. We believe the Food Safety Enhancement Act is such a strong bill. We urge the Subcommittee and the Committee when they mark up this legislation to reject weakening amendments that would undermine public safety. We urge Congress to pass the Food Safety Enhancement Act.

Mr. PALLONE. Thank you. Dr. Jones.

STATEMENT OF TIM F. JONES

Dr. JONES. Mr. Chairman, members of the subcommittee, thank you for the opportunity to be here today. Recent high profile outbreaks demonstrate the huge challenges and opportunities for improvement in the Nation's food supply and food safety infrastructure. Laws, policies, and, to be frank, philosophies developed decades ago no longer suffice to successfully meet these new demands.

The legislation we are discussing today is therefore a critical step in reviving the food safety capacities of the FDA. I work in a state health department as a epidemiologist responsible for investigating food-borne diseases and in effect cleaning up the mess left when things go awry in the food safety chain.

I am excited to see that this proposed legislation addresses many of the problems that I experience firsthand in my role both investigating and helping prevent food-borne disease.

Improving the traceability of food as called for in this legislation is fundamental to successfully achieving many of the other tasks described. If traceback information had been more promptly available and shared faster, I think that many of the problems associated with the recent tomato/jalapeno incident could have been mitigated. And likewise tracing peanut butter from one plant to 4,000 different commercial products would have been utterly impossible with many other types of foods.

Ensuring that all foods are traceable efficiently and accurately is critical to maintaining food safety. Contamination of produce and foods which are eaten uncooked are of particular concern because consumers have less control over the safety of those foods in their own kitchens. Setting standards for pre-harvest food production starts to close a major current gap in the Nation's food safety system.

Suspected produce-associated illnesses are particularly difficult to investigate from both the public health and regulatory perspectives. While large food service corporations and the suppliers often have excellent quality control programs with impeccable records, many other companies don't.

The portions of this bill requiring country of origin labeling, improved distribution records, and plans to regulate the safe production and harvesting of fruits and vegetables are important to help address these problems.

I am pleased to see that the agency is being encouraged to markedly increase the scrutiny of food-handling entities. I would like to emphasize the importance of basing inspections and product testing and any other interventions by the agency on sound science. The bill does have important directives to improve testing in the science base of the agency's activities.

It is critical that from top to bottom activities are more efficient and effective and not just more frequent. This bill's requirement that the agency's activities are risk-based is particularly critical. It is likely that as technology improves, the value of traditionally defined inspections will change dramatically. And I urge that the agency retain sufficient flexibility and authority to adapt to changes rapidly and with as few barriers as possible.

I think it is important that in any discussion of the food safety system to emphasize the importance of interaction between FDA and CDC along with state and local partners and meeting the directive to enhance the science of food safety and develop risk-based approaches. Data from CDC and its partners on things like outbreaks, disease surveillance, and attribution of human disease to specific foods will be critical. It is imperative that such data are developed and shared cooperatively to meet the needs of all the partners involved in the system.

In every discussion that I have been in pertaining to food safety, the importance and current inadequacy of effective information sharing is probably the most common single topic that is raised. I am pleased to see that issue addressed in this bill. Improving the technological capacity to share information will be important in accomplishing this, but perhaps even more important is changing the engrained policies of not sharing information among partner agencies far beyond any logical limit, even when the failure to do so threatens the public health.

To meet the mandates of this bill, FDA will have to increase interaction and coordination with state and local agencies, which will require funding and focused attention. Federal regulatory agencies frequently are prohibited from sharing proprietary information obtained during investigations. The flow of information in both directions between FDA and CDC as well as state public health partners is critical.

Examples of this include such things as distribution lists during recalls, information on suspected products or producers, and information on potentially exposed people.

The FDA, CDC, and other partner agencies must have both the authority and expectation to share actionable information with the public health partners to the extent necessary to protect the public's health.

And I will conclude with a final comment about the importance of ensuring FDA and its state and local partners have adequate resources to meet the responsibilities with which they are charged in this bill. No one would argue that the FDA is currently underfunded, overworked and essentially overwhelmed. State and local food safety capacity must also be robust in order to maintain an effective food safety system.

Adequate and consistent funding and resources must be dedicated explicitly to sustain the food safety programs at FDA as well as the state and local partners who work with them to keep the food supply safe. Americans will eat a billion meals today, and I can't think of a better investment than one that will keep every one of those meals safe.

[The prepared statement of Dr. Jones follows:]

Written Testimony of

Timothy Jones, MD
State Epidemiologist, Tennessee Department of Health
and
Co-Chair, Council to Improve Foodborne Outbreak Response

Before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

June 3, 2009

The views expressed here are those of the author and do not necessarily reflect those of the Tennessee Department of Health. I am also a member of an Institute of Medicine committee that is looking at a related topic. However, none of my testimony arises from or should be taken as reflecting the confidential deliberations of the IOM committee or its eventual conclusions or recommendations.

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to be before you today.

As a public health practitioner, I appreciate the opportunity to comment on this important new bill. Recent high-profile, nationwide outbreaks running the gamut from frozen dinners and spinach to jalapenos and peanut butter demonstrate the huge challenges and opportunities for improvement in the nation's food safety infrastructure. The global distribution, intensive production, and rapidity of transport of our food supply are markedly increasing the challenges faced in ensuring its safety. That 76 million Americans experience foodborne illness each year, resulting in 325,000 hospitalizations, is unacceptable. A typical American meal includes foods from six different countries, fresh produce travels an average of 1500 miles to get to our plates, 80% of our seafood is imported, outbreaks involving several hundred victims no longer shock us... a long list of dramatic statistics demonstrate the changing environment faced by the FDA and other agencies in attempting to ensure food safety. Laws, policies, and to be frank philosophies developed decades ago no longer suffice to successfully meet these new demands. The legislation we are discussing today is therefore a critical step in reviving the food-safety capacities of the FDA and giving it the authority and resources necessary to accomplish the goal of maintaining the safest food supply in the world.

I work in a state health department as an epidemiologist, responsible for investigating foodborne diseases- in effect helping detect and "clean up the mess" left when things go awry in the food chain. I am excited to see that this proposed legislation addresses many

of the problems that I experience first-hand in my roles both investigating and helping prevent foodborne disease.

From this perspective, there are a number of important aspects of this bill which I would like to address. Improving the traceability of food, as called for in this legislation, is fundamental to successfully achieving many of the other tasks described. Appropriately, a large proportion of this bill strengthens control measures high up in the food chain at the steps of production and importation. That said, obviously those are overwhelming responsibilities, and inevitably they can't be controlled perfectly. When problems are introduced at or sneak through to later stages in the food chain, and result in contaminated food in our kitchens or on our plates, it is crucial that they can be responded to quickly and effectively and then prevented in the future. If traceback information had been more promptly available and shared faster I think that many of the problems associated with the recent tomato/jalapeno incident could have been mitigated. Likewise, tracing peanut butter from one plant to 4000 different commercial products would have been utterly impossible with many other types of foods. Ensuring that all foods are traceable efficiently and accurately is critical to maintaining food safety.

The sections of this bill that improve identification and registration of food producers and importers, and enhance the safety of imported foods will facilitate important steps toward preventing problems before they occur.

Contamination of produce and foods which are eaten uncooked are of particular concern because consumers have less control over the safety of those foods in their kitchens. Setting standards for pre-harvest food production starts to close a major current gap in the nation's food safety system. Suspected produce-associated illnesses are particularly difficult to investigate, from both the public health and regulatory perspectives. Typical produce items pass through a myriad of hands along the "farm to fork" continuum, and product tracebacks are susceptible to complete breakdown at the weakest link in the chain. Produce is generally purchased by consumers unlabeled, with no information on its origin. Produce from more than one source is often mixed at different distribution points. The challenges to performing subsequent tracebacks through such a complex food-handling chain are formidable. While large food service corporations and their suppliers often have excellent quality-control programs with impeccable records, many other companies don't. The portions of this bill requiring country-of-origin labeling, improved distribution records, and plans to regulate the safe production and harvesting of fruits and vegetables are important to help address these problems.

This bill has a number of sections addressing the nature and frequency of inspections of food facilities. I am pleased to see that the agency is being encouraged to markedly increase the scrutiny of food-handling entities. While this bill details defined inspection frequencies, I would like to emphasize the importance of basing inspections, product testing and any other interventions by the agency on sound science. The bill does have important directives to improve testing and the science-base of the agency's activities. Even with substantially increased resources the responsibilities of the FDA will be

tremendous, and it is critical that from top to bottom activities are more efficient and effective, and not just more frequent. This bill's requirement that agency activities are "risk based" is particularly critical, so that resources can be focused on issues of highest risk, and interventions that are the most effective. It is likely that as technology improves, the value of traditionally defined "inspections" will change dramatically, and I would urge that the agency retain sufficient flexibility and authority to adapt to changes rapidly and with as few barriers as possible.

The directive to expand sampling of foods for microbiologic testing is an example of a means to collect additional information to support development of "risk-based" policies. An example of this is a current project in which the state/CDC FoodNet program collaborates with FDA's Center for Veterinary Medicine to systematically collect retail meats for testing. Expanding such programs to other foods, and potentially targeting such efforts to geographic areas where there is active foodborne disease surveillance, could be an important way to identify problems before they lead to large outbreaks like those recently associated with peanut-butter, frozen foods and produce.

I think it is important in any discussion of the food safety system to emphasize the importance of interaction between FDA and CDC, along with state and local partners. In meeting the directive to enhance the science of food safety and develop risk-based approaches, data from CDC and its partners on things like outbreaks, disease surveillance, and attribution of human disease to specific foods and commodities will be critical. It is

imperative that such data are developed and shared cooperatively to meet the needs of all partners involved in the system.

In every discussion I've been in pertaining to food safety, with any permutation of agencies or stakeholders, the importance (and current inadequacy) of effective information-sharing is probably the most common single topic that is raised. I am pleased to see the issue addressed in this bill, though if anything it is understated. This legislation calls for establishing science-based performance standards, and making improvements in the surveillance systems for human illness by which success can be measured. That said, there is a tremendous amount of information already available, within CDC, USDA and other agencies as well as the FDA, which is not currently maximally utilized due to barriers in sharing among those partners. Identifying new information needs is clearly important, but it is obviously equally important to take advantage of existing resources that can help meet those needs before expending more. Improving the technological capacity to share information will be important in accomplishing this. Perhaps even more important, however, is changing the ingrained policies of not sharing information among partner agencies, far beyond any logical limit, even when failure to do so threatens public health.

To meet the mandates in this bill, FDA will have to increase interaction and coordination with state and local agencies, which will require funding and focused attention. There are many examples of situations in which state health departments have proceeded with their own product testing or limited tracebacks, and gathered important data long before

information was available from the federal agencies involved in the investigation. I don't believe that these agencies are purposely withholding critical information from public health partners, but I do think that they are required to operate under such restrictive legal constraints (or perceptions thereof) that they are unable or unwilling to share data as fully as necessary, even in urgent situations. Federal regulatory agencies are frequently prohibited from sharing proprietary information obtained during the course of their investigations. Flow of information in both directions between FDA and CDC, as well as with state health department partners, is critical. Examples of this include such things as distribution lists during recalls, information on suspected products or producers, and information on potentially exposed or ill people. The FDA, CDC and partner agencies must have both the authority and expectation to share actionable information with public health partners promptly and fully, to the extent necessary to protect the public's health.

I will conclude with a final comment about the importance of ensuring that FDA and its state and local partners have adequate resources to meet the responsibilities with which they are charged. No one would argue that the FDA is currently underfunded, overworked, and essentially overwhelmed. State and local food safety capacity must also be robust in order to maintain an effective food safety system. Adequate and consistent funding and resources must be dedicated explicitly to sustain the food safety programs of the FDA, as well as the state and local partners who work with them to keep the US food supply safe. Americans will eat a billion meals today, and I can't think of a better investment than one that will keep every one of those meals safe.

Thank you.

Summary

- This bill will facilitate important strides toward improving the nation's food safety infrastructure.

- Adequate and consistent funding and resources must be dedicated explicitly to sustain the food safety programs of the FDA, in addition to other federal, state and local partners who work with them to keep the US food supply safe.

- The FDA and partner agencies must have both the authority and expectation to share actionable information with public health partners promptly and fully, to the extent necessary to protect the public's health.

- The provisions in this bill to improve the safety of food imports, strengthen regulations to ensure the safety of foods produced domestically and in foreign countries, and improve the traceability of foods effectively through the entire farm-to-fork chain are critical.

- The importance of state and local public health partners, who perform a tremendous amount of work that supports the efforts of the FDA in protecting the US food supply, must also be recognized. Support for that critical infrastructure must also be maintained in order for FDA's activities to be successful.

Mr. PALLONE. Thank you, Dr. Jones. Mr. Stenzel.

STATEMENT OF THOMAS E. STENZEL

Mr. STENZEL. Good afternoon, Chairman Pallone, Ranking Member Deal, and members of the subcommittee. I am pleased to be with you. As you know, the fresh produce industry has been a leading proponent of strong federal government oversight of food safety. My name is Tom Stenzel. I am president and CEO of the United Fresh Produce Association. Our organization has been privileged to testify 10 times in the last two years before this committee or other members of Congress, perhaps only runner up to Caroline on this panel.

Our board of directors in January of 2007 adopted a series of policy principles calling for mandatory, science-based regulation by the federal government. Today we congratulate you and the leadership of the full committee in presenting the draft of the Food Safety Enhancement Act of 2009 for consideration.

While my written statement contains a number of suggestions for strengthening the bill, I will focus just now on three key areas of concern. Let me start by repeating those policy principles I mentioned. To protect public health and ensure consumer confidence, produce safety standards must allow for a commodity-specific approach based on the best available science, must be consistent and applicable to the identified commodity, no matter whether it was grown in the United States or imported, and it must be federally mandated with sufficient federal oversight of compliance in order to be credible to consumers.

We are pleased that these principles are recognized in the draft Food Safety Enhancement Act. In looking specifically at the draft, we strongly support the bill's intent in Section 104 for FDA to focus on maximizing public health by implementing regulatory standards for those specific raw agricultural commodities that it believes are most critical. The FDA has estimated that only five commodities have been associated with 80 percent of all produce-related foodborne disease outbreaks in the past 10 years, and that is where we must direct our resources.

In a highly diverse industry that is more aptly described as hundreds of different commodity industries, one size does not fit all. We support Congress specifying that FDA have broad authority to regulate any produce commodities it determines necessary. But with a clear mandate to develop rule making that focuses resources for maximum public health benefit on those specific types of commodities for which the secretary determines that such standards are necessary to minimize the risk of serious adverse health consequences.

We also recommend that Section 104 strengthen the support for collaboration between HHS and the U.S. Department of Agriculture and all state agencies in all areas of education, research, and enforcement with regard to produce. It is important that we bring the broadest knowledge and resource base possible to assist all stakeholders in understanding and complying with FDA set public health standards.

Dealing with Section 107 on traceability, I want to assure the committee that fresh produce industry is committed to farm to fork

traceability of our products. As I presented in detailed testimony before the House Committee on Appropriations, Chairwoman Delaro's Ag Subcommittee earlier this year, we have underway a produce traceability initiative to provide electronic traceability for 6 billion cases of fresh produce that move annually within the United States. This is a massive and extremely expensive long-term undertaking, but it is a commitment that we have made.

However we are concerned that the prescriptive nature of Section 107 could actually derail these important efforts to bring the most cost efficient and cost effective technology to bear on this challenge. As you weigh various traceability provisions, we urge that Congress set the goal to mandate for food traceability but not overly prescriptive requirements such as those in this bill.

Rather we believe Congress would be more effective in mandating an intensive evaluation of technologies, systems, and pilot tests that will truly lead to the end result we all desire. To that point, this legislation should set a goal for total supply chain traceability across the food industry, not single out individual food categories for traceability.

Finally on the question of imports, I believe the committee should carefully examine all of the provisions regulating imported foods to assure equal treatment and fair standards for imported and domestically produced foods. This should be a principle maintained throughout all provisions.

In Section 201, we support the bill's intent to require importers to register with FDA and comply with good importer practices. The committee should make clear that this is the standard protocol for importing foods, and that the limitations and restrictions envisioned in Section 109 provide very extreme authorities to be used by FDA only in worst case scenarios when required to minimize the risk of severe adverse health consequences.

With regard to imports, we also strongly support the concept of the safe and secure food importation program in Section 113 and urge that the bill require FDA to implement such a program with clear direction that it shall be implemented rather than may be implemented.

Finally, let me mention 143 and country of origin labeling. The fresh produce industry is already required under the 2008 Farm Bill to provide mandatory country of origin labeling at retail point of sale. Our industry has moved rapidly to ensure compliance with this law and urges that those products which are already covered be specifically exempted from any new duplicative coverage under the FDNC Act.

Let me conclude with a comment about public health. The very Department of Health and Human Services that regulates our safety has the dual responsibility to promote public health but consider the fact that we need, as Americans, to double our consumption of fruits and vegetables to meet the very simply U.S. dietary guidelines.

With that public health imperative, fears of food safety have no place in the fresh produce department. Thank you for your leadership on this effort.

[The prepared statement of Mr. Stenzel follows:]

United Fresh
PRODUCE ASSOCIATION

Prepared Statement

Thomas E. Stenzel
President and CEO
United Fresh Produce Association
Washington, DC

Before the
U.S. House of Representatives
Committee on Energy and Commerce

Subcommittee on Health

June 3, 2009

Introduction

Good morning Chairman Pallone, Ranking Member Deal, and Members of the Subcommittee. My name is Tom Stenzel and I am President and CEO of the United Fresh Produce Association. Our organization represents more than 1,500 growers, packers, shippers, fresh-cut processors, distributors and marketers of fresh fruits and vegetables accounting for the vast majority of produce sold in the United States. We bring together companies across the produce supply chain from farm to retail, including all produce commodities, both raw agricultural products and fresh ready-to-eat fruits and vegetables, and from all regions of production.

I mention these characteristics because our organization's views on food safety are shaped by this broad and diverse membership across the entire produce industry, not any one sector or region. In the area of science and food safety, our association works to develop industrywide consensus on the best overall policies and practices to serve the consumer.

Let me begin by repeating something you've heard many times before, and will hear many times in the future. Food safety is our industry's top priority. The men and women who grow, pack, prepare and deliver fresh produce are committed to providing consumers with safe and wholesome foods.

That is what drives food safety to be a process of continuous improvement, not a static achievement. We are on a continuum, constantly striving toward perfection, while understanding scientifically that perfection – or zero risk – is not possible. Because our products are enjoyed by consumers in their fresh and natural state without cooking, we have to be right every single time – not one in a million, or even one in a billion. But as long as there is the potential of even one individual getting sick, we will do all we can to prevent that from happening.

Now, I personally am confident in my produce choices today. I know many of the people who are growing and processing fresh produce, and I trust them to be doing their very best to market safe products. I know that their results are overwhelmingly successful, with the actual incidence of illness extremely low. Just look at the numbers.

- Over a billion servings of fresh produce are eaten every day.
- More than 5 million bags of fresh salads are sold every day.
- And, out of the hundreds of fruits and vegetables offered in a typical supermarket, only a very few have been implicated in illness outbreaks, and then rarely as compared with their volume of consumption.

But, we also know that consumers today are walking into grocery stores and restaurants with concerns, doubts, and sometimes fears about produce. They don't understand those statistics; they don't know what farmers and processors are doing to protect the safety of their produce; and equally important, they do not have complete confidence that government is doing all it should to protect their health.

Most importantly, we cannot lose sight that health experts are unanimous that Americans must increase our consumption of fruits and vegetables for better health. That's the juxtaposition we face today on food safety – it is simply unacceptable for Americans to fear consuming fresh fruits and vegetables that are essential to their good health.

Principles for Produce Safety

Mr. Chairman, over the past several years, you know that the fresh produce industry has been a leading proponent of strong federal government oversight of food safety. Our organization has testified before the House or Senate some 10 times since January 2007, when our Board of Directors adopted a series of policy principles calling for mandatory, science-based regulation by the federal government. Let me repeat those principles once more:

> *To protect public health and ensure consumer confidence, produce safety standards:*
>
> - *Must allow for a commodity-specific approach, based on the best available science.*
> - *Must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country.*
> - *Must be federally mandated with sufficient federal oversight of compliance in order to be most credible to consumers.*

We are pleased that the consensus in Congress has grown in support of these principles, which have largely been incorporated into all major food safety legislative vehicles before the House and Senate.

Let me now turn specifically to the Food Safety Enhancement Act of 2009, and discuss how these principles are addressed in the draft bill, and how we believe this legislation can be strengthened. While the bill appropriately is comprehensive over the entire food industry, my testimony today speaks specifically to a produce industry view.

First, we congratulate you and the leadership of the full committee in presenting this draft for consideration. We believe you have created a framework bill that, with certain key enhancements, has the potential to garner widespread support in the Congress.

1. Section 104 – Safety Standards for Produce

First, we strongly support the bill's intent in Sections 104 and 419A for FDA to focus on maximizing public health by implementing regulatory standards for those specific raw agricultural commodities that it believes are most critical. The FDA has estimated that only five commodities have been associated with 80% of all produce related foodborne disease outbreaks in the past 10 years, and that is where we must direct our resources. In a highly diverse industry that is more aptly described as hundreds of different commodity industries, one size clearly does not fit all. For example, the food safety requirements of products grown close to the ground in contact with soil are far different from those grown on vines or trees.

We support Congress specifying that FDA have broad authority to regulate any produce commodities it determines necessary, but with the clear mandate to develop rulemaking that focuses resources for maximum public health benefit on those types of raw agricultural commodities for which the Secretary determines such standards are necessary to minimize the risk of serious adverse health consequences.

We also recommend that Section 104 strengthen its support for eventual FDA regulatory standards, recognizing that such regulations must set the "most appropriate" standards for safety, not "minimum" standards.

Finally, we recommend that Section 104 strengthen its support for collaboration between HHS and the U.S. Department of Agriculture and state agencies in all areas of education, research and enforcement with regard to produce. It is important to bring the broadest knowledge and resource base possible to assist all stakeholders in understanding, implementing and complying with FDA-set public health standards.

2. Section 107 -- Traceability

The fresh produce industry is committed to farm-to-fork traceability of our products. As I presented in my detailed testimony before the House Committee on Appropriations Agricultural Subcommittee on March 26 of this year, our industry has underway a massive commitment to a Produce Traceability Initiative (PTI) www.producetraceability.org to provide labeling and electronic traceability for the 6 billion cases of produce that move annually within the United States. This is a massive and extremely expensive long-term undertaking, but it is a commitment made by our industry to drive standardization and efficiency of traceability systems.

However, we are greatly concerned that the prescriptive nature of Section 107 could easily derail these important efforts to bring the most efficient and cost-effective technology to bear on this challenge. As you weigh various traceability provisions, we urge that Congress set the goal for food traceability, not mandate the process. The overly prescriptive mandates in this bill from the top down are not as likely to be as effective as bottom up efficiencies and real-world systems designed for unique challenges.

We also believe this legislation should set a goal for total supply chain traceability across the food industry, not single out individual food categories or processes for traceability. With that overall goal, we believe Congress should then mandate an intensive evaluation of

technologies, systems and pilot tests that will truly lead to the end result we all desire – traceability across the entire food supply to determine the source of contamination in any food product. Let's not have Congress start inventing how the mousetrap should work, but instead set the path forward with clear direction that allows industry innovation to flourish.

3. Sections 201, 109, 113 Imports

We strongly recommend that the committee examine all imported food provisions to ensure that they comply with all legal trade responsibilities and assure equal treatment and standards for both imported and domestically produced foods. This should be a principle maintained throughout all provisions.

In Section 201, we support the bill's intent to require importers to register with FDA, and comply with good importer practices. The committee should make clear that this is the standard protocol for importing foods, and that the limitations and further restrictions contained in Section 109 provide extreme authorities to be used by FDA only when "required to minimize the risk of severe adverse health consequences." Should FDA issue blanket condemnations of entire countries or commodity groups, we are concerned that the certification procedures of Section 109 would be impossible to achieve, and thus offer no real means of meeting acceptable import status regardless of the safety of such foods. Section 109 should require a standard for implementation only when such restrictions are necessary to minimize the risk of severe adverse health consequences, and thus allow the Secretary to determine whether to refuse to admit such article.

Finally, with regard to imports, we support the concept of the Safe and Secure Food Importation Program in Section 113, and urge that the bill require FDA to implement such a program with a direction that it "shall" be implemented rather than "may" be implemented. This program is a critical component of a secure food importing system that can both assure safety while meeting the volume demands for safe foods moving quickly through well-established and rigorous channels in global commerce.

4. Section 143 – Country of Origin

The fresh produce industry is already required under the 2008 Farm Bill – the Food, Conservation, and Energy Act of 2008 – to provide mandatory country of origin information at retail point of sale for all perishable agricultural commodities. Our industry has moved rapidly to ensure compliance with this law, and urges that those products which are now required to have retail point-of-sale country of origin labeling under the Agricultural Marketing Act of 1946, as amended by the 2008 Farm Bill, be specifically exempted from any new duplicative coverage under the Food, Drug & Cosmetic Act.

While we hold specific concerns about various provisions as contained in the Food Safety Enhancement Act draft, we believe the simplest solution for fresh produce is a direct exclusion from the bill. However, should that not be the case, let us also say that country of origin is not a food safety issue and we do not believe it belongs in a food safety bill. The country of origin provision in this bill could be misleading to consumers, and is also extremely prescriptive and overly burdensome without enhancing food safety.

5. Section 105 – Risk-Based Inspections

We support the concept of risk-based inspections, including increased frequency of inspections for certain facilities. However, we believe FDA should be required to complete rulemaking to establish a science-based transparent system for determining classifications

for what facilities shall be included in different categories, rather than be left to the Secretary's discretion. In addition, we recommend that the terms "high-risk" and "low-risk" not be used to define category 1 or category 2. Any individual facility can be either a high- or low-risk facility based on how it's operated, and there should be no general pejorative terms applied to whole classes of facilities. The statute can require a science-based process for determining appropriate inspection frequency for individual facilities, which may at times vary in risk profile and inspection need.

6. Section 133 – Quarantine Authority

We oppose this section giving HHS authority to quarantine foods from vast geographic areas within the United States, based only on the modest standard that "FDA reasonably believes" such food may have originated from a particular region. First, food safety is not determined by geographical or political boundaries such as state or county lines, but by the preventive controls and practices applied by any individual producer or manufacturer. With the intensive new regulatory requirements of this bill, such a broad-based swipe against entire regions of food production is certainly regulatory overkill, and fraught with potential unintended consequences.

Consider our industry's experience last summer, in which the combined efforts of the CDC and FDA advised consumers against consuming tomatoes from vast regions of the country for suspected Salmonella contamination, only to find months later that the real source of the problem was contaminated jalapeno peppers from a farm 500 miles south of the U.S.-Mexican border.

Or, consider the spinach outbreak in 2006, when our entire industry immediately pulled all spinach from shelves nationwide, and the nation's primary spinach growing regions were under an FDA public relations cloud for weeks and weeks. In fact, we now know that the only contaminated product came from one 50-acre farm, packaged in one processing plant, and only on one production shift.

Should FDA have had the simple ability to quarantine vast geographical regions, I fear the stampede to action that could have occurred in either of these cases. We see no wisdom in providing statutory authority to magnify the damage of this type of decision-making.

We support mandatory product recall, but not mandatory "geographical recall" based on local, county, state or country boundaries.

7. Section 101 – Facility Registration Fees

We continue to advocate strongly that user fees are an inappropriate means of funding food safety inspections. Assuring a rigorous food safety inspection system is properly the responsibility of the nation at large, and thus appropriated funds, rather than a role for individual food companies. This is a long-held principle shared by many stakeholders in this debate, and one that should not be compromised for short-term budget expediency.

Should any type of fees be included in a final bill, we strongly urge that they must not be used for inspection programs; must be targeted to specific and justified needs not met through recent and potential increased appropriations; must be transparent and capped in legislation (we oppose the open-ended fee concept of Section 201); must be fair and equitable to both imports and domestically produced foods; and must not create trade barriers that are likely to result in reciprocal financial barriers established by other countries to U.S. exports.

Conclusion

In conclusion, let me thank you again for your leadership on this bill, and return to the important role fresh fruits and vegetables play in public health. The very Department of Health and Human Services that regulates our safety has the dual responsibility to promote the importance of eating more fruits and vegetables to prevent chronic diseases such as cancer, heart disease, stroke, and more. And now, our nation is faced with an obesity crisis that threatens the long-term health of our children and out-of-control escalation in health care costs unless we radically change eating habits to consume more fruits and vegetables.

With that public health imperative, fears of food safety have no place in the fresh produce department. We, as an industry, must do all we can to prevent illnesses from ever occurring, and we will.

But because science tells us there is no such thing as zero risk, government must also be able to assure the public that even if something does go horribly wrong in an isolated case, consumers can continue to have confidence in fresh produce. We must all be able to trust the overall system of government oversight and industry responsibility, working together to produce the safest possible supply of fresh, healthy and nutritious fruits and vegetables.

THOMAS E. STENZEL
President and Chief Executive Officer
United Fresh Produce Association

Tom Stenzel
President and CEO
United Fresh Produce Association
1901 Pennsylvania Avenue NW, Suite 1100
Washington, DC 20006

202/303-3400
tstenzel@unitedfresh.org

Tom Stenzel is President and CEO of the United Fresh Produce Association, a position he has held since 1993. United Fresh is the pre-eminent trade association for the produce industry in shaping legislative and regulatory policies; providing scientific and technical leadership in food safety and nutrition; and developing educational programs for its members. Founded in 1904, United Fresh represents the interests of companies from small family businesses to the largest international corporations throughout the global fresh produce supply chain.

United Fresh is widely known for its work in government affairs, food safety, and nutrition policy, well as education programs such as the Produce Industry Leadership Program, Cornell University Senior Executive Development Program, and programs to promote produce consumption such as its Retail Produce Managers Awards and Excellence in Foodservice Awards. The United Fresh Research and Education Foundation addresses key food safety research challenges, education and training needs in the industry, and also spearheads *Project Fresh Start*, an international program promoting political and environmental change to help the next generation of children double their consumption of fresh produce.

Tom has been recognized often by the produce industry throughout his career, and was honored as the 2002 *Produce Man of the Year* by *The Packer* newspaper. He has served in many government and industry leadership positions, including the first U.S. Department of Agriculture Fruit and Vegetable Industry Advisory Committee. He is a member of the Executive Committee of the Board of Directors of the Produce for Better Health Foundation.

Tom was the founding President of the International Food Information Council (IFIC) in 1986, where he worked with leading food and beverage companies to build a credible and sound scientific program in food safety, risk communications, and crisis management working with the media, government, public health community and public. He previously was director of public affairs for the National Soft Drink Association. Tom is a 1977 magna cum laude graduate of the University of Richmond, and achieved the Certified Association Executive (CAE) designation in 1990 from the American Society of Association Executives.

Mr. PALLONE. Thank you, and thank all of you. We will now take questions from the panel, five minutes each, and I will start.

I wanted to start with Ms. DeWaal. Many in the industry have called for prevention, or I should say a stronger emphasis on prevention. And many feel that we need to share the responsibility for making food safe. The FDA obviously does an important job, but manufacturers must also be responsible for the foods that they make.

Now, one of the ways that the draft before us proposes to do this is through a new emphasis on prevention. It requires companies to conduct hazard analysis to identify potential safety risks for the food they handle. It then requires that the facility owner adopt preventive measures to reduce or eliminate these risks.

So, Ms. DeWaal, can you elaborate on how preventive controls, such as those put forth by the bill, will help make food safer? And could you give us some examples of preventive controls and how they might be implemented or applied?

Ms. DEWAAL. Thank you, Chairman Pallone. The systems that are going to be applied in this bill are well tested. We have watched the implementation of what are called HACCP or hazard analysis critical control point systems in the seafood industry, in the beef and poultry industries, and in the—also in fresh juice and several other industries.

The problem would be the approach that FDA has been taking up until now and the solution that your bill will bring to the agency is that they have been trying to apply these systems one by one, industry by industry. And I think what you see here is a unitary view, among industry and consumer organizations, that these systems are needed across the board. They are developed by the industry. They are driven by the industry. They design the programs, but the government can use them to actually go in and conduct inspections, which are much more meaningful than the ones they do today.

Mr. PALLONE. Well, let me ask each of you. I will ask Ms. Bailey and then go to the others quickly if you would respond, whether you support these preventive approaches to food safety.

Ms. BAILEY. Absolutely. Yes, sir.

Mr. PALLONE. OK, Mike?

Mr. AMBROSIO. Yes.

Mr. PALLONE. Dr. Jones?

Dr. JONES. Yes, sir, we do.

Mr. PALLONE. All right, great. I mean obviously a consensus on the preventive approach being the critical part of the bill. I wanted to ask about access to records though too. One of the new requirements in the bill references access to records. Section 106 requires that food manufacturers and producers retain records relating to the foods they produce, and upon request, provide these records to the FDA. FDA would, in the event of a food-borne disease outbreak or during an inspection, have access to information on how foods were produced, manufactured, transported or stored. And I will initially ask Dr. Jones. Can you describe for us how this type of records access would be helpful to the FDA in the event of a food-borne disease outbreak?

Dr. JONES. Well, I mean I think access to those records are critical in order for them to sort of pinpoint their interventions, but I also think the ability for FDA to share that data with other agencies that assist them in those investigations is critical. And that has been a huge barrier for us. I mean I worked on outbreaks where FDA had the names and phone numbers of people that had consumed contaminated product and would not or thought that they could not share that information with public health departments that are responsible for calling those people and telling them not to eat the stuff. And that is just mind-boggling to me. I mean I think it is subtle, but there is some addressing that issue in this bill.

Mr. PALLONE. You want to comment also, Ms. DeWaal on whether you believe that this access to records provision will help protect public health?

Ms. DEWAAL. The access to records provision gives the agency the ability to look at plants. When they visit them, they can look at them as they are operating over time. Today when an FDA inspector goes into a plant, they just see the four walls of the plant. They may not even get access to any records in that facility. They can look at production practices as they are happening on that day.

But with the access to records provision together with this preventive control system and this written food safety plan, the inspector will be able to go and look back and where the company has faced perhaps challenges in its operation and how they have addressed them.

Mr. PALLONE. OK, thank you. I mean I don't know if anybody else wanted to address that, but I think that is fine. Thank you. Mr. Deal.

Mr. DEAL. Thank you. Mr. Stenzel, I guess I am going to start with you from the producer side of it. First of all, in a general context, do you see any problem or potential of this legislation creating overlaps with FDA jurisdiction and requirements to do things versus current USDA requirements to do things in our food supply?

Mr. STENZEL. We don't see any jurisdictional issues in public health in that sense. FDA has the statutory authority now to regulate the fresh produce industry. We do suggest strongly that there be a good coordination with the U.S. Department of Agriculture in education, enforcement. Certainly one of the keys to implementing this bill is going to be an effective structure with FDA working with USDA and state and local agencies in compliance, enforcement, inspections. That needs to be strengthened, but there is not a jurisdictional issue of competing authorities.

Mr. DEAL. My understanding is that at the production level that good agricultural practices are the primary preventive tool and mechanism for dealing with it at the production level. Do you see perhaps that an updating or improvement on those agricultural practices standards as they apply to fruits and vegetables is important? And is there anything here that would prevent that from taking place?

Mr. STENZEL. Yes, sir, Mr. Deal, that is an extremely important part. The FDA's good agricultural practices are called to be updated in this draft legislation. We strongly support that as the baseline guidance for all fruit and vegetables. For those specific

commodities in which FDA has determined a significant level of risk, then you move into the rule making procedure. But that is one of the key things. It is the way we can best focus our public health resources on the greatest risk.

I said in my testimony that 80 percent of all the outbreaks have been associated with just five commodities. So the basic good agricultural practices are very appropriate for all fruits and vegetables, but let us focus the rule making on those specific commodities that require it.

Mr. DEAL. And, Ms. Bailey, I believe you made the point that since we have mandated studies and pilot projects, et cetera, that those be completed before we start trying to write the rules and regulations. Is that one of the points you were making?

Ms. BAILEY. On traceability, yes.

Mr. DEAL. Yes. It seems to me that if we are going to do the studies and the pilot projects, we ought to do that before we write the regulations because presumably they will give us the information to guide us in the rule making process. So I think your point is well made. In that regard, Mr. Stenzel, your industry has already put in place some traceability standards. How do you see your current efforts in traceability? How do they correspond with what is in this legislation?

Mr. STENZEL. I tell you this is proving to be a massive, massive undertaking, and, you know, we are committed to doing it even on a voluntary basis before any type of requirement. But extremely complex system of creating that interoperable system that can see the life cycle all the way through of our products. But some of the specific language in this bill, the full pedigree of each product, gives us great cause for concern.

Even though we are moving down a path of hundreds of millions of dollars being invested in interoperable traceability systems, we don't think they might meet exactly the terms of this bill. So we would also strongly advise that FDA be mandated to get involved in the technology, in the pilot test, learn about each industry, and then write the regulation.

It is premature to tell every industry exactly how it should be done until we have this greater learning.

Mr. DEAL. One of the scares that we have alluded to here was the Mexican pepper scare that adversely impacted the tomato industry. And I guess I would ask you again how do we ensure that foreign producers meet the kind of standards that we would need? Would it require, in your opinion, some kind of foreign producer verification system of some sort?

Mr. STENZEL. Well, I think the requirements in the import section are appropriate. That importers will now be required to register with the FDA, and as part of good importer practices, they will have to assure that their products have been grown in accordance with these standards. We believe that is an appropriate step to be taken.

I don't think anyone envisions going, searching around on every farm around the world, nor every farm in America to be honest with that. That is simply not going to be the case. The authority should be there for FDA if they need to investigate an issue, but

the basic responsibility is going to lie with the importer or the food manufacturer.

Mr. DEAL. Does your organization represent the organics producers?

Mr. STENZEL. Yes, sir, we have a number of organic suppliers in our group.

Mr. DEAL. Thank you. I have a statement, and I think we have cleared it with your staff from the Frozen Food Institute to be inserted in the record?

Mr. PALLONE. Without objection, so ordered. Chairman Dingell.

[The information appears at the conclusion of the hearing.]

Mr. DINGELL. Mr. Chairman, thank you. I would like to commend the panel for their very helpful testimony and thank you all. I would particularly like to address my questions, however, to Ms. Bailey from GMA. I would like to first begin by welcoming you. I would like to follow up by thanking you for the cooperative way in which you and GMA have been working with the staff to try and resolve the difficulties which we confront. And I would like to also express my particular thanks to you for the most helpful way in which you have behaved and the remarkable change that has occurred under your leadership. So I thank you.

First of all, am I fair in stating that FDA has been so underfunded that they have not been able to provide the necessary services to protect either the industry or the consumers for a number of years?

Ms. BAILEY. That is right.

Mr. DINGELL. And as a result, they have been unable to adequately fulfill their role in ensuring the safety of the Nation's food supply?

Ms. BAILEY. Yes, we would agree.

Mr. DINGELL. Unfortunately our reporter doesn't have a nod. You have to say yes or no.

Ms. BAILEY. I am sorry. I said yes, and if I could give an example, FDA has not been able to update good manufacturing practices since 1986, and that is just one example of something they have not been able to do without adequate resources.

Mr. DINGELL. That sounds like a very serious matter. Tell us what that means.

Ms. BAILEY. Well, good manufacturing practices serve the basis——

Mr. DINGELL. Those are required both in food and drugs, cosmetics and also——

Ms. BAILEY. That is right.

Mr. DINGELL [continuing]. In pharmaceuticals.

Ms. BAILEY. That is right, and so the preventive controls that we are talking about, in HACCP for example, are one step up from good manufacturing practices. You want to have them updated, and as we all know, there have been enormous advances in manufacturing and food processing since 1986 relating to pathogen control, environmental testing, all of the advancements. And FDA has not been able to incorporate them into updated good manufacturing practices guidance for industry.

Mr. DINGELL. Would you also agree that FDA's science base has eroded?

Ms. BAILEY. Absolutely yes.

Mr. DINGELL. And that the FDA's information technology systems are inadequate?

Ms. BAILEY. Yes.

Mr. DINGELL. And that FDA has not been doing an acceptable level of surveillance and research?

Ms. BAILEY. That is right.

Mr. DINGELL. Would you agree that they have not conducted a satisfactory number of inspections over the years? This figure I got, which seems interesting. FDA conducted 6,562 domestic food facility inspections in 2008, 152 foreign food facility inspections in 2008. The total number of registered facilities is 378,000, but there are many more out there in the world who are shipping stuff to us. Is that a fair statement?

Ms. BAILEY. That is an accurate statement, yes.

Mr. DINGELL. Thank you. And I am sure that you agree, as you have said in your statement, that FDA needs additional resources to do their job?

Ms. BAILEY. Yes.

Mr. DINGELL. And I want to commend you very much for the way that you have been working with us on the registration and the fee question. And I want you to know that we are going to try very hard to see to it that we come up with something that enables industry to work, prosper, have a satisfactory Food and Drug Administration, one which protects the consumers but also which doesn't overburden the industry. And we look forward to continuing our efforts on that, and I hope that you will continue to give us those assistances.

And again the reporter has no nod but——

Ms. BAILEY. Yes, we look forward to that. I thought that Dr. Hamburg this morning laid a good basis for those discussions going forward.

Mr. DINGELL. I am troubled about foreign people who deliver food into the United States. Food and Drug doesn't have the right number of inspections and inspectors at the border, do they?

Ms. BAILEY. No, that is right. They do not.

Mr. DINGELL. I am told they only inspect about one percent of foods coming into the United States. And the games are played oftentimes where they are turned back, rather where food shipments are turned with the result that they go out and come in another port. Are you troubled about that?

Ms. BAILEY. Yes, we need strong inspections at the border.

Mr. DINGELL. Now, I am also troubled about the fact that Food and Drug has no understandings with their sister agencies, with customs, with immigration. So as a result a lot of times, their inspectors will be at the ports, and there is no Food and Drug folk. We ought to see to it that there is a cooperative agreement there to make that possible so that they would work together instead of ignoring each other's business. Isn't that right?

Ms. BAILEY. I think that sounds like a good idea, yes.

Mr. DINGELL. Now, I note that I am three seconds overtime. Pleasure to have you before us. Thank you. Thank you, Mr. Chairman.

Ms. BAILEY. Thank you, Mr. Dingell.

Mr. PALLONE. Thank you, Chairman Dingell. Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I have a lot of questions. I am going to try to be quick. You all sat in the first testimony. Can any of you tell me what "may cause" means? Mr. Ambrosio, do you know what "may cause" means?

Mr. AMBROSIO. It is a very vague term.

Mr. SHIMKUS. OK, Ms. Bailey, "may cause"?

Ms. BAILEY. I am not certain, no.

Mr. SHIMKUS. OK, Ms. DeWaal?

Ms. DEWAAL. Thank you. The actual subsection says "if the secretary has reason to believe that the use or consumption of or exposure to an article of food may cause adverse health consequences." So the actual standard, sir, is "reason to believe" and the "may cause" is in there, but it really is a standard which is very protective of public health. Thank you.

Mr. SHIMKUS. Dr. Jones?

Dr. JONES. I agree with those comments.

Mr. SHIMKUS. And Mr. Stenzel?

Mr. STENZEL. I believe that it is a much more vague standard than that.

Mr. SHIMKUS. And I hope we can work to clean up that language, and I think there is an opportunity to do that. Let me ask this subpoena question again to those who may want to talk about that. There are three criteria in Section 311 which I didn't allude to the first. First, "does any hearing, investigation, and other proceeding, respecting a violation of the act"? I think most people agree subpoena.

"Any hearing, investigation or other proceeding to determine if a person is in violation of a specific provision of this act"? I think an average person would say oK, subpoena these babies.

The third one, "any other matter relative to the commissioner's jurisdiction under this act, the Public Health Service Act, and the Federal Anti-Tampering Act." Any other matter, vague or not? Mr. Ambrosio?

Mr. AMBROSIO. It is vague.

Mr. SHIMKUS. Thank you. Ms. Bailey?

Ms. BAILEY. Yes, that—it is vague.

Mr. SHIMKUS. Ms. DeWaal?

Ms. DEWAAL. Actually these acts are important to protect us against swine flu, against bioterrorism. So in fact, these acts, if you understand the relationship between the Food, Drug, and Cosmetic Act, and these other legal statutes, I think the language may be appropriate but——

Mr. SHIMKUS. It may be. It may not be. It may be.

Ms. DEWAAL [continuing]. We will go back and look at it.

Mr. SHIMKUS. OK, thanks. Dr. Jones?

Dr. JONES. I am a physician, not a lawyer.

Mr. SHIMKUS. OK, neither am I, but I pretend to be one here.

Dr. JONES. You know, so my tendency is to err on the side of protecting the public's health, but I agree it is somewhat vague.

Mr. SHIMKUS. My tendency is to question the legal language of the law that may harm folks by the—I found the language of the law is very important. And interesting things can be done as this gets crafted. Mr. Stenzel, I think it is also quit a general standard

and do suggest it is an area to look at throughout the bill. Thank you.

Mr. Stenzel, I want to ask specifically on Section 104, which calls for the secretary to issue regulation on produce safety standards. The language in the bill says the standard may include minimum standards for safety. This is a lot of the language stuff that I have been focusing on today. Why would we want the agency to issue minimum standards instead of the appropriate standards for safety?

Mr. STENZEL. Mr. Shimkus, thank you for raising that. That is actually a subject I addressed in my written testimony. I don't think we should be using such terms as minimum or expecting minimum standards. We should have the agency write the standards that are most appropriate that all producers should follow. I can tell you this: that as soon as we have minimum standards, the first thing that is going to happen is someone is going to say that is not good enough.

So if we are going to go down this path, let us make sure the agency writes the most appropriate standards.

Mr. SHIMKUS. And that is that whole debate that we always have appear about some certainty. Industry needs certainty. If we have vague language, there is uncertainty, and with uncertainty comes higher risk because of trying to comply. I appreciate that. Ms. Bailey, what was surprising in the draft is—and I was on the ONI last Congress. I can't talk about what was the hearings in previous Congresses or what is going on this time.

But baby formula has popped into this debate, and I know of no hearings on baby formula in the last Congress when I was ranking on ONI. Have there been any reported problems that would suggest that there needs to be a reason to change the way infant formula is regulated? In the premises, it is highly regulated already. Do you want to comment on that?

Ms. BAILEY. Yes, we are not familiar either with the origin of that provision. We noticed it in this draft, and we are, of course, aware of how high the regulated baby formula is. And we are interested in receiving further information, but it obviously is very important, as is the safety of the product and the availability to mothers and children.

Mr. SHIMKUS. And thank you, Chairman. My time expired. I would have gone on with a pilot program. I think that has been discussed a little bit. I know Mr. Ambrosio has some comments, and I think a pilot program might be important. And I yield back.

Mr. PALLONE. The problem that we have is there is an important vote on our other subcommittee. So I would like to adjourn for just five minutes so that the members can go and vote in the other subcommittee, and we will come right back. So the subcommittee, if you bear with us, is just in recess for five minutes.

[Recess.]

Mr. PALLONE. Ms. DeGette.

Ms. DEGETTE. Thank you very much, Mr. Chairman. I want to echo Mr. Dingell's thanks to every single witness here for working with us on this legislation. All of your input has been very, very important, and none of you will be surprised to know I want to talk

about the mandatory recall provisions of the bill, and I want to start with Ms. DeWaal.

First of all, do you think, Ms. DeWaal, that the current provisions of the Bioterrorism Act are sufficient to give us the mandatory recall that we need in a robust food safety system?

Ms. DEWAAL. No, I don't.

Ms. DEGETTE. And why is that?

Ms. DEWAAL. Well, the Bioterrorism Act actually didn't really give them mandatory recall, but it does give them the authority to take certain actions like administrative detention and some other actions when they meet a very high——

Ms. DEGETTE. But to interrupt you, it really has the one step back and one step up. Is that sufficient to give us the whole traceability?

Ms. DEWAAL. I am sorry.

Ms. DEGETTE. I said mandatory recall, and I meant traceability.

Ms. DEWAAL. OK, I am sorry. Traceability——

Ms. DEGETTE. That is what happens when you break my train of thought.

Ms. DEWAAL. Thank you for that clarification. The one step up and one step back traceability was a good first step into this area, but I think the provisions in this bill are much improved on that. What we have seen over the years, since that law was passed, is that the FDA itself has had trouble with identifying food products involved in major recalls and outbreaks.

Ms. DEGETTE. Because it just doesn't go far enough forward or backward, correct?

Ms. DEWAAL. Right.

Ms. DEGETTE. And, Dr. Jones, you are nodding your head yes as well.

Dr. JONES. Yes, I mean I think there is such a huge food production chain that if there is one point in the chain where records aren't good——

Ms. DEGETTE. You lose the whole thing.

Dr. JONES. I mean if Bruno's produce doesn't know where it came from, you could have the rest of the industry known, and you can't get anywhere.

Ms. DEGETTE. Right, thank you. Now, I want to ask you, Mr. Amobrosio, Ms. Bailey, and Mr. Stenzel, I have read all of your testimony and listened to you here today. You don't object in general to the concept of traceability, do you, Mr. Ambrosio?

Mr. AMBROSIO. No.

Ms. DEGETTE. Ms. Bailey?

Ms. BAILEY. No.

Ms. DEGETTE. And Mr. Stenzel?

Mr. STENZEL. No, ma'am.

Ms. DEGETTE. And in fact, Mr. Ambrosio, in your testimony, you recommended that the secretary be allowed to design systems based on information gathered and not be mandated to develop a specific type of system prior to those efforts, correct? And, Ms. Bailey, in your testimony, your written testimony, you talked about the concept of including intermediate distributors and brokers in the labeling of bulk ingredients to the supplier so that we could get that traceability, correct?

Ms. BAILEY. That is right, yes.

Ms. DEGETTE. And, Mr. Stenzel, I have to say the produce industry in this country was really—maybe I shouldn't say this in front of everybody else, but you folks were the ones that gave me courage to believe that we could do traceability because you are doing such a great job. So I want to commend you. I guess the issue, as I heard in all of your testimony today, is some concerns with the specific language of Section 7 of the committee draft. Would that be accurate to say, Ms. Bailey?

Ms. BAILEY. That is right.

Ms. DEGETTE. And I just want to—you know you talk in your verbal testimony today about the tomato recall, and you were talking about mandatory versus voluntary recalls. But that made me think about traceability too because it doesn't really matter if the recall is mandatory or voluntary. If it is overbroad, it is still—I guess I should ask you, Mr. Stenzel, since it is produce. If it is overbroad, it still devastates the entire market, correct?

Mr. STENZEL. Yes, that is absolutely correct.

Ms. DEGETTE. So really what you want to have is the ability to quickly trace where contamination came from foods, correct? And, you know, what we have been seeing lately, I was thinking about the latest, the pistachios, where they were saying just don't eat any pistachios. Then I thought well, what if you had pistachios that were incorporated in granola or something like that that went a long way. You could really devastate a food agency. Ms. Bailey, I wonder if you want to comment on that.

Ms. BAILEY. I think first of all we are absolutely sympathetic with your goal and the importance of improving our traceability systems. I think it is a matter of prioritizing how we go about it. That is why we recommended—first of all, there is a difference between a single product like a strawberry that is ready to eat versus ingredients that may be co-mingled and——

Ms. DEGETTE. Right.

Ms. BAILEY [continuing]. And put into additional products.

Ms. DEGETTE. Exactly, right.

Ms. BAILEY. And we saw in the peanut paste problem that when there are brokers involved, PCA would sell the paste to a broker who would then sell it to an end manufacturer. And that is why we included the recommendation that the distributor label it.

Now, going forward, what we have learned working with our member companies and other areas of the food industry, it can be enormously expensive when you start to deal with co-mingled ingredient commodity products, and that is where we caution. And we think the legislation has it absolutely right. Let us ask FDA to first identify cost/benefit because in the end resources are finite.

Ms. DEGETTE. Right, let me just say, because my time has expired, that I really hope all of you will come in and work with us on this particular traceability language because from the very early days of my working on this issue, what you are saying is exactly my view, which is we need to have traceability throughout the industry but that we can't have a one-size-fits-all traceability system or technology. The key is those things be interoperable.

So if you have tomatoes and peppers mixed in a salsa, that is one level of complexity. If you have that salsa incorporated in a proc-

essed food, that is another layer of complexity. And then if you have that put into something at a restaurant or any place, that is another layer. So we have to really work on that.

What I am amazed about though is that we do have the technology, and we just need to work on it. So I hope you will all work with us in the next week to improve this language. Thank you for your indulgence, Mr. Chairman.

Mr. PALLONE. Mr. Buyer.

Mr. BUYER. I had to take a deep breath because Mr. Matheson and I and I guess now Chairman Dingell and Gene Green, you know, we have taken this trying to educate the committee here on electronic pedigree with regard to drugs. Yet now all of a sudden, there is this great interest to do something expansive on pedigree with food.

So I just want you to stop and ponder and think about this, Mr. Chairman, because as we move to the Drug Safety Bill, it is the reason I went right at the FDA Commissioner. You can't say I have this level of interest in making sure that they go after tainted food but with regard to drugs well, maybe that is a little bit different. We are not going to send this message to the country that tainted food, bad lettuce, that is really awful, but we can have a different standard when it comes to bad Lipitor. I am uncomfortable.

Let me ask some questions because I don't think I completely understand. When I look at Section 106 and Section 107, we have sort of an all-in, and then under traceability, we have some exemptions. So you know I come from a very small town. I grew up on the Tippecanoe River, Buffalo, Indiana. We have two stops signs on either side of a bridge. That is the size of the town I come from. So I think about small businesses, and I worry.

So when we think about access to records, and we are going to say requirement with regard to restaurants. Are we going to include concessionaires? Does anybody anticipate that, that we would include concessionaires? So that when you go to MCI Arena, how about when you go to the college football game? How about high school? How about little league? You know we make deer chili at our little league games. I mean what all is going to be included?

How about convenience stores? How about when you pull into that mom-and-pop gas station and they have created something? You can get elk sausage. I mean what kind of requirements are we going to be placing, and where do we stop? Has anybody thought about do we as a committee need to have better definition as to who is in and who is out? Total silence. Yes?

Mr. STENZEL. Congressman, at the risk of your wrath, I just don't think that food safety is something that is determined by scale or size of company. I run a trade association that has many very small members who are going to be extremely challenged to comply with this regulation. We also have very many big members, but in last summer's outbreak, we also found that some of the issues and some of the issues where people were getting sick were the very smallest restaurants. And we have to be able to have a system that takes care of——

Mr. BUYER. Well, there is food handling. There is a different between food processing and food handling, right?

Mr. STENZEL. Yes, sir.

Mr. BUYER. So the people up here on this dais love to talk about all these food-borne pathogens and all these sicknesses that everybody comes down to predominantly deals with the handling of food, right, not so much always the processing of food at a manufactured facility? I almost feel like they are being used as a scapegoat when, in fact, it is other handling. And probably everybody here in the audience and around the country, we have all gotten sick because somebody left the mayonnaise out overnight or something.

Well, when I look at the traceability requirement, we decide, I guess, farms, for example, they got to keep their records or, I guess, little league has to keep their records or everybody that is going to be involved with food is going to have to keep their records, but we are going to exempt now restaurants and farms would be required to maintain the safety records. But direct sales by farms are exempt.

What about seafood? So if we are going to exempt on the farm, are we going to exempt seafood? How about that trawler that goes right out there, gets the seafood and he owns the restaurant and the trawler and processes the food? Should they be exempted just like we are going to exempt on the farm? Total silence. See those are the same kind of questions I have. When we start picking and choosing where we draw the line. Ms. Bailey?

Ms. BAILEY. If I could, the language in that section at the end is very important and I think goes to the heart of our concerns. There are a number of questions. There has to be a sense of what is feasible technologically, what the cost/benefit is, and what the relation is to food safety.

Mr. BUYER. If we are going to exempt farms, should we exempt trout farms, catfish farms? How about fish caught on the Great Lakes? What about seafood?

Ms. BAILEY. I think those are all questions that need to be answered, and if I could offer, the analogy might be—this is very similar to electronic medical records in that it is a concept that makes good sense. But it is not easy to achieve and there are many reasons why it is not easy to achieve both technologically and——

Mr. BUYER. Well, see it is easier for me to be able to achieve electronic pedigree in the drug industry when I have specific companies, yet I can't get cooperation here to do this. But they say that what I am trying to do is too complex? What the heck is this? This is a decentralized model of the umpteenth degree. I would love to work with you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you. OK, we are done with our questioning, and just a reminder again. You heard us earlier about that you may get written questions by the close of business tomorrow, and we would like you to answer them by the close of business on Monday. And again I want to thank you all. This was very helpful. I can't emphasis enough that even though, you know, our plan is to go to markup next week, that we would very much like and we intend to, you know, consider a lot of the statements that were made today as we move forward over the next week. And several members have commented on how valuable, you know, your testimony is going to be as we move forward.

Without objection, the meeting of the subcommittee is adjourned. Thank you.

[Whereupon, at 2:30 p.m., the subcommittee was adjourned.]
[Material submitted for inclusion in the record follows:]

Submit for the record

HOUSE ENERGY AND COMMERCE COMMITTEE
June 3, 2009

National Food Safety Reform

Testimony of Rod Nilsestuen,

Secretary, Wisconsin Department of Agriculture, Trade and Consumer Protection

Thank you for the opportunity to submit comments for the record of the June 3, 2009 public hearing on federal food safety reform legislation. Food safety and food security are life and death matters for all of us, and we commend the Committee for moving to address this urgent national priority.

I am Secretary of the Wisconsin Department of Agriculture, Trade and Consumer Protection. Our department licenses and inspects over 30,000 food businesses and regulates many other aspects of the food chain, from the farm to the table.

The United States food safety system is primarily a state and local system. State and local inspectors and food scientists perform over 90% of the food and dairy inspections, investigations, and testing in the U. S.

Any truly effective change to improve the U. S. food safety system nationwide must fully integrate state and local food safety programs as equal partners with FDA. Leveraging the existing state food and local expertise, funding, staffing, and experience is critical to improving the system.

A fully integrated system requires full reporting and sharing of all federal, state, and local licensing, inspection, sampling, testing, compliance and enforcement information into a common database to monitor and prevent food-borne illnesses nationwide.

Like FDA, state government food safety agencies are underfunded. An integrated food safety system should provide matching federal grants to states to help pay for the day-to-day costs to operate food safety programs that are part of this integrated system.

A fully integrated system must also eliminate duplication and overlap of existing inspection, sampling, and testing between federal and state programs.

I am suggesting a framework for an integrated national food safety system in which FDA and the states work as equal partners and share responsibilities for protecting the public health and preventing food-borne illness.

Framework for an Integrated Food Safety System: How it would Work

The framework for a fully integrated national food safety system would include clear roles and responsibilities for FDA and state and local agencies:

State and Local Governments in an Integrated Food Safety System Would:

- Be full and equal partners with FDA in the national food safety system
- License and inspect domestic food processing, distribution, storage, and sale in their states
- Obtain and analyze food and environmental samples from licensed and inspected facilities in their states
- Analyze food samples at certified state laboratories
- Conduct self audits of their state programs based on FDA program standards
- Investigate consumer complaints and food safety violations
- Take regulatory, compliance and enforcement actions within their states
- Respond to emergency food safety problems within their states
- Adopt and maintain conformance with the FDA manufactured food, retail food, and Grade A regulatory program standards
- Establish and maintain Rapid Response Teams that are part of the national rapid response network for food-borne outbreaks
- Share, report, and upload all food safety surveillance data and records into an integrated electronic national food safety database including data on licensing, inspection, and testing results

FDA in a Fully Integrated National Food Safety System Would:

- Set standards for Food. Develop science-based performance standards to minimize, prevent, and eliminate the occurrence of food-borne biological, chemical, and physical hazards
- Set standards for State Food Safety Regulatory Programs. Develop state program standards for regulatory processes, protocols, and systems that represent the best management practices necessary for state programs to effectively prevent outbreaks of food-borne illnesses

- Develop and maintain a national food safety database for use by federal, state, and local government agencies
- Monitor federal, state, and local government food safety inspection and laboratory data to ensure multi-state and nationwide food safety surveillance
- Provide technical and research support to state and local food safety programs
- Provide training, set minimum training requirements, and evaluate training for state and local food safety programs
- Register, inspect, and regulate imported food at points of entry
- Set standards for imported foods and conduct inspections and investigations of imported food at points of entry
- Provide matching grants to states to assist them in the day-to-day operations of their food safety programs
- Evaluate state and local food safety regulatory programs

Other Important Reform Elements Needed to Strengthen the System

- Establish mandatory science and risk-based guidelines for food establishments
- Develop a nationwide electronic food safety surveillance database for use by federal, state, and local agencies to monitor food safety. The database should include:
  - federal, state, and local data collected on licensed and inspected food facilities, food sampling and testing, and compliance and enforcement.
  - food-borne illness surveillance data
  - information on reported activities concerning food-borne illnesses
  - state and federal laboratory data including data from the national food emergency response laboratory network
  - PULSE NET outbreak surveillance and response information
- Authorize and develop a rigorous product recall system which delineates and coordinates responsibilities between the industry and federal, state, and local agencies

- Revamp and expand FDA's oversight of imported foods and ingredients, strengthen import inspection, and develop a foreign supplier verification program
- Develop and enforce an achievable industry "one forward and one back" food trace back system for industry
- Authorize administrative detention
- Authorize mandatory reporting of pathogen positive results of in-commerce products
- Provide federal funding to state programs
- Strengthen the role and increase food safety funding for CDC
- Increase funding for FDA food safety import surveillance and inspection
- Eliminate duplication and overlap between state and FDA responsibilities and smarter targeting of state and federal resources

I am attaching two appendices to my testimony: 1) a proposal for federal grant funding for states and 2) a fact sheet highlighting the significant role that states currently play in regulating food safety in the United States.

Wisconsin supports an integrated food safety system, under federal leadership, that draws on the strengths of state programs and includes states as full partners. States have much to offer, but they need federal leadership and financial support. In return, I believe they are willing to be held accountable as full partners in the national effort to prevent food-borne illness and protect public health.

-Appendix A-

Proposal: Federal Grant Funding for States

For A Fully Integrated National Food Safety System

- In an integrated national food safety system, states would have a significant role and major food safety responsibilities with FDA.
- States would also need to strengthen their state and local programs
- State accountability for food safety programs can be accomplished by expecting states to adopt, and conform to, the current FDA regulatory program standards for manufactured food and retail food.
- Currently, like the FDA, state food safety budgets are underfunded.
- Currently, states receive no FDA federal funding for the important day-to-day operations that their food safety programs play in preventing food-borne illnesses throughout the United States.
- A commitment of federal funds to states can make a significant difference as those states work as partners with FDA to meet the challenges of this national priority.

Two Grant Proposals for State Funding

Grant Proposal: Expedite State Conformance with FDA Program Standards

To expedite state conformance to the FDA manufactured and retail food regulatory program standards, the Food and Drug Administration should provide one-time grants to states. Under this grant proposal:

- FDA would provide a $100,000 grant to each state for one year to conduct the baseline assessments related to the FDA manufactured and retail food regulatory program standards and implement plans to bring state programs into substantial conformance with the standards.
- These one-time grants would be available to all states, including those states currently conducting the baseline assessment and those states currently implementing the programs standards.

Grant Proposal: Provide Annual FDA Grants to State Food Safety Programs

FDA would provide ongoing, annual grants to states to carry out their food safety responsibilities as an equal partner in the national food safety system.

To Qualify for a FDA Food Safety Grant – each state must commit to implementing the current FDA Manufactured Food and Retail Food Regulatory Program Standards and the FDA General Guidelines for Evaluation of State Grade A Dairy Programs (MI-03-12 Supplement 1, March 6, 2007)

A State would Begin to Receive the Grant – once it completes the FDA program standard baseline assessments and begins implementing the FDA regulatory program standards.

Grants to States would be Provided Annually – as continuing funds through a cooperative agreement.

The State Grant Amount would be Based on – the number of state licensed and inspected food production and processing facilities in the state multiplied by a factor of $150 or approximately 50% of the state's current food safety annual budget. For example, Wisconsin has 30,150 licensed and inspected food production and processing facilities. Under this formula, Wisconsin would receive an annual grant estimated to be $4.523 million per year.

State Grant Funds are Allocated for – a state's day-to-day food safety activities to maintain conformance with the FDA program standards, including food safety program standard work related to:

- Regulatory authority
- Training regulatory staff
- Inspection, sampling and testing
- Self audits and quality assurance
- Emergency response for food-borne illness and food security
- Compliance and enforcement
- Industry, consumer, and community relations
- Program resource management and program assessment
- Laboratory support

A Minimum State Funding Match – equal to the grant amount is required.

FDA Would Audit the Grant Expenditures – once every five years on the same schedule for auditing the implementation of the program standards.

States Would be Authorized to Pass Some of their FDA Grant Funds on to Local Agencies – for food safety work done by the local governments in conjunction with their state programs, working toward conformance with the FDA program standards.

-Appendix B-

State and Local Food Safety Regulatory Programs

Facts

Nationwide – State and local governments conduct more than 90% of the food safety regulatory work in the United States. This includes facility inspection, food and environmental sampling and testing, surveillance, food-borne outbreak response, compliance, and enforcement. FDA is responsible for regulating 80% of the nation's food supply, but it is state and local inspectors and field scientists in the field doing more than 90% of this food safety work!

Retail Food Establishments – More than 3,000 state, local and tribal agencies have primary responsibility to regulate the retail food and food service industries in the United States. They are responsible for the inspection and oversight of over one million retail food establishments.

State Laboratories – State food safety program laboratories analyze more than 300,000 food samples each year, including more than 252,000 microbiological samples.

Food Establishments – State and local food safety programs conduct more than 2.5 million food safety inspections annually.

Food-Borne Illness Investigations – State and local food safety programs conduct more than 3,000 food-borne illness investigations each year.

Consumer Complaint Investigations – State and local food safety programs investigate more than 46,000 consumer food safety complaints each year.

Emergencies and Disasters – State and local food safety programs respond to over 2,800 emergencies and disasters involving food products each year.

Food Product Recalls, Embargos, Seizures, Prosecutions, Warning Letters, Injunctions – More than 128,000 state and local regulatory actions including embargos, seizures, stop sales, injunctions, criminal prosecutions, warning letters, informal hearings, and food recalls are done each year.

Note: These facts and statistics are taken from 2001 survey data collected from state and local governments by the Association of Food and Drug Officials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

JUN 03 2009

The Honorable Bart Stupak
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 03 2009

Dear Mr. Chairman:

Thank you for your continued interest in the status of the laboratories of the Food and Drug Administration (FDA or the Agency). Please let me assure you that FDA has no current or future plans to close or consolidate any of our 13 field laboratories. Our laboratories are an integral part of FDA's ability to carry out its regulatory responsibilities and achieve its public health mission. If, at any point in the future, we consider closing or consolidating any of our field laboratory facilities, the Agency commits to having a transparent process and working with the Committee on Energy and Commerce before any decisions on proposed closures are finalized.

Currently, FDA's Office of Regulatory Affairs (ORA) is engaging in efforts to position the laboratories to meet the current and future analytical challenges. These efforts include plans to increase both the capacity and capability of ORA laboratories, to achieve efficiencies in laboratory operations through implementation of best business practices, and to design and implement information technology solutions to aid in the determination and delivery of timely analytical results.

In addition, ORA is developing high throughput operations within several laboratories to aid in the quick screening of food products for selected pathogens, such as *Salmonella*. In fiscal year 2009, ORA will hire over 70 new analysts for the 13 laboratories to replace staffing losses in the past few fiscal years. These efforts will position the laboratories to better respond to challenges and to continue their important work.

Thank you again for your continued interest in this matter. If we can be of further assistance, please let us know.

Sincerely,

Margaret A. Hamburg

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

AMERICAN FROZEN FOOD INSTITUTE

Testimony of Kraig R. Naasz
President & CEO
American Frozen Food Institute

Before the Subcommittee on Health
Of the House Committee on Energy and Commerce

June 3, 2009

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

AFFI is committed to being a leader in food safety, which is our highest priority. Since 2004, we have led a coalition with more than 60 food-industry trade associations and food companies to advocate for modernization of the Current Good Manufacturing Practice regulations (CGMPs). CGMPs were promulgated by the Food and Drug Administration (FDA), and were last updated in 1986. These regulations form the foundation for food safety assurance programs in manufacturing facilities. A number of recent recalls appear to have been caused by failures to follow basic CGMPs. AFFI continues to encourage FDA to complete the much needed task of

2000 Corporate Ridge | Suite 1000 | McLean, Virginia 22102 | 703.821.0770 (p) | 703.821.1350 (f) | info@affi.com | www.affi.com

reviewing and modernizing CGMPs in order to strengthen the building blocks of safe food production.

AFFI also leads several other industry-wide food safety initiatives, including the Microwave Working Group, through which we have developed recommended cooking instructions, guidance and a consumer friendly microwave cooking website. We are currently working with the Partnership for Food Safety Education, FDA and the Food Safety and Inspection Service of the Department of Agriculture to develop consumer friendly safe microwave cooking information. In addition, AFFI leads the Alliance for Listeriosis Prevention, an industry coalition working toward the reduction of Listeriosis through education and appropriate regulation.

AFFI is supportive of the general direction of Chairman Waxman's draft food safety legislation, the Food Safety Enhancement Act of 2009. We want food to be as safe as possible and thereby engender high levels of consumer confidence in food products. We are particularly supportive of the following provisions of the draft legislation:

- All food companies should be required to develop and implement written food safety plans and preventive controls, based on a hazard analysis of their own products and facilities.

- As part of the food safety plan, all food companies should be required to monitor the compliance of their suppliers with food safety standards.

- FDA should be provided clear authority to regulate fresh produce and be required to establish science-based standards for the safe production of fresh produce.

- FDA's oversight over imported food needs to be strengthened.

- FDA should have stronger enforcement authorities prescribed by statute, provided that such authorities are not overly broad or vague and incorporate basic elements of due process.

While we are in agreement with the general direction of this draft legislation, there are several provisions that AFFI believes need to be modified as follows.

First, we believe the draft legislative provisions on preventive controls and food safety plans, which properly place a high emphasis on prevention as a major cornerstone of food safety, require some important "fine tuning." FDA's authority over the contents of food safety plans should be exercised in the form of broad agency guidance. It is not appropriate for FDA to require that manufacturers make changes to their company-specific food safety plans. Additionally, key terms such as "validation" need to be characterized in a way that is scientifically accurate and reflects current usage within the food industry. We also suggest that FDA be required to consider existing international standards when developing regulations involving preventive controls, and to urge the agency to make its regulations as consistent with international standards as possible. Finally, FDA should have the authority to exempt warehouses and certain other facilities from the same extensive requirements that justifiably apply to manufacturers. For example, frozen food warehouses receive and ship all foods in a frozen state. There is no opportunity for a food safety hazard to develop even if refrigeration is temporarily lost as the products are already packaged and frozen warehouses are built to maintain product for several days without an operating refrigeration system. This would be consistent with the recognition in the draft bill that warehouses should not be inspected as frequently as other facilities.

Second, we are deeply concerned with the draft legislation's traceability requirements, and we believe that these provisions need significant revision. Although the goals behind these provisions are laudable, as written the traceability requirements are simply impracticable and could not be implemented by industry. The food supply chain is extremely complex, and there are no current technologies in existence that would enable manufacturers to fulfill the requirements called for

by the draft bill. We suggest that the legislation make information gathering activities the centerpiece of the traceability provision and a clear prerequisite to any governmental rulemaking. Such information gathering is absolutely necessary to determine what traceability actions are feasible, practicable and useful. We also suggest that the international standard under GS1, which would create a common coding system, should be acknowledged and facilitated by the legislation. We live in a global economy, and U.S. systems will thrive if they reflect what is going on in the world around us.

Importantly, there are several different types of complexities involving traceability that must be considered. For example, the draft legislation does not recognize that companies intentionally blend ingredients from different sources to produce the correct consistency needed for manufacturing products. Such processes would make it virtually impossible to implement the draft legislation's traceability requirements. Accordingly, we believe that the word "pedigree" in the draft legislation should be eliminated and the bill revised to contain a more achievable goal. Clearer language should also be used to ensure that the proposed legislation refers to the major points of transformation in processing, and not every intermediate point of transport. Similarly, the word "interoperable" with regard to computer systems should be deleted as a mandate. Because such technology does not exist in any sector, whether governmental or private, the vision of computer systems that "talk to each other" should be a goal and not a requirement. Finally, the draft legislation does not establish reasonable start and finish points for production with regard to the traceability requirements, resulting in a lack of cost-effectiveness. As such, the draft bill does not recognize direct-store delivery limitations. It would be insurmountable for a manufacturer to know exactly which lots are delivered to each of the vast array of retail units serviced from a central distribution point. To be clear, we favor improvements in traceability, but to see these improvements become reality, we need the statute to foster innovation for those improvements to be made, with achievable mandates and a clear process for getting there.

Third, we strongly disagree with the country of origin labeling requirements in the draft bill because they do not help further the goal of food safety. The purpose of food safety legislation is to ensure that food is safe, regardless of its source. Rather than arbitrarily distinguishing between foods based on their source and imposing significant new costs on manufacturers, the provisions in this draft legislation should operate to ensure that food is safe. Those provisions that do not further this objective should be deleted.

Fourth, we recognize the need for FDA to have stronger enforcement powers. We support mandatory recall where: (a) the company is first given the choice to issue a voluntary recall and refuses to do so; (b) the recall is tied to a serious food safety risk; (c) the company is given reasonable due process rights, even if on an expedited basis; and (d) such authority can only be exercised by a senior agency official. Unfortunately, the draft legislation fails to accomplish all but the first of these goals. We would be glad to work with the committee to recast this and other enforcement provisions in an effective way. In particular, we call into question the new authority for FDA to quarantine food from an entire region as being overly broad and lacking sufficient safeguards and focus. Given the very substantial economic consequences associated with invoking such a provision, we believe that much more clarity and focus needs to be incorporated.

Finally, we wish to comment on the user fees provisions as outlined in the draft bill. We understand that FDA needs more funds, and we have strongly supported increases in FDA's appropriated funding. We are glad to see that the FDA's appropriated budget is finally moving in the right direction. We applaud the President's proposed FY 2010 budget, which would add more than $100 million in appropriated funds to FDA's food safety program. As drafted, the bill contains a spectrum of new fees. At one end are user fees we could support—situations where industry receives a direct benefit from the funds, as with export certificates. In contrast, at the other end of the spectrum, we believe that industry fees should not be used to pay for inspections or enforcement activities because these tasks are inherently governmental functions. In the middle are fees that would reimburse FDA for additional time spent reinspecting a particular food facility or monitoring

the effectiveness of a specific product recall, fees that are specifically targeted and which are calibrated to the level of effort expended by the FDA. This is clearly an important subject and one on which we would welcome further discussion with the Committee.

Thank you for this opportunity to testify. AFFI looks forward to working with the Committee to shape the future of food safety and to ensure the well-being of American consumers.

Questions for the Record

Subcommittee on Health, Energy and Commerce Committee
"Food Safety Enhancement Act of 2009 Discussion Draft"
June 3, 2009

Chairman Pallone

1. When you said a recall should only be for serious adverse health effects, did you mean for both non-emergency and emergency recalls or for just emergency recalls?

Answer: The Food and Drug Administration (FDA or the Agency) believes the emergency recall authority, in which the Agency may order a recall before offering an informal hearing, should be reserved for instances involving the threat of serious adverse health consequences or death, as in the draft.

2. Could you give us your views on the provision to cease distribution, section 420(c)?

Answer: This provision permits the Agency, without a hearing, to issue an order to require a person to cease distribution of a food under the jurisdiction of FDA that may cause adverse health consequences or death and notify people to whom the food was distributed. The Agency may then, after a hearing, order a recall of the food.

Questions for the Record

Subcommittee on Health, Energy and Commerce Committee
"Food Safety Enhancement Act of 2009 Discussion Draft"
June 3, 2009

Representative Joe Barton

1. You mentioned in your testimony section 101 that requires facilities to register annually with the FDA. How much would it cost the FDA to process an individual registration?

Answer: The cost to the Food and Drug Administration (FDA or the Agency) of processing these registrations would be approximately $28 per registration in the first year of operation. This includes the one-time costs of information technology development (both hardware and software), plus the ongoing costs of maintaining the system and providing user assistance. The ongoing cost in year two and thereafter is estimated to be about $19 per registration. These cost estimates reflect solely the cost of processing registrations but do not include other costs related to registration, for example, food safety activities aimed at ensuring registered facilities are complying with requirements of the FDCA.

2. Under the U.S. Customs regulations, section 134 of Title 19 of the Code of Federal Regulations requires imported products bear a country of origin marking. Under the regulation "Country of origin" means the country of manufacture, production, or growth of any article of foreign origin entering the United States. Does this regulation apply to food?

Answer: Congress assigned responsibility for enforcing mandatory Country of Origin Labeling (COOL) requirements to USDA's Agricultural Marketing Service (AMS), not FDA. Section 304 of the Tariff Act of 1930, as amended, which is enforced by Customs and Border Protection, generally requires imported articles to be marked to indicate country of origin to the ultimate purchaser. Foods in their natural state, however, such as fresh produce, are not required to be marked individually when imported. Containers holding the produce must be marked to indicate country of origin.

The 2002 and 2008 Farm Bills amended the Agricultural Marketing Act of 1946 to require retailers to notify their customers of the country of origin of muscle cut and ground meats including beef, veal, lamb, pork, chicken, and goat meat; wild and farm-raised fish and shellfish; perishable agricultural commodities (fresh and frozen fruits and vegetables); peanut, pecans, and macadamia nuts; and ginseng. On October 5, 2004, AMS published an interim final rule for fish and shellfish that went into effect on April 5, 2005. Legislation delayed the implementation of mandatory COOL for all covered commodities except fish and shellfish until September 30, 2008. On August 1, 2008, AMS published an interim final rule for all remaining covered commodities. On January 15, 2009 AMS published a final rule for all covered commodities combined, which became effective on March 16, 2009.

3. Section 141 of this draft bill requires the Secretary of Health and Human Services to list carbon monoxide as a color additive if it is used with meat or seafood. I would note that this is the only provision in this entire bill that directs the Secretary to list anything as a color additive.

   a. Is modified atmosphere packaging new?
   b. Are there other technologies besides Carbon Monoxide that is designed to preserve the color of packaged meat?
   c. Why is modified atmosphere packaging used for fresh meat? Before now, has the agency ever ruled on the safety of using carbon monoxide in modified atmosphere packaging?

Answer: Various types of modified atmosphere packaging (MAP) technology have been used in food and drug processing and packaging since the 1970s. The primary goals of the technology are to reduce bacterial contamination and to extend the shelf life of products. The typical gases used in MAP applications are nitrogen, carbon dioxide, and oxygen in varying ratios to achieve the desired results. Argon, an inert gas, is sometimes used in specialized cases. MAP systems, with and without carbon monoxide (CO), allow meat distributors flexibility in packaging and displaying retail cuts of meat. Additionally, MAP systems have been shown to increase the shelf life, and to enhance the appearance and maintain the color and flavor of packaged fresh meat.

Since 2001, FDA has considered and reviewed the safety of the use of CO gas in meat packaging systems in response to five GRAS notifications that were submitted to the Agency. These notices provided evidence supporting the notifiers' determinations that the use of CO in MAP systems for fresh meat is safe. In its evaluation of these notices, the Agency thoroughly reviewed the use and safety of carbon monoxide in fresh meat packaging, and found that the information submitted supported the safety of CO under the proposed conditions of use. FDA concluded that the use of CO, as described in the GRAS notices, is not a color additive because it does not impart color, but rather fixes the natural red color of myoglobin, the color that consumers associate with meat products.

In addition, a food additive regulation was issued for a combustion gas product (produced by controlled combustion in air of butane, propane, or natural gas) for use in the processing and packaging of certain foods under 21 CFR 173.350. This regulation permits the use of up to 4.5 percent by volume of carbon monoxide in the finished product. This additive is approved for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food. This regulation does not include use in fresh meat.

4. Under the draft legislation that was circulated last week, there was a change to a prior section dealing with the registration of and fee collection from commercial importers. In the current draft, can you tell me what entities would pay this new fee? Why should drug and device manufacturers who already pay an annual establishment registration fee to the FDA, have to pay an additional duplicative fee?

Answer: The user fee for importers in the discussion draft as of June 3 is to pay for a distinct set of activities -- the costs of registering importers, custom brokers, and filers and ensuring compliance with good importer practices (see section 742(c)(4)(A)(ii) on pages 95-96 of the draft). The fees are not duplicative of current fees for drug and device manufacturers. These annual establishment registration fees are part of the Medical Device User Fee program and the Prescription Drug User Fee program authorized in the Federal Food, Drug, and Cosmetic Act (FFDCA). Fees under those programs are used solely to pay for costs of resources allocated for the review of drug and device applications.

5. In advocating for Section 201, your testimony states, "At present, importers and brokers are not required to register with the FDA." Do you think we should clarify that this provision is intended only to affect entities that are currently not registered and currently do not pay fees?

Answer: The importer fee in the discussion draft will be used to pay the costs of registering importers, custom brokers, and filers and ensuring compliance with good importer practices. These activities are new for FDA, as importers, custom brokers, and filers are not currently required to register with the Agency, nor are importers currently required to comply with Good Importer Practices (GIPs).

6. Alleged violations of whistleblower protections would be investigated by the Secretary of Labor, specifically the Occupational Safety and Health Administration (OSHA). Are you concerned or comfortable with OSHA's ability to investigate alleged violations of the Food Drug and Cosmetic Act?

Answer: In general, section 208 of the discussion draft as of June 3 prohibits certain actions against employees in retaliation for providing information or otherwise assisting in investigations regarding conduct the employee reasonably believes constitutes a violation of the FDCA or certain other federal laws. An employee who alleges such retaliation can seek relief by filing a complaint with the Department of Labor. The Department of Labor would thus not be investigating violations of the FDCA per se, but would be making determinations regarding whether an employee had a reasonable belief that conduct was violative.

7. Please explain the FDA's Office of Food Additive Safety's role in the ongoing BPA review and assessment and when will the review be finished?

Answer: Currently, the Office of Food Additive Safety is supporting FDA's BPA Task Force and other FDA scientists in considering revisions to the Agency's draft assessment on the safety of BPA uses in food contact materials by:

- Re-examining exposure to BPA from infant-related food contact materials using newly gathered data;
- Revising the draft assessment of food contact uses of BPA to take into consideration comments made by the FDA Science Board BPA Subcommittee with regard to newly published data and existing data sets;

- Exploring the conduct of biomonitoring and epidemiology studies in collaboration with other HHS Agencies;
- Providing input on the design and conduct of a pharmacokinetic study and assisting in drafting protocols on subchronic, and neurodevelopmental studies to be conducted at the National Center for Toxicological Research (NCTR) and with continued collaboration with NTP scientists.

At the FDA Science Board meeting in February 2009, the Agency presented its plans to revise the draft safety assessment based on interpretation and use of existing data. Since taking office, Commissioner Hamburg has asked FDA's Acting Chief Scientist, Dr. Jesse Goodman, to work with FDA scientists to take a fresh look at the science on BPA. The Agency plans to report on the findings of this review as soon as possible.

8. Will the review take into consideration assessments prepared by food safety agencies in other countries?

Answer: Throughout FDA's ongoing review of BPA and products that contain the compound, the Agency has communicated regularly and shared information with our regulatory counterparts in Canada, Europe and Japan. FDA is aware of multiple safety assessments on BPA performed in recent years, including those conducted by the European Chemicals Bureau, the European Food Safety Authority's (EFSA) Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food, and the Japanese National Institute of Advanced Industrial Science and Technology. FDA considers the findings of all such analyses seriously and we will continue to monitor new data as it becomes available, acting on them as appropriate.

9. Under section 415 of Food Drug and Cosmetic Act, food facilities are required to register with FDA. Please explain how this requirement applies to trucks.

Answer: Section 415 only applies to facilities that manufacture, process, pack or hold food. Mobile facilities, including trucks, which perform manufacturing or processing activities would be required to register. However, trucks that simply hold food in the normal course of transporting it from one location to another without modifying or manipulating the food do not have to register. FDA has provided information regarding the requirements in our existing registration rule at 21 CFR Part 1, Subpart H, as they pertain to trucks in our Guidance for Industry: Questions and Answers Regarding Registration of Food Facilities (Edition 4); Final Guidance. The two questions and answers below are from those included in the guidance, and they help illustrate which truck operations are subject to the registration requirement and which are not.

> **Question 2.12:** As vegetables are harvested on some farms, after field trimming and washing, the harvested product is transferred to a truck mounted operation in the field where it is placed in a consumer package and cooled. The mobile unit is not permanently located at the farm, but moves from farm to farm for the same operation. The packaged product is then transferred to a truck for movement off-farm. Does the farm or truck mounted packaging/processing unit, or both, need to be registered with FDA?

Answer: Neither the truck nor the farm is required to be registered. A mobile facility located on a farm conducting an operation that results in the packaging of the food must be registered. As noted in the answer to question 2.10, "packaging" is an example of "manufacturing/processing," which is defined in § 1.227(b)(8) as involving some modification or manipulation of the food, and simply placing produce into containers (such as clamshells, baskets, mesh bags, or plastic bags) without altering or manipulating food is more akin to packing, even if the containers are ultimately received by the consumer. A truck mounted operation that does not include modifying or manipulating the food is not manufacturing/processing within the meaning of § 1.227(b)(6) and thus, the truck is not required to be registered.

Question 2.13: Is a truck-mounted operation under separate ownership from the farm required to register if it cuts produce grown on the farm (e.g., chops carrots) before placing them into consumer-ready bags and transporting them off the farm? If the truck is required to register, what address should it use?

Answer: The truck is required to register in this example, as it is performing a manufacturing/processing activity and does not meet the definition of a farm. In this example, the farm does not need to be registered, even if the truck is engaged in manufacturing/processing, because the truck and the farm are separately owned and thus, are not the same establishment. The truck in this scenario is a mobile facility. Generally, the owner, operator, or agent in charge of a mobile facility has a fixed address. FDA recommends that that fixed address be provided in the truck's food facility registration. Addresses of mobile facilities are addressed further in the preamble to the Interim Final Rule.

Questions for the Record

Subcommittee on Health, Energy and Commerce Committee
"Food Safety Enhancement Act of 2009 Discussion Draft"
June 3, 2009

Congresswoman Tammy Baldwin

1. The draft legislation we are considering creates a risk-based inspection system for food facilities. The bill authorizes the Secretary of HHS to recognize state agencies as meeting standards established for conducting inspections. Could you please discuss how and when you would defer to state food safety inspections as sufficient evidence of food safety, and how you would help to support those efforts with funding? Please feel free to discuss the current relationship FDA has with states as well.

Answer: The Food and Drug Administration (FDA or the Agency) has over three decades of experience of leveraging resources with our state regulatory partners under the state contract program, as well as our regulatory partners at USDA, which has jurisdiction over the production of meat, poultry, and processed egg products. We currently contract with the vast majority of states to conduct over 15,000 food and feed contract inspections per year on our behalf. FDA also collaborates with states under a variety of grants and cooperative agreements ranging from rapid response teams, BSE and the Food Emergency Response Network, to innovative food defense grants.

FDA's goal is to implement a risk-based food safety program by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. To help achieve this goal, FDA has jointly developed and shared with the states the Manufactured Food Regulatory Program Standards (MFRPS), which establishes 10 standards that describe the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. Currently, 25 states have elected to participate in implementing this program. When fully implemented and audited, we believe meeting these standards will provide the foundation for strong regulatory programs in which all stakeholders may have confidence. FDA is supporting the efforts of the states to implement the MFRPS as part of the state contract program.

2. As the FDA has acknowledged, third party laboratories can serve as a critical supplement to the oversight and inspection responsibilities, especially with imported foods. Unfortunately, I am concerned that the language as currently drafted will not allow companies to provide inspection support to the FDA and separate services to their food company customers. Could you please clarify whether contract research organizations that provide testing services to food manufacturers will also be able to work on behalf of the FDA? Is there any other way that we could ensure that the best private labs available are able to support the FDA and to test the food produced by private manufacturers?

Answer: Section 110 of the draft "Food Safety Enhancement Act of 2009" addresses Testing by Accredited Laboratories. We are supportive of the provisions in the bill that recognize that private laboratories should be accredited to perform analytical testing by appropriate accreditation bodies. Under this provision, in certain circumstances when a food company is conducting analytical testing, such testing must be done by an accredited laboratory that is independent of the food company, among other requirements. These requirements would apply whenever an importer conducts analytical testing of imported food that has been detained (i.e., as part of testimony for the purposes of section 801(a) of the Federal Food, Drug and Cosmetic Act (FFDCA)), or for other purposes as the Secretary deems appropriate.

An example may help illustrate how FDA believes the provision would operate. If a food processor is importing an ingredient and wishes to have samples tested to support testimony it will provide to FDA to support admission under section 801(a) of the FFDCA, under section 110 of the bill the testing must be done by a laboratory that is independent of the food processor. If a laboratory is a subsidiary of the food processor, FDA may well conclude that this laboratory is not independent of the food processor for these purposes and, therefore, the food processor would not be able to contract with this laboratory to conduct the testing to support its testimony. If, however, the laboratory is a third party, not directly owned by the processor, the laboratory would be considered to be independent of the food processor for the purposes of providing analytical testing as part of testimony under 801(a) of the FFDCA.

3. What does the FDA currently do to ensure that labs are using the most advanced technology? How does the FDA consult with the advanced technology field to keep their inspection efforts on the cutting edge? Do you think the FDA needs new legal authority to establish common laboratory methods using this advanced technology?

Answer: FDA takes advances in analytical testing technologies into account in its regulatory activities. For example, when a firm submits evidence from a third-party laboratory to the Agency as evidence of compliance (e.g., that seafood is not contaminated with a particular chemotherapeutic), FDA evaluates the submission to determine its credibility. FDA considers, among other aspects, whether the laboratory used an acceptable methodology. The acceptability of a methodology, in turn, depends on its accuracy, sensitivity, and other factors. Thus, with advances in technology, a methodology that was once acceptable for a particular type of analytical testing may no longer be acceptable and new methods may become acceptable. FDA provides updated information on its Web site about acceptable methodologies. The draft legislation would bolster FDA's authority in this area by requiring, in appropriate situations, that analytical testing be conducted by laboratories that are independent and are accredited by a recognized accreditation body, including being accredited for the analytical method used.

For the FDA testing laboratories, ORA is actively assessing commercially available technologies to use in its regulatory science efforts and programs that support the Agency's public health and enforcement programs. The assessment of a commercial method includes a critical examination about the acceptability of the method for FDA-regulated products. To support public health decision-making and enforcement programs, FDA considers whether the method consistently yields valid results for the commodity of interest and for the adulterant of interest. One current example of FDA's assessment of advanced technology is outlined in ORA's Science Strategic

Plan and involves the Analytical Tool Initiative (ATI). ATI is managed by a team of FDA field laboratory scientists of various scientific disciplines to review and recommend portable technologies for use in a field setting (e.g., while examining imported food at a border crossing).

As part of this Initiative, FDA has met with representatives from industry to review and learn more about cutting-edge technologies. The available technologies are being assessed to determine if they are fully developed and readily applicable to FDA programs, or whether they require additional development, customization, or refinement by ORA before they can be relied upon for decision-making.

4. Section 141 of this draft bill requires the Secretary of Health and Human Services to list carbon monoxide as a color additive if it is used with meat or seafood. As you know, carbon monoxide has been used in Modified Atmospheric Packaging (MAP) for a number of years. Is it common for Congress to direct the agency to list color or food additives? Is MAP new? Why is MAP used for fresh meat? Before now, has the agency ever ruled on the safety of using carbon monoxide in MAP?

Answer: We are aware of no recent examples in which Congress directed the Agency to list any specific color or food additive. Various types of MAP technology have been used in food and drug processing and packaging since the 1970s. The primary goals of the technology have been to reduce bacterial contamination and to extend the shelf life of products. The typical gases used in MAP applications are nitrogen, carbon dioxide, and oxygen in varying ratios to achieve the desired results. Argon, an inert gas, is sometimes used in specialized cases. MAP systems, with and without carbon monoxide (CO), allow meat distributors flexibility in packaging and displaying retail cuts of meat. Additionally, MAP systems have been shown to increase the shelf life, and to enhance the appearance and retain the color and flavor of packaged fresh meat.

Since 2001, FDA has considered and reviewed the safety of the use of CO gas in meat packaging systems in response to five GRAS notifications that were submitted to the Agency. These notices provided evidence supporting the notifiers' determinations that the use of CO in MAP systems for fresh meat is safe. In its evaluation of these notices, the Agency thoroughly reviewed the use and safety of carbon monoxide in fresh meat packaging, and found that the information submitted supported the safety of CO under the proposed conditions of use.

In addition, a food additive regulation was issued for combustion gas product (produced by controlled combustion in air of butane, propane, or natural gas) for use in the processing and packaging of certain foods under 21 CFR 173.350. This regulation permits the use of up to 4.5 percent by volume of carbon monoxide in the finished product. This additive is approved for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food. This regulation does not include use in fresh meat.

Questions for the Record

Subcommittee on Health, Energy and Commerce Committee
"Food Safety Enhancement Act of 2009 Discussion Draft"
June 3, 2009

Rep. Joseph R. Pitts

1. I am concerned with a provision in the "Food Safety Enhancement Act" which would introduce a new fee for importers of food, drugs, and devices. Should device manufacturers who already pay an annual establishment registration fee to the FDA, have to pay an additional duplicative fee?

Answer: The fees are not duplicative. The annual establishment registration fee to which you refer is part of the Medical Device User Fee program found in sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Fees under that program are used solely to pay for costs of resources allocated for the process for the review of device applications, as defined in section 737(5) and (6) and specified in section 738(h)(2)(A)(ii). By contrast, the user fee for importers in the Food Safety Enhancement Act is to pay for a distinct set of activities, the costs of registering importers, custom brokers, and filers and ensuring compliance with good importer practices (see section 742(c)(4)(A)(ii) on pages 95-96 of the draft).

2. The new fee which will be duplicative for device manufacturers also does not contain direction to the FDA on how it will be calculated. There is also no direction that the fees taken from specific sectors, such as food, prescription drugs, and medical devices will then be used for inspection and registration activities of the FDA for those specific areas. For instance, fees that manufacturers of medical devices pay for registration, could then be used by the FDA to inspect food-related facilities. I am concerned that with the new mandates on the FDA to inspect food facilities, which far outnumber drug and device manufacturer facilities globally, that this new fee provision is simply a way to take money from one industry in order to police another. How can we ensure that FDA has the appropriate direction and parameters to ensure they are fairly assessing fees and using those fees appropriately?

Answer: The importer fee in the discussion draft will be used to pay the costs of registering importers, custom brokers, and filers and ensuring compliance with good importer practices. These activities are new for the Food and Drug Administration (FDA or the Agency), as importers, custom brokers, and filers are not currently required to register with FDA, nor are importers currently required to comply with Good Importer Practices (GIPs).

With respect to directing the Agency how to set the fee, this description defines the activities for which FDA may use the funds, and so defines the sum total that may be generated from this fee. Using this sum total and the number of registered entities will allow the Agency to calculate the fee per registered entity.

The revenues generated from this fee may be used only for registering these entities and looking at their compliance with GIPs -- they may not be used to inspect food, device, or drug manufacturing facilities. The Agency does not anticipate that the costs of registering importers and ensuring compliance with GIPs will differ from importers of food to importers of devices to importers of drugs.

3. Currently manufacturers of medical products are subject to the Quality System Regulation (QSR) established by the FDA. The FDA is also currently in the process of establishing Good Importer Practice (GIP) guidelines, which incorporate requirements similar to those delineated in the QSR that device manufacturers are already required to comply with in order to commercially distribute devices in the US. However, it is important to note that the GIP guideline is still in draft form and considered to lack clarity needed to ensure appropriate compliance. If we are enacting a provision for importers that would include a duplicative fee for manufacturers, who are already also subject to the Quality System Regulation (QSR), how can it be ensured that there is enough clarity so that manufacturers would not be at risk for losing their registration due to vague, draft guidelines?

Answer: As noted, the GIPs guidance document is still considered draft and is written in collaboration with several other federal agencies. The comment period closed on April 12, 2009, and the Agency will review all comments that have been submitted and make any appropriate changes. Guideline documents like the GIP do not establish legally enforceable rights or responsibilities, but are issued to help communicate FDA's current thinking and help industry comply with applicable regulations and in this case, to help assure imported medical devices are in compliance with applicable U.S. statutes and regulations, including the Quality System Regulation (QSR).

FDA recognizes that importers are uniquely positioned to ensure the safety of the products they import and to prevent risk from being passed on to U.S. consumers. The Agency also recognizes that our regulated products can be widely divergent and that the size and scope of resources of the importing firm can vary significantly. As such, there is no one-size-fits-all approach to meeting the standards set forth in the guidance document.

If a device manufacturer is also registered as an importer under the bill, it will be their responsibility to design and implement a program that will ensure the products that they are importing meet applicable FDA requirements. If the bill were enacted, the Agency would consider whether the GIP guidance document, when finalized, would present an appropriate mechanism for doing so.

4. As you know, imported honey currently accounts for nearly 70% of the U.S. honey supply, much of which is produced in and imported from China. Imported honey is an ingredient in a wide array of food products, including bread, cereal, snack foods, meats and beverages. It is therefore imperative that our Customs and Border Protection Agents are given every tool possible to ensure the purity and safety of imported honey and to safeguard American consumers against those who seek to circumvent our trade and food safety laws.

Three years ago, the honey industry submitted a citizens' petition asking FDA to issue a national standard of identity for honey. On June 13, 2007, 15 Senators wrote to then FDA Commissioner von Eschenbach on this same topic. In that letter, the Senators emphasized the importance of standard of identity and requested an update on the status of FDA's review of the proposed honey standard. Since 2007, we understand that the FDA has taken no further steps toward promulgating a final rule.

As stated in the 2007 letter, there have been for some time reports of adulterated Chinese food products entering the U.S. food supply. Additional and distinct incidents have been reported since 2007, further raising the importance of this issue. With respect to honey, we understand that Chinese importers have been mislabeling pure honey as "honey blends", thereby avoiding applicable antidumping duties. In other instances, we understand that "honey blends" have been falsely labeled and marketed as pure honey after entering the U.S. market. In 2008 alone, these schemes cost the U.S. Government nearly $100 million in lost duties.

Successful circumvention schemes raise serious concerns about the safety of imported honey and the ability of the U.S. Government to sufficiently protect U.S. consumers. While the FDA is not responsible for enforcing trade law, the Agency is responsible for ensuring food safety. A national standard of identity for honey is a first and critical step in the right direction. Such a standard would provide Customs and Border Protection Agents with a tool to ensure the purity of imported honey, the existence of potentially hazardous additives, and the country of origin of the honey. In addition to safeguarding the food supply, this tool would allow agents to take appropriate enforcement actions against those who seek to exploit loopholes in our food safety system.

What is the status of your review of the pending standard of identity for honey? Is there a reason why a rule cannot be promulgated within three months? If a standard of identity cannot be issued within three months, can you give me a firm commitment as to when it can be issued?

Answer: FDA intends to respond to the citizen petition this year.

Section 401 of the FFDCA (21 USC 341) provides that "[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing . . . a reasonable definition and standard of identity. . . ." A standard of identity describes the basic nature and essential characteristics of a food.

FDA acknowledges that the petition regarding honey has been pending for a significant time period in light of other Agency priorities. FDA notes that, were the Agency to initiate a rulemaking to issue a standard of identity for honey, it would take longer than three months in light of the actions necessary to conduct such a rulemaking. The development of a proposed standard of identity, preparation, and publication of a proposed standard in the Federal Register (including any analyses required by statutes, such as the Regulatory Flexibility Act and Small

Business Regulatory Enforcement and Fairness Act), provision of a period for public comment, receipt and analysis of the comments, and preparation and publication of a final standard of identity and response to comments in the Federal Register could not be accomplished in three months, even with the diversion of resources from public health priorities in the Food Program.

It is worth noting that, even in the absence of a food standard, FDA has several tools available to protect consumers of honey. For example, food that is adulterated or misbranded may not be distributed in interstate commerce and is subject to seizure. Honey may be adulterated or misbranded under a number of circumstances, a few of which are described below.

If honey contains an added deleterious substance which may render it injurious to health, the honey would be adulterated under section 402(a)(1) of the FFDCA (21 USC 342(a)(1)). Further, if a substance has been added or mixed so as to make the honey appear to be better or of greater value than it is, the honey would be adulterated under section 402(b)(4) of the FFDCA (21 USC 342(b)(4)).

If honey is not truthfully labeled, the honey is misbranded under section 403(a)(1) of the FFDCA (21 USC 343(a)(1)), which prohibits false or misleading labeling. In addition, section 403(i)(2) of the FFDCA (21 USC 343(i)(2)) requires that all ingredients of a food fabricated from two or more ingredients must be declared by their common or usual names. Thus, if water or other sweeteners are added to honey, they must be declared on the food label.

Questions for the Record

Subcommittee on Health, Energy and Commerce Committee
"Food Safety Enhancement Act of 2009 Discussion Draft"
June 3, 2009

Michael C. Burgess, M.D.

1. How many inspectors does the FDA currently employ to inspect food facilities?

Answer: As background, during the last 10 years the Food and Drug Administration (FDA or the Agency) has had variable levels of food investigators. FDA experienced an increase in investigators performing work in the foods area as a result of funding increases provided by Congress in the Counter Terrorism Funding Supplemental in 2002.

The table below provides a history of food investigators (number of Full-Time Equivalents, or FTEs) for FY 2001 through FY 2009.

FY 2009 – 900 (estimated)	FY 2004 – 700
FY 2008 – 722	FY 2003 – 870
FY 2007 – 622	FY 2002 – 542
FY 2006 – 640	FY 2001 – 512
FY 2005 – 670	

It should be noted that these numbers involve investigators that will perform both foreign and domestic inspections, as well as import operations at U.S. ports of entry. The number of inspections that these staffing increases may yield will be impacted by the fact that new hires will need to be trained and to gain professional experience before they will reach the necessary level of competence to perform full and independent inspections. Typically, new employees first gain experience in the domestic arena before moving on to foreign inspections.

2. How many inspectors does the FDA need in order to comply with the new time table for inspection in this discussion draft?

Answer: FDA estimates that the Office of Regulatory Affairs (ORA) would need up to 6,600 investigator FTEs to comply with the inspection frequencies per establishment category set forth the discussion draft. We also estimate that ORA would need up to 1,880 additional FTEs to support the 6,600 investigator FTEs. These support FTEs include supervisors, compliance officers and administrative personnel, which are critical to achieving maximum public health impact from our inspections. For example, these employees assure appropriate review of inspections, make sure all necessary regulatory follow up is conducted, arrange logistics of travel and needed equipment, provide scientific and technical expertise, and develop regulatory policy.

These estimates do not include, however, the FTEs that would be needed to accomplish the following additional tasks associated with the inspections process:

- additional sampling and analytical laboratory work generated by the increased inspection outputs;
- additional resources needed for reinspection of establishments found to be out of compliance with regulations;
- personnel outside of ORA needed to support the inspection process, such as product center reviewers and compliance officers, policy and legal advisors, etc.

Finally, we note that these estimates are subject to additional uncertainty because of imprecise estimates on the number of food facilities that would be subject to inspection under the draft bill. Under current law, food facilities are required to register with FDA only once and provide only a limited set of information. Facilities may voluntarily include the type of activity conducted at the facility, but not all facilities have provided that information in their registrations. They are also not required to inform FDA of a change in their activities -- even a cessation of activities. Based on the best available information we now have and the total number of facilities registered with FDA, we estimate that there are approximately 73,000 domestic and 113,000 foreign facilities that manufacture, process, pack or hold food that would be subject to inspection each year based on the schedules set forth in the draft bill.

3. How long does it take a food inspector to inspect a food facility?

Answer: Inspection time is based on historical averages for the type of activity being inspected. For example, a small firm with limited processes of low risk products may be adequately inspected in a few hours, while a large facility with highly complex manufacturing operations of a high risk product may take hundreds of hours to complete.

In 2008, on average it took 28.8 hours for an investigator to conduct a domestic food inspection and 53.4 hours to conduct a foreign food inspection. It should be noted that foreign food inspections are frequently selected based on problematic firm histories, and may cover more complex processes. Therefore, our data indicates that such inspections take more time, on average, to complete. Also, there is additional time related to conducting a food inspection not covered by either figure, such as supervisory and compliance officer review time, time needed for administrative support, and for sample collections and analyses.

4. How much money does the FDA need to carry out its food safety responsibilities?

Answer: The amount of funding needed will depend in part on what new responsibilities are placed on the Agency in new food safety legislation, including the number of food facilities FDA must inspect annually. Under current law, food facilities are only required to register with FDA once and provide a limited set of information to the Agency, thus limiting our ability to determine the number of facilities that would be subject to FDA inspection.

Taking these considerations into account, FDA's current resource estimate to inspect 186,000 registered facilities far exceeds the resources provided in the bill, even assuming the minimum inspection schedule requirements.

5. Is the $375 million dollars – which will be generated by user fees in this bill – enough to carry out the inspection of both domestic and foreign food facilities?

Answer: The amount of resources required to achieve these inspection goals would far exceed even the historic increases in food safety funding contained in the President's FY 2010 budget. The draft legislation, including the fees, makes an important investment in the resources needed for major progress. However, the user fees would not be enough to carry out the inspection schedule in the version of the bill that was the subject of the June 3 subcommittee hearing.

6. If a company can demonstrate its laboratory testing capability meets or exceeds the criteria the agency and this committee are contemplating for third party labs, including records access, auditing and so forth (i.e. that its lab and practices meet the world gold standards we want to see met for accreditation) shouldn't these companies be allowed to conduct their own testing?

Answer: Section 110 of the draft "Food Safety Enhancement Act of 2009" addresses testing by accredited laboratories. We are supportive of the provisions that recognize that private laboratories should be accredited to perform analytical testing by appropriate accreditation bodies. Under this provision, in certain circumstances when a food company is conducting analytical testing, such testing must be done by an accredited laboratory that is independent of the food company, among other requirements. These requirements would apply whenever an importer conducts analytical testing of imported food that has been detained (i.e., as part of testimony for the purposes of section 801(a) of the Federal Food, Drug and Cosmetic Act (FFDCA)), or for other purposes as the Secretary deems appropriate.

An example may help illustrate how FDA believes the provision would operate. If a food processor is importing an ingredient and wishes to have samples tested to support testimony it will provide to FDA to support admission under section 801(a) of the FFDCA, under section 110 of the bill the testing must be done by a laboratory that is independent of the food processor. If a laboratory is a subsidiary of the food processor, FDA may well conclude that this laboratory is not independent of the food processor for these purposes and, therefore, the food processor would not be able to contract with this laboratory to conduct the testing to support its testimony. If, however, the laboratory is a third party, not directly owned by the processor, the laboratory would be considered to be independent of the food processor for the purposes of providing analytical testing as part of testimony under 801(a) of the FFDCA.

7. How many resources does it take for the FDA to prepare for a hearing before the Energy and Commerce Committee?

   a. How many staff?
   b. How much time?
   c. Approximately how much money?

Answer: It is very difficult to provide precise answers to these questions, in part because the answers vary significantly from hearing to hearing, depending upon factors such as the nature of the hearing (subject matter, full committee vs. subcommittee, etc.), the familiarity of FDA's witness or witnesses with the range of potential issues, and whether the Agency has a history of

involvement in hearings on the particular subject. However, we would like to provide information on how FDA prepares for hearings in the Committee and thereby provide a sense of the time and resources involved.

Preparation for hearings typically involves FDA's Office of Legislation, the relevant program center (in the case of food hearings, the Center for Food Safety and Applied Nutrition, or "CFSAN"), the Office of Chief Counsel, the Office of Regulatory Affairs ("ORA," which oversees the activities of FDA's field staff) and other offices such as the Office of Policy or the Office of Food Protection.

Generally, FDA witnesses at Committee hearings are high-level officials, such as a Center Director; a Deputy, Assistant, or Associate Commissioner; or the Commissioner of Food and Drugs. Often, the primary witness will be accompanied by a subject matter expert such as one of the previously noted officials or someone at the Office Director level. Therefore, the preparation for just the witness or witnesses themselves involves numerous hours of preparation for individuals at the Senior Executive Service level.

Considering the six offices or Centers identified above as primary participants in hearing preparation, it is reasonable to estimate that each of those offices (except Chief Counsel, which would involve less people) would utilize at least three professional staff at the senior executive or GS-14 or 15 level as key participants in hearing preparation, involving anywhere from three to twelve hours of work per hearing. In addition, some of these offices, including the Office of Legislation, the program Center, and ORA typically would additionally utilize between three and six professional, clerical and support staff, at GS levels 9 to 14, involving from three to six hours work each. These individuals would be involved in activities that include drafting and review of testimony, participation in briefings for the witness, preparation of briefing documents or statistical data, responding to information requests from the witness or briefers, attendance at the hearing, and drafting or reviewing post-hearing follow-up questions.

Questions for the Record

Subcommittee on Health, Energy and Commerce Committee
"Food Safety Enhancement Act of 2009 Discussion Draft"
June 3, 2009

Rep. Steve Buyer

1. As you interpret FDA's authority, do you believe FDA has the authority to destroy counterfeit, adulterated, or misbranded pharmaceuticals entering our nation's international mail facilities? If you do not believe FDA has such destruction authority, would you support legislation to grant FDA such authority? Do you support the FDA's current "return to sender" policy under which, if the FDA inspectors at the international mail facilities in our country determine a pharmaceutical package to be inadmissible, they return the package to sender?

Answer: The Food and Drug Administration (FDA or the Agency) currently has the authority to seek, through the judicial process, the destruction of any drug or other FDA-regulated product that violates the Federal Food, Drug, and Cosmetic Act (FFDCA) introduced into interstate commerce, including those imported or offered for import. In addition, FDA can request that U.S. Customs and Border Protection (CBP) seize, forfeit, and destroy imported drugs or other FDA-regulated products that violate the FFDCA, under CBP's authority under 19 USC 1595a. Streamlining the destruction process for violative products could be beneficial.

2. As you support a national track and trace system for food in our country, would you support a national track and trace standard for pharmaceuticals in our country? Additionally, you note that a "one up, one back" approach to tracking food is insufficient for the FDA. Would a "one up, one back" approach also be insufficient for tracking pharmaceuticals in the U.S.?

Answer: We support a national track-and-trace system for pharmaceuticals in the United States. The Food and Drug Administration Amendments Act of 2007 granted FDA the authority to develop standards for identification, validation, authentication, and track and trace as a start in this direction. As noted in several reports from FDA's Counterfeit Drug Task Force, we believe that a universal electronic pedigree that documents the movement of every prescription drug product from the manufacturer to the dispenser, would be an important step in providing transparency and accountability to further ensure supply chain security. A "one up, one back" approach would not achieve this goal.

3. Would you support one federal standard for a pharmaceutical track and trace system as opposed to 50 separate state systems?

Answer: As noted in several reports from FDA's Counterfeit Drug Task Force, we believe that a single, national, uniform standard for a drug track-and-trace system and

electronic pedigree would be ideal to help ensure efficient distribution of safe and effective drugs in the United States and eliminate confusion in the marketplace and the stifling of interstate commerce that could occur if each state had its own pedigree requirements.

4. It is my understanding that the FDA entered a Memorandum of Understanding (MOU) with the Bureau of Alcohol, Tobacco and Firearms (ATF) on November 20, 1987 regarding the regulation of alcoholic beverages. Are alcoholic beverages still regulated by the ATF (now the Tobacco Tax and Trade Bureau, TTB), per that MOU? Do you support TTB's continued regulation of alcoholic beverages? If not, please explain.

Answer: Yes, FDA supports TTB's continued regulation of alcoholic beverages as set forth under the MOU between FDA and ATF. As stated in the 1987 MOU, both agencies have authority with regard to alcoholic beverages.

Pursuant to the Federal Alcohol Administration Act (FAA Act) and the Internal Revenue Code (IRC) of 1986, TTB has authority over distilled spirits, wines, and malt beverage products, both domestic and imported. In particular, section 5 of the FAA Act vests TTB with the authority to promulgate regulations regarding the labeling and advertising of alcoholic beverages to ensure that they provide the consumer with adequate information concerning the identity and quality of such products. TTB's authorities include premarket label review. In addition, TTB is charged with the administration and enforcement of Chapter 51 of the IRC, relating to Distilled Spirits, Wines and Beer. This chapter, in conjunction with the FAA Act establishes a comprehensive system of controls of alcoholic beverages, including on site inspections and procedures that require the advance approval of statements of process and of formulas showing each ingredient to be used in the product. The IRC also vests authority in TTB to detain any container that will be removed in violation of law and vests TTB with seizure and forfeiture authority.

FDA regulates alcoholic beverages as a "food" under the FFDCA. As such, alcoholic beverages are subject to the Act and FDA's implementing regulations applicable to food. For example, manufacturers of alcoholic beverages are responsible for registering their facilities with FDA, importers of alcoholic beverages are responsible for providing prior notice to FDA, and manufacturers of alcoholic beverages must comply with FDA's current Good Manufacturing Practice (cGMP) regulations for foods.

As provided for under the MOU, TTB is responsible for the labeling of distilled spirits, wines, and malt beverages pursuant to the FAA Act. However, certain alcoholic beverages are not subject to the labeling provisions of the FAA Act and thus, are subject to FDA's labeling requirements. These alcoholic beverages include (1) wine beverages containing less than seven percent alcohol by volume, such as wine coolers, and (2) beers that are not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice or wheat) or without hops.

FDA also has authority to take action with respect to adulterated food products, including adulterated alcoholic beverages. The MOU notes that FDA has this authority, and also recognizes that TTB has a system of specific statutory and regulatory controls over alcoholic beverages. The MOU provides that TTB has primary responsibility for issuing recall notices and monitoring voluntary recalls of alcoholic beverages that are adulterated under FDA law or mislabeled under the FAA Act by reason of being adulterated. The MOU specifies that, when TTB learns or is advised that an alcoholic beverage is or may be adulterated, TTB will consult with FDA before it takes any action with respect to a notice of recall for the product, and FDA, in turn, will expeditiously provide TTB with a written health hazard evaluation (HHE) of each product involved in a recall situation or potential recall situation.

5. Are you aware of any reasons which would justify taking away TTB's regulation of alcoholic beverages and giving that regulation to the FDA? If so, please explain why these regulations should no longer be carried out by the TTB.

Answer: We believe there is no reason the draft legislation should alter the current regulatory framework, nor do we believe that the legislation does alter the current framework for alcohol regulation.

6. Does the FDA currently have any involvement in the health safety regulations of alcoholic beverages, including beer, wine, and distilled spirits?

Answer: Yes, if FDA determines that the presence of an ingredient in food products, including alcoholic beverages, poses a recognized public health problem, and that the ingredient or substance must be identified on a food product label, the MOU provides that TTB will be responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wine, and malt beverages pursuant to the FAA Act. For example, TTB requires ingredient labeling for FD&C Yellow No. 5, saccharin, and sulfites.

In addition, FDA, at the request of TTB, will provide TTB with an HHE for any contaminant substance found in an alcoholic beverage that may cause the beverage to be adulterated under the FFDCA. The HHE may be used by TTB in support of an enforcement action it may take under its legal authority, or in advising the responsible firm that a voluntary recall is an appropriate course of action.

7. Is the FDA aware of any recalls conducted for adulterated alcoholic beverages for public health and safety reasons in the last 25 years?

Answer: Based on the available FDA historical recall data dating back to 1990, FDA has classified two recalls associated with alcoholic beverages. The first involved a wine that contained excessive lead. The second involved an imported wine that contained the pesticide procimidone.

8. Is the FDA aware of any recalls that have been carried out by food processors and food manufacturers located in the State of Indiana in the last ten years? Has the FDA inspected food manufacturing, processing, and warehousing facilities in Indiana in the past 10 years? If so, how many such inspections occurred, and were there any violations found? If there were such violations, what were they? Were fines ever assessed because of such violations?

Answer: Based on the available FDA historical recall data dating back to 1999, FDA has classified 37 recalls that were conducted by food processors and food manufacturers located in the State of Indiana. FDA has conducted approximately 2,900 inspections of food facilities in Indiana over the past 10 fiscal years, of which approximately 1,900 were inspections where some violations were observed.

Examples of violations found include those related to quality control instrument accuracy and maintenance, calibration of process-monitoring equipment, storage of raw materials and other ingredients, cleaning and sanitizing operations, general records requirements, and pest control. Fines are not assessed by FDA.

9. How much of our nation's food is imported, and of this imported food, how much is inspected?

Answer: FDA describes the volume of imported foods on the basis of entry lines. An entry may contain any number of lines, each specific to a particular commodity. For example, within a single entry line could involve 100 crates of tomatoes while a second line involved 50 crates of artichokes. FDA would make a separate admissibility decision for each line.

During FY 2008, FDA made admissibility decisions on 8.2 million entry lines of human food, not including food contact substances such as dinnerware.

FDA electronically screens all commercial entries of foods that are subject to FDA jurisdiction. Many lower-risk entry lines are allowed to proceed directly into commerce after this screening. Higher-risk entry lines are referred by the electronic system to field personnel, who further review the entry for admissibility. Products subject to Import Alert are flagged and controlled during the screening process, some of which are subject to detention without physical examination by FDA. The Agency has established work plans for routine surveillance of products offered for import, and also targets products of known concern for field examination and/or product sampling and laboratory analysis. The volume of work in this area is dependent on the resources for such operations. The percentage physically examined or sampled by FDA varies by commodity but is approximately one percent of food entry lines.

10. Does the FDA inspect foreign food processing facilities sending food to the U.S.? If so, how often are these foreign food facilities inspected?

Answer: Yes, FDA inspects foreign food processing facilities that export food to the United States. The FY 2009 foreign food work plan calls for the inspection of 200 foreign facilities. We anticipate that this figure will triple by FY 2010. To assist in accomplishing the significant increase in foreign food inspections, FDA's Office of Regulatory Affairs (ORA) has established a dedicated cadre of experienced investigators, who are stationed in ORA field offices in the United States, and who will exclusively conduct foreign food inspections. There is currently no specific frequency for inspection of foreign food facilities, but the volume of such facilities compared to the resources available to conduct such inspections clearly demonstrates to the Agency that FDA inspections alone will not provide adequate coverage of the firms exporting products into the U.S. market.

11. Does the FDA have a good grasp on the number of foreign food facilities manufacturing, processing, or warehousing food that is sent to the U.S.? How many such facilities does the FDA estimate exist today?

Answer: Under current law, food facilities are required to register with FDA once and must provide a limited set of information to the Agency. Facilities may voluntarily include the type of activity conducted at the facility (e.g., manufacturing), but are not required to do so. Therefore, our ability to determine the number of facilities that would fall into each category is limited, as not all facilities have provided activity type in their registrations. Based on the best available information we now have and the total number of foreign facilities registered with FDA as of April 20, 2009, we estimate that there are 174,000 to 184,000 foreign facilities that manufacture, process or pack food and 22,000 to 33,000 foreign facilities that hold food.

12. Has the FDA seen a decrease in its food inspectors and scientific staff dedicated to improving food safety in the last 10 years? Has the FDA seen a decrease in the number of inspections that it has been able to carry out over the last 10 years?

Answer: During the last 10 years FDA has had variable levels of food investigators. FDA experienced an increase in investigators performing work in the foods area due to funding increases provided by Congress in the Counter Terrorism Funding Supplemental in 2002. However, funding decreases in following years led to a decline in the number of foods investigators. This downward trend was reversed with the FY 2008 Funding Supplemental and the FY 2009 Omnibus Appropriations. Due to these funding increases, ORA has undertaken a wide-scale hiring effort with a focus on investigator hiring.

The decline in ORA investigators after 2003 led to a decline in the number of inspections the field had the capacity to conduct. However, as new investigators join FDA and are trained, the number of inspections will increase. In addition, ORA collaborates with state agencies to perform inspections on behalf of FDA.

The table below provides a history of food investigators for FY 2001 through FY 2009.

FY 2009 – 900 (estimated)
FY 2008 – 722
FY 2007 – 622
FY 2006 – 640
FY 2005 – 670
FY 2004 – 700
FY 2003 – 870
FY 2002 – 542
FY 2001 – 512

13. Is there a clear line of distinction between the USDA and FDA responsibilities to ensure the safety of our nation's food? If so, how are those responsibilities split?

Answer: Under the President's Food Safety Working Group, USDA and HHS have been working together to improve the nation's food safety laws. FDA and USDA authorities over food safety are set out in several statutes, including the FFDCA, the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA). Under the FFDCA, food is defined to include, among other things, "articles used for food or drink for man or other animals," 21 USC 321(f). Further, the FFDCA, FMIA, PPIA, and EPIA contain provisions addressing jurisdiction between the two agencies. Under 21 USC 392(b), 467f(a) and 1052(c), clear distinctions of each agency's jurisdictions are drawn.

Under the statutory framework referenced above, FDA has jurisdiction over all food except meat, poultry and processed egg products while these products are in official USDA establishments. FDA and USDA share concurrent jurisdiction once these products leave official USDA establishments. More information is provided in response to question 14 below.

14. Is there any overlap in the USDA and FDA's authorities over food safety? Would there ever be an instance in which both USDA inspectors and FDA inspectors would have jurisdiction over the same food processing line?

Answer: Under the President's Food Safety Working Group, HHS and USDA are working together to improve our nation's food safety laws. FDA and USDA share concurrent jurisdiction over meat, poultry, and processed egg products after such foods are inspected by USDA in official establishments. Under an established Memorandum of Understanding (MOU), FDA and FSIS notify each other if there are problems within facilities or with products under each respective agency's jurisdiction. To prevent duplication of effort, FDA's policy is to inform FSIS when an apparent violation is encountered involving a product that has left a USDA inspected establishment.

Food additives used in a meat or poultry product are another area of shared responsibility. The agencies entered into an MOU to establish how the agencies work together in responding to requests for the sanctioning of the use of food ingredients and sources of radiation subject to regulation by FDA and intended for use in the production of meat products and poultry products regulated by USDA.

15. As the Food Safety Enhancement Act of 2009 is drafted, the Department of Agriculture is not included in the comprehensive food safety plan proposed.

Would you support a comprehensive food safety proposal which covers food safety responsibilities of both the Department of Agriculture and the FDA? Do you have concerns about a proposal that ignores the USDA's food safety responsibilities?

Answer: FDA believes that it needs additional authorities to deliver on its responsibilities with respect to food safety. In her testimony, the Commissioner broadly endorsed the draft legislation and spoke to the need for particular provisions to enhance and modernize its authorities. Through the President's Food Safety Working Group, HHS and USDA have been diligently working together to improve America's food safety laws.

16. In your testimony, you voiced support for the concept of universal, interoperable traceability for all foods. How do you envision enforcing adoption of these electronic tracking systems overseas, especially in remote areas where source ingredients like spices, seafood, and coffee are produced? Further, do you see a role for the foreign governments in enforcing this mandate?

Answer: It is our intention to work with the food industry and food importers, as well as foreign governments, as we develop our policies and regulations to implement these requirements. Traceability for foods is an essential component to safeguarding our domestic food supply, and will have an impact on the entire life cycle of food products, including source ingredients.

There may be some foods for which traceability would not help protect public health. The current draft bill allows FDA to exempt such foods. FDA would need to undergo notice-and-comment rulemaking to amend this provision and/or to implement section 107 of the bill. At that time, the Agency would determine the costs and benefits of the requirements it proposes, which would include the costs associated with the record retention location as it applies to entities not currently subject to this requirement.

To help make a traceability system effective, FDA will work with foreign governments to develop and/or support traceability systems within their countries comparable to our own system, and we will consider the possibility of accepting the findings of foreign governments to facilitate implementation. For example, the European Union (EU) is midway through a four-year traceability study it began in 2007, which has as its goal ensuring total traceability of food and feed along the whole chain from production to consumption. As part of this effort, the EU will develop, test, and evaluate two full pilot traceability systems, including one for the tomato food chain. FDA is closely tracking the results of this study, along with our own efforts and those contemplated under the bill. Traceability also will promote industry responsibility and due diligence when working with foreign suppliers and others involved in production of food products, as it will be incumbent upon each member of the supply chain to document product distribution information. In addition, FDA is supportive of Good Importer Practices (GIPs) and other proposals related to importers and brokers to emphasize the role these entities play in safeguarding our food supply.

17. You stated during the hearing on Wednesday that you believe user fees are necessary to help FDA meet its growing food safety mandate. Several members of the Committee raised the question about how, specifically, you plan to spend the nearly $350 million in additional revenue that would be generated in Chairman Waxman's discussion draft. Would you please explain your spending plan for these new fees?

Answer: If Congress authorizes these fees, the Agency would spend those fees as directed in the authorizing legislation. The current draft would direct the Agency to spend those fees for the "costs of food safety activities." The term "costs of food safety activities" is defined on pages 14 and 15 of the draft, and the term "food safety activities" is defined on pages 15 and 16.

18. Doctors, health professionals and the US Government are encouraging all Americans to eat seafood twice a week for optimal health. I believe access to a sustainable seafood supply is imperative. As you know, the Department of Commerce and NOAA have primary jurisdiction over the management of US federal waters where a significant portion of our seafood is harvested. How would you plan to incorporate the new FDA traceability program and enforcement of these new regulations into the ongoing work done aboard vessels at sea by NOAA scientists, observers and enforcement agents?

Answer: Section 107 of the bill, the traceability provision, amends the existing recordkeeping requirements that were added to section 414 of the FFDCA by the Public Health Security and Bioterrorism Preparedness Act of 2002 (the BT Act). FDA's regulations that implement the existing requirements in section 414 are provided in 21 CFR Part 1, Subpart J. The Department of Commerce and NOAA do not currently have a role in enforcing these requirements -- rather, their oversight on vessels in U.S. waters is to ensure that persons are not harvesting certain seafood, such as dolphins, and to track harvest quantity for resource management. It is not clear at this time what the linkage would be between the work of NOAA and a traceability program for seafood. However, as FDA moves to implement this provision, should it be enacted into law, FDA can explore with our NOAA colleagues the possibilities for leveraging the resources and capabilities of the two agencies through MOUs or other appropriate arrangements.

19. As you know, Chairman Waxman's discussion draft mandates several procedural steps be taken in addition to issuing a proposed rule on traceability, including public meetings, pilot projects and a feasibility and cost study. However, the traceability program must be enacted regardless of the outcome of these tests and studies. My question is how would you plan to address the implementation of the new traceability program if the public meetings, feasibility studies and cost analyses indicate that certain portions of the program – or the entire program – would be cost-prohibitive or impractical?

Answer: We will work through the procedural steps that are directed by Congress, and then implement the legislation in a manner that is transparent and consistent with the direction we have received from Congress and what we have learned from the meetings, studies and analyses. That process will include issuing a proposed rule that meets all applicable requirements of governing statutes, including the requirements to examine burden and the practical utility of the information under the Paperwork Reduction Act; provide a benefit-cost analysis under the Regulatory Flexibility Act; consider the impacts on small businesses under the Small Business Regulatory Enforcement and Fairness Act; assess whether the "major rule" provisions of the Unfunded Mandates Reform Act apply; and select the least costly, least burdensome, or most cost-effective option for meeting the bill's mandate. Stakeholders will have a further opportunity to provide comment on FDA's proposed rule, which FDA must consider as we develop the final rule. Through this open and transparent process, FDA believes that it will be able to develop a regulatory approach that accomplishes the bill's objectives. FDA further notes that section 107 does allow the Secretary to exempt a food from the traceability requirements if she determines that a tracing system for such food is not necessary to protect public health.

20. The seafood HACCP (Hazard Analysis Critical Control Point) program has been very successful in ensuring the safety of our nation's seafood supply. However, it is unclear whether Chairman Waxman's legislation would mandate duplicative food protection steps be taken by seafood companies who are already HACCP-compliant. Has HACCP been a successful model for protecting seafood? If no, please explain.

Answer: Yes, the Seafood HACCP program has been successful in providing greater assurance of the safety of seafood available to U.S. consumers. Seafood processors that currently are in compliance with the provisions of the Seafood HACCP Regulation would meet many of the preventive controls provisions in the draft bill and would not need to duplicate these efforts to comply with the bill. The bill, however, includes some additional preventive controls requirements that could go beyond the scope of the Seafood HACCP Regulation in certain circumstances, such as controls for intentional contamination and written procedures to ensure a safe and secure supply chain. These controls would cover hazards that presently are not covered in the Seafood HACCP program and/or would provide greater assurance of control for hazards that are covered in the Seafood HACCP Regulation. The bill would require seafood processors who do not currently have these controls to add them.

21. As you know, current statute requires milk and dairy products to undergo pasteurization, and FDA's Grade "A" Pasteurized Milk Ordinance (PMO) has been highly successful in ensuring the safety of our nation's milk and dairy products. However, it is unclear whether Chairman Waxman's legislation would mandate duplicative food protection steps be taken by milk and dairy facilities who are already covered complying with the PMO under extensive state inspection. Would you agree that FDA's milk safety program under the PMO program has been a successful model for protecting food safety?

Answer: There presently is no statutory requirement that milk in interstate commerce be pasteurized or that milk products in interstate commerce be made from pasteurized dairy ingredients. Rather, that requirement is within an FDA regulation (21 CFR 1240.61), which was promulgated in 1987. The National Conference on Interstate Milk Shipments (NCIMS) is the cooperative program between FDA, the states, and the regulated industry. NCIMS operates to ensure the safety of Grade A milk products in this country and uses the Grade A Pasteurized Milk Ordinance (PMO), which is a model, but not a federally enforceable regulation, to do so. The various states utilize the PMO, typically by adoption in whole or in part, as a basis for their regulations governing the safety of milk and milk products. Since its inception, this cooperative program has been an unquestionable success and Grade A milk and milk products in the United States are perhaps the safest in the world.

The provisions in the draft bill would largely complement the requirements stated within the PMO, and FDA does not foresee a conflict for any aspect of the Grade A program. The legislation contains additional provisions that would provide further assurance of safety for these products, such as controls for intentional contamination and written procedures to ensure a safe and secure supply chain.

22. Would you also agree that raw, or unpasteurized milk presents the greatest threat to public health and is not covered anywhere in the draft Waxman legislation?

Answer: In 1987, FDA issued a regulation (21 CFR 1240.61) which prohibits the interstate sale or distribution of raw milk. Over the last several years, FDA has identified an increasing number of violations of this regulation, and a number of people involved have been the subject of FDA enforcement activities. FDA has shared its concerns regarding the safety of unpasteurized milk with numerous states as they considered legislative initiatives that would either allow raw milk sales or distribution, or expand access to raw milk and raw milk products within states. Presently, several states are actively considering legislation related to raw milk and already this year, at least two states, Vermont and Tennessee, have relaxed their regulations to allow greater access to raw milk. The Centers for Disease Control and Prevention has indicated that states which permit raw milk sales have nearly four times as many outbreaks relating to raw milk when compared with states that prohibit sales. Accordingly, FDA agrees that this is an increasing threat to public health, but is not prepared to categorize it as "the greatest threat" to public health. FDA also agrees that the draft bill does not address this threat.

23. The OMB manual on user fees ("Circular A - 25) requires that fees provide "special benefits derived from Federal activities beyond those received by the general public." Can you please explain how required food safety inspection, as opposed to for instance, accelerated import approval services, provides a "special benefit" to the industry? Please cite the specific section of OMB Circular A-25 that covers regulatory safety inspection as a "special benefit" to the regulated industry.

Answer: The registration fees provided for in both the President's budget request and the draft legislation will pay for registration as well as food safety inspections and other food safety activities, which will reduce food-borne illness outbreaks. The registration of a facility is a special benefit to the registrant. Because foodborne illness outbreaks over the past several years have demonstrated that losses within the sector experiencing the outbreak can accrue to all firms within the sector and to other firms in the food industry if the outbreak involves an ingredient, these activities provide a special benefit under OMB Circular A-25. In particular, they "provide[] business stability or contribute[] to public confidence in the business activity of the beneficiary" (OMB Circular A-25, 6.a.1.(b)).

24. Taxpayers have always funded government mandated food safety inspections both at FDA and at the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS). Food safety inspection is a requirement that protects the public at large, and is not a special service or benefit to the food industry. Can you tell me why the FDA budget requests user fees for safety inspection, but USDA's Food Safety Inspection Service does not request fees for routine inspection?

Answer: The FDA budget requests user fees for food inspections and other food safety functions because the Agency needs additional resources to perform these functions, and these functions do provide a benefit to the food industry. For example, food inspections will encourage compliance with preventive controls, reduce foodborne illness outbreaks, and thereby provide business stability and contribute to public confidence in the business activity of the food industry.

The global marketplace poses unprecedented challenges to FDA's ability to protect public health. There are more ready-to-eat foods, and farm-to-table delivery of foods is faster than at any point in history. Moreover, the global nature of the supply chain for foods means that more finished products and ingredients enter the United States from more countries in greater and greater volume. For this reason, the FY 2010 budget for FDA requests $75,000,000 for Food Registration and Inspection User Fees.

25. According the General Accounting Office report GAO-05-549T, there are 1,451 facilities that have both FDA and FSIS inspection. How will these facilities be treated with regard to the proposed fees in FDA's Budget request and the performance fees in the FSIS budget?

Answer: Any food facility required to register under section 415 of the FFDCA would be required to pay the registration fee proposed in the Agency's budget request or in the Food Safety Enhancement Act draft, including facilities that may also be subject to inspection by FSIS.

26. In Section 107 of the discussion draft, "direct sales by farms" are exempt from the tracking and tracing requirements. As you read the discussion draft, would such farms include oyster beds, rice farms, cranberry farms, fish farms, and crustacean farms?

Answer: Yes, if they meet the definition of "farm." Section 107 of the bill, the traceability provision, amends the existing recordkeeping requirements that were added to section 414 of the FFDCA by the BT Act. FDA's regulations that implement the existing requirements in section 414 are provided in 21 CFR Part 1, Subpart J. In 21 CFR 1.328, FDA defined a farm, in part, as "a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both . . .."

27. How will the traceability regulation of this legislation affect farms such as that supply meat, poultry, and eggs? Specifically, meat, poultry, and eggs are used in making different kinds of foods and are regulated by the USDA, what will be required of these farms in terms of supplying records so their products may be traced back to the farm or place of processing?

Answer: FDA currently has food safety jurisdiction over the farms described in the question. Generally, farms are covered by section 107 and could be subject to tracing requirements. FDA notes, however, that under section 107 there are a number of actions required before any binding requirements regarding traceability could even be proposed. Specifically, the Secretary is required to identify technologies for tracing the distribution history of a food that are, or may be, used by members of different sectors of the food industry. Further, to the extent feasible, the Secretary is required to assess the costs, benefits, and feasibility of adopting and using such technologies in different sectors of the food industry, and the compatibility of such technologies with tracing requirements. The Secretary also is required to conduct public meetings and one or more pilot projects.

Section 107 authorizes the Secretary to exempt a food if the Secretary determines that a tracing system for such food is not necessary to protect public health. All of the information developed in the activities described above would be considered in formulating the proposed rule, including what foods would be covered. In addition, information and comments received in response to the proposed rule would be considered when the final rule is developed.

28. In the instance that this legislation requires farms and processing plants to supply records for traceability how do you envision the USDA and FDA working together to regulate record-keeping standards?

Answer: As appropriate, FDA and USDA could develop an MOU to cover the requirements and leverage the resources of both agencies to share information to ensure coverage and consistency in the required recordkeeping form and format. The proposed public meetings to obtain input and information from persons and other organizations prior to issuance of the regulations will also help ensure food tracing and recordkeeping standards are consistent for both agencies and achievable by industry.

29. How will the traceability standards of this regulation affect the hospitals, schools, nursing homes, restaurants and convenient stores, who all prepare food on location? Will these institutions be required to house all the records of

traceability on location? What is the perceived cost of this requirement to such institutions?

Answer: Section 107 of the bill, the traceability provision, amends the existing recordkeeping requirements that were added to section 414 of the FFDCA by the BT Act. FDA's regulations that implement the existing requirements in section 414 are provided in 21 CFR Part 1, Subpart J. This regulation provides that persons subject to the establishment and maintenance of records requirements must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location. Further, under the regulation, if records are stored offsite, persons must be able to provide access to FDA upon a proper request within 24 hours of the request. FDA would need to undergo notice-and-comment rulemaking to amend this provision and/or to implement section 107 of the bill. At that time, FDA would determine the costs and benefits of the requirements it proposes, which would include the costs associated with the record retention location as it applies to entities not currently subject to this requirement.

30. As you understand the discussion draft, would it allow FDA to regulate commodities? Do you support FDA regulation of commodities?

Answer: FDA regulates many foods, some of which are described in the FFDCA as raw agricultural commodities and many of which are sold as commodities. Section 201(r) of the FFDCA defines "raw agricultural commodity" as "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in the unpeeled natural form prior to marketing."

CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of
Nutrition Action Healthletter

June 8, 2009

The Honorable Frank Pallone, Jr.
Chairman
House Committee on Energy and Commerce, Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone,

Attached are my responses to the questions for the record submitted by the Subcommittee following the June 3 hearing on the Food Safety Enhancement Act.

Thank you again for the opportunity to testify on behalf of the Safe Food Coalition, an organization of consumer and victim advocacy groups. If I or any member of the SFC can be of assistance to you, please feel free to call on us.

Sincerely,

Caroline Smith DeWaal

Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest

Enclosure

Food Safety Modernization Act of 2009 Discussion Draft
June 3, 2009
FRANK PALLONE, JR., NJ-6TH
Questions for Caroline Smith DeWaal and Margaret Hamburg
Response of Caroline Smith DeWaal, Director of Food Safety, CSPI

Question: When you said a recall should only be for serious adverse health effects, did you mean for both non-emergency and emergency recalls or for just emergency recalls?

The Food Safety Enhancement Act, as drafted, sets out two standards for recall. Under normal circumstances, it requires the agency to request a voluntary recall before proceeding to a mandatory recall. The only exception is when a food-related event involves serious adverse health effects or death, and under this narrow circumstance, the bill allows the Secretary to proceed directly to an emergency recall.

As a practical matter, these authorities will be rarely used. Most food companies take a responsible attitude toward protecting their customers once they learn their product is implicated in an outbreak. But, following the Peanut Corporation of America outbreak, mandatory recall authority is both needed and widely supported by consumers.

Question: Could you give us your views on the provision to cease distribution, section 420(c)?

Authority to issue an order to cease distribution is an appropriate backstop to the reportable food registry and allows FDA to have a measured response when it suspects but does not know with certainty that a food may be the source of people becoming ill or being injured.

This provision is protective of public health, and allows for a preliminary response prior to ordering a recall. This mirrors the administrative detention provision, which allows an inspector to order a product held prior to shipping so that it can be tested. However, administrative detention is an inspectional authority and would not capture those instances where a contaminated product may escape the control of a facility during routine operations. Combined with the reportable food registry's reporting requirement, a cease distribution order would permit FDA to immediately control hazardous products until the facts can be ascertained. If necessary, the cease distribution order can be modified to require a recall.

Food Safety Modernization Act of 2009 Discussion Draft
June 3, 2009
MICHAEL C. BURGESS, M.D., TX-26TH
Questions for Caroline Smith DeWaal

1. The Chairman's discussion draft contains language regarding traceability. Specifically, the language provides that company would have to maintain the "full pedigree of the origin and previous distribution history of the food" and a company would have to be able to "link that history with the subsequent distribution history of the food." To accomplish that task a company would have to "establish and maintain a system for tracing the food that is interoperable with

the systems established and maintained by other such persons" as well as use the "unique identifier for each facility" required by the bill. That sounds like quite a task, particularly for small businesses. Given your experiences with your respective industries, do you believe this type of mandate is achievable, particularly for small companies with limited resources?

Better traceability would be highly beneficial to the food industry, regulators and consumers. This becomes most apparent during a food emergency. The lack of rapid traceability can result in slower investigations, larger outbreaks, and the necessity for broad consumer advisories warning the public to avoid entire categories of food. If identifying information moved with food products, it would help investigators identify foods implicated in an outbreak much more rapidly.

The lack of traceability was cited by senior FDA officials as contributing to the lengthy *Salmonella Saintpaul* outbreak last summer, which affected over 1,400 consumers. FDA Deputy Commissioner David Acheson said, "What a faster system would have done is allowed us to trace back more quickly to get into the distribution centers and onto farms, to eliminate suspected areas quickly."[1]

Traceability will benefit the food industry as well. The costs to the industry, including the very smallest producers, are enormous when a food emergency occurs. A food scare or a consumer warning during an outbreak can destroy consumer demand for an entire class of product. Faster and more accurate outbreak investigations will protect both consumers and the small producers. Many in the food industry understand this, and have developed proprietary systems that are already in use for U.S. products. Driven by retailer demands on suppliers, they may rely on scan-readable codes or lot numbering to link a product to its source either directly or through a database.

The fact that the produce industry is already developing a comparable system voluntarily shows that the legislative design is appropriate and doable. Technology exists today that would allow an identifying number to be carried with a food product. The use of a microchip could allow information to be added along the distribution chain, and nearly universal internet access would allow information to be uploaded from many points and allow viewing by others along the distribution chain. The risk of not setting up a mandatory standardized traceability system is that many different systems will evolve independently, without the "interoperability" needed to be truly effective in an outbreak situation.

When it comes to traceability, the United States may be falling behind many other countries. Japanese stores have displays that permit customers to scan a product and see information on the farm where it was grown. The Europeans through their TRACE research program are developing a number of innovative solutions to product tracing. Some of these systems are capable of capturing the full history of a product.

The need to consider a number of factors is why the bill wisely provides a series of pre-requisite steps before facilities will be required to implement the traceability system. It does not set a

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[1] Bina, Venkataraman, *Amid Salmonella Case, Food Industry Seems Set to Back Greater Regulation*, The N.Y. Times, July 31, 2008.

specific date for implementing the new system, to allow time for development of a reasonable, cost-effective traceability system. The bill preserves one-up/one-down[2] in the interim period so that traceability is not lost while we wait for an improved system.

The bill also provides some relief for small business. Where a short supply chain makes it reasonable to do so, the bill does not require farms to institute trace systems. Also, the Secretary can determine a trace system is not necessary for some processors, and retain one-up/one-down recordkeeping as the option of choice. These authorities combined with a requirement to do a cost-benefit analysis on available traceability systems should protect small processors from having to adopt excessively costly systems.

2. *How much would it cost each small business to comply?*

Instituting traceability systems will entail costs on industry, but this is mitigated by several considerations. First, food manufacturers and retailers often require traceability of their suppliers. For these companies, many of which may be small ingredient suppliers that already have sophisticated traceability systems, the legislation would entail no additional costs.

Small companies that sell intrastate or that have short supply chains (direct sales to retailers for example) would likely fall under the exemption allowed in the proposed paragraph (4)(B) of the traceability section[3].

Finally, in considering the cost to business generally, you should balance that against the cost of the current system. Spinach growers lost a reported $350 million because delays in tracing the contaminated spinach caused FDA to issue a general call for people to stop eating all spinach. Peanut butter makers had to spend millions of dollars on advertising to alert consumers that their products were not implicated in the Peanut Corporation of America outbreak. Even so, they saw sales decline by 13 percent. Meanwhile, peanut growers reported losing as much as $1 billion in reduced prices and foregone sales. A rapid, accurate traceability system would permit investigators to quickly identify the particular source of an outbreak and lower these costs, which fall on small and large food suppliers alike.

3. *What is your definition of a small business?*

First and foremost, we believe it is incumbent on anyone selling food to the American public to ensure it is safe. Therefore, we don't support the use of small-business exemptions for provisions that are necessary to protect consumers from unsafe food. And, as stated earlier, better traceability can directly impact the size of outbreaks and ensure that fewer consumers become ill.

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[2] Section 106(b)(2) is a savings clause, but should be clarified to ensure one-up/one-down is not lost before a new system is in place.

[3] Amending section 414 of the Food, Drug, and Cosmetic Act to add a new subsection (c).

Defining who is a small business in the food industry is difficult. There are a variety of parameters, including employment, income, or volume of production. For example, a company with few employees may produce a product that is an ingredient in many other foods. That product may represent a small volume within a large market. Peanut Corporation of American is an example of this. With 90 employees and less than $25 million in sales, it manufactured about 2.5 percent of peanut products on the market. It was arguably a small business. However, it supplied ingredients for more than 3,000 products – many produced by large companies. For comparison, PCA's income is dwarfed by losses suffered by Kelloggs, a company it supplied. Kelloggs spent $70 million on its recall of products with PCA ingredients.

The PCA outbreak must also be viewed in terms of the human misery it caused. PCA's misconduct resulted in more than 700 confirmed cases of illnesses and nine deaths.

There are many difficulties to carving out a small business exemption for food safety purposes. In today's global marketplace, small producers can supply many different companies. Thus small companies can impact many lives and the economic fortunes of entire industries. Every food facility regardless of size must have food safety at the forefront of its operation.

4. I understand that USDA has required companies to use HACCP plans in meat and poultry plants since 1998 and those industries have enjoyed notable success in reducing pathogen levels. I also understand that under the USDA system, that it's the companies' responsibilities to conduct the hazard analysis, and develop the preventive controls and HACCP plan. USDA's role is to verify that companies have conducted a proper hazard analysis, identified the hazards reasonably likely to occur in their operation, and developed and implemented an appropriate HACCP plan. Given the success of the USDA system, shouldn't the government be focused on verifying that companies do what they say they are going to do and whether the company meets the standard set and not meddling in HACCP plan development, which are often are unique to a particular plant?

While HACCP plan development can be unique to different operations, the Hazard Analysis should not be unique. Companies producing the same or similar products should be controlling for the same hazards. When USDA implemented HACCP, it found whole segments of industry had failed to analyze and control for such common hazards as *E. coli* O157:H7 and *Listeria*. As a result, USDA had to go back and require industry to reanalyze hazards. We know from this experience that industry can fail to identify common hazards, placing the public at risk. Also, hazards can change over time, with the emergence of new pathogens or intentional contamination, as illustrated with the recent events involving melamine. In this instance, authority should not be limited to just evaluating the plan. Instead, the agency must have authority to act preemptively to ensure the hazard is addressed by all the affected facilities simultaneously. These are the reasons for including authority in the legislation to allow FDA to highlight a hazard that is not adequately addressed by the industry. Without this authority, FDA would be placed in the position of having to address safety on a facility-by-facility basis. As a result, the public would be exposed to potential hazards longer than necessary. We believe the authority to direct action in the limited circumstances above is essential to providing FDA with the ability to protect public health and avert human illnesses.