FOOD AND COSMETIC PROVISIONS OF THE FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT DISCUSSION DRAFT LEGISLATION

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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[1] Mr. Ambrosio did not submit a prepared statement for the record in time for printing.

FOOD AND COSMETIC PROVISIONS OF THE FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT DISCUSSION DRAFT LEGISLATION

THURSDAY, APRIL 24, 2008

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

The subcommittee met, pursuant to call, at 10:12 a.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. [chairman of the subcommittee] presiding.

Members present: Representatives Pallone, Towns, Green, DeGette, Baldwin, Hooley, Matheson, Dingell [ex officio], Deal, Buyer, Pitts, Myrick, Murphy and Barton [ex officio].

Staff present: Jeanne Ireland, Jack Maniko, Virgil Miller, Ryan Long, Nandan Kenkeremath, Melissa Sidman, Chad Grant, Brin Frazier, and Lauren Bloomberg.

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

Mr. PALLONE. I call the meeting to order.

Today we are having a hearing in the subcommittee on the Food and Drug Administration Globalization Act, and I will recognize myself initially for an opening statement.

The draft of this legislation was released by Chairman Dingell, Mr. Stupak, and myself and it builds upon H.R. 3610 introduced by Chairman Dingell, as well as H.R. 3115 introduced by Mr. Stupak, H.R. 3484 introduced by Ms. DeGette, and my bill, H.R. 3624. This draft also incorporates findings from the Subcommittee on Oversight and Investigation of the full committee, the report released by the FDA Science Board's Subcommittee on Science and Technology, the Administration's Food Protection Plan and Import Safety Plan, and input from key stakeholders in the field. This draft is significantly different from the bill we discussed last fall on food safety. the Committee staff worked very hard to incorporate all the comments and feedback we received during and since the last hearing, and as a result we have before us today a more expansive discussion document. Due to its length and density of information, we have decided to hold at least two hearings so that we have enough time to devote to each issue, and today we will focus on the food-related provisions only.

Something must be done to strengthen and improve the regulation and safety of our food supply. Too often, consumers hear on the news about a food product recall and too often we read about people getting sick after consuming everyday foods like spinach and peanut butter. These instances are taking an enormous toll on consumer confidence in food items. In 2007, consumer confidence in the safety of food purchased in supermarkets reached its lowest level since 1989. A public opinion poll conducted by the Trust for America's Health last year found that 67 percent of Americans are worried about food safety. Meanwhile, consumer confidence in the FDA itself is plummeting. A Harris poll conducted in 2006 indicated that only 36 percent of Americans believe the FDA is doing a good job, and that is down from 61 percent in 2000.

And this is not just about consumer confidence. However, these instances truly endanger the American people. Each year 76 million Americans get sick due to unsafe food products. Every year 325,000 individuals will be hospitalized and 5,000 will even die from foodborne hazards. It is estimated that the medical costs and lost productivity due to foodborne illnesses cost us $44 billion annually, and these illnesses are completely preventable, in my opinion.

All of this raises questions about our current food safety laws, many of which were enacted in the 1900s. Obviously, laws that were written in the early 20th century are no longer current, particularly as the food industry becomes increasingly more global. And rather than continuing to simply react to outbreak after outbreak of contaminated products, it is about time that we put in place a stronger and more thorough system to prevent contaminated food products from reaching store shelves. We must work with players at every stage of food production from producers to processors to manufacturers to retailers, as well as government entities and the scientific community in order to ensure the full and active participation required to protect our food supply.

In the United States today, there are 44,000 food manufacturers and processors and 114,000 food retailers. If you factor in international facilities, that number increases dramatically. And yet the FDA, the agency that is tasked with overseeing 80 percent of the food supply, has had to face eroding budget resources year after year. Not surprisingly, this has forced the FDA to cut resources. Since 2003, the number of FDA field staff dropped by 12 percent, and between 2003 and 2006, federal inspections dropped by 47 percent. As I understand it, there is widespread acknowledgement that the FDA is woefully underfunded. The FDA Science Board itself issued a report in which they deem the agency as powerless to improve and will be unable to complete its tasks without a significant increase in funding, and it is up to us in Congress to ensure that this agency gets the funding levels it needs to protect the American people.

Now, the draft before us will generate revenue, adding to the funding the FDA receives through the appropriations process by requiring all food facilities to register on an annual basis with the FDA and pay a registration fee. This will benefit the agency in two ways. First, the FDA will have an up-to-date list of all food facilities, both domestically and abroad, and second, it will generate the

resources necessary to allow the FDA to conduct inspections of food facilities and other safety-related activities, tasks they cannot currently perform. The draft will also require each and every one of these facilities to have a comprehensive food safety plan that is available to the FDA, particularly during on-site inspections, and these safety plans are an important tool for preventing food safety problems from occurring and quickly and appropriately addressing incidents of contamination should something slip through the cracks. The draft also creates incentives for companies to be in compliance with food safety standards while establishing strong penalties for bad actors.

We will hear testimony this morning from industry experts on how the provisions related to food safety in this discussion draft could improve the safety of our Nation's food supply and what areas within this draft still need to be explored in greater detail.

I want to thank all the witnesses. I want to especially welcome Mike Ambrosio, who is from my home State of New Jersey, and also Cal Dooley, who of course is a former Member of Congress and a friend.

Mr. PALLONE. I now recognize my colleague, Mr. Deal, for his opening statement.

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

Mr. DEAL. Thank you, Mr. Chairman. I want to thank you for providing the subcommittee with the opportunity to evaluate this discussion draft addressing food, drug, cosmetic and device safety.

I think it goes without saying that a bill that is this comprehensive in nature would make very fundamental changes in the way the FDA regulates all of these items. Obviously, with legislation which includes these kinds of sweeping changes, we must take adequate care to evaluate the bill's impact. Looking at the different components of this legislation separately I think helps to facilitate that goal, and I want to thank you for affording this opportunity.

Like I mentioned at our hearing on food safety last September, I think we have all heard from constituents in our districts about their concerns over the safety of this Nation's food supply and the products that we are importing into this country. Now more than ever, however, we are also starting to hear about the burden being faced by American families on account of rising food prices. As we move forward in this arena, I think we are going to have to carefully balance our desire to secure the Nation's food supply without unnecessarily increasing food prices. As we work to ensure American families can have confidence in the food products they consume, I think it is critical for this committee to wrestle with the most cost-effective way to achieve this. Spending more money does not necessarily result in safer food products.

Moreover, as we discussed at length last year during the reauthorization of the Prescription Drug User Fee Act, PDUFA, we seem to be moving toward a total reliance upon the regulated industry to fund the regulating agency. My limited understanding of some of the fee structures in this bill makes this seem more true, not less. There are many who are already uncomfortable with the FDA's dependence on funds from the prescription drug industry,

and now it seems that we are moving the food industry in the same direction. These food safety issues are certainly important ones that we should be addressing, and I look forward to the testimony of our witnesses about this draft and steps that Congress should be taking to secure our food supply.

I thank you for the time, and I yield back to the Chairman.

Mr. PALLONE. Thank you, Mr. Deal.

I recognize our vice chair, Mr. Green, for an opening statement.

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

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing today on the discussion draft of the Food and Drug Administration Globalization Act.

Over the past year there have been several high-profile food contamination incidents in the United States. These outbreaks also led the GAO to our food safety program, High Risk, and the FDA's own Science Board to say the FDA does not have the capacity to ensure the safety of food for the Nation. Mr. Stupak and the Subcommittee on Oversight and Investigation had a series of hearings on the state of food safety which found the FDA simply didn't have the money, technology, or manpower to fulfill its mission. The findings of this committee, the GAO, and the Science Board are alarming, to say the least, and most certainly indicate the FDA needs more resources to protect our food supply. I wholeheartedly support legislation that would improve the ability of the FDA to protect our food supply, and I commend the chairman of our full committee for the dedication to improving food safety.

I do have concerns regarding the port-of-entry provisions in the discussion draft. I appreciate the fact that the Committee did make some changes regarding the provision from H.R. 3610, but I still have some concerns with the section on the port-of-entry provisions in the draft. I have the honor of representing Houston, and the Port of Houston is vital to our economy and provides thousands of jobs in our district as well as southeast Texas. The port is the largest port in the United States 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 products in 2007.

The discussion draft has a provision that would allow foreign and domestic food facilities to voluntarily seek certification from the FDA, and the FDA would have a list of certified companies. After 5 years, uncertified foreign food facilities would only be allowed to enter the United States at a port of entry which has an FDA lab. The Port of Houston does not have an FDA lab. In fact, there is no FDA lab in the entire State of Texas, even though we share the longest border with Mexico. I have yet to understand why Texas, with the level of trade and the 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. The FDA lab for the State of Texas actually is in southern Arkansas. Again, I don't know how much food is imported into Arkansas since it is not near a border or a port.

With regard to the discussion draft, we don't know if foreign food facilities will actually register with the FDA because their registra-

tion is voluntary. If these companies choose not to register and go to these 13 ports with labs, I question whether the FDA can handle the actual certifying of all these facilities and if the FDA labs at the 13 ports will be able to handle an increased number of imports from unregistered food facilities. Therefore, I respectfully request the chairman of the Committee work with me to address the concerns regarding the port-of-entry provision. I don't think we should pick winners and losers based on a decision that was made decades ago and not based in reality, of where the food products are actually imported today.

With that, I look forward to working with you, Mr. Chairman and staff, and I yield back my time.

Mr. PALLONE. Thank you, Mr. Green.

Next I recognize the ranking member of the full committee, Mr. Barton, for an opening statement.

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

Mr. BARTON. Thank you, Mr. Chairman. We appreciate the regular order on this bill. Having a legislative hearing on it I think is a good start.

I must say, as we have discussed the issue of food safety this year, Chairman Dingell and myself and a number of members on both sides of the aisle have numerous times said that we hope we could work together on this issue. I am very disappointed that the drafting of these bills so far, Republicans have not been allowed any input. It does not bode well for moving legislation if we are given drafts that we were not allowed to have input into or expected to accept them as is. Having said that, the fact that you are having a legislative hearing is a good step and we hope that we may have some input into the process.

I would say the bill before us needs some improvements. I would start with some basic principles. The bill is replete with user fees. If you look at the price of food and how much it has gone up just in the last 6 months to a year, I think we should tread lightly on imposing additional costs on our food industry because ultimately the consumers pay those costs. Yesterday's Washington Post had a front page story about hunger in the world and, as food prices are exploding, how it is going to be more and more difficult to deal with just some of the basic food commodities.

I also have a problem with the restriction of ports of entry, as my good friend from Texas, Mr. Green, just pointed out. We don't have an FDA laboratory in Texas yet we do have a number of very active ports and it would seem somewhat over-micromanagement to restrict the imports basically to places that have these laboratories already in place. So I think that is something that we need to work on.

Overall, I could go through three or four more pages of my opening statement but suffice it to say, I take Chairman Dingell at his word when he says that that is an important issue to him and he would like to move legislation. My preference on the minority side is to be cooperative, but in order for us to be cooperative, we have got to be allowed to be cooperative, and the draft bill before us we

had absolutely no input into, therefore, we have no ownership of, therefore we tend to look at somewhat skeptically.

With that, Mr. Chairman, I yield back.

Mr. PALLONE. Thank you, Mr. Barton.

I next recognize the chairman of the full committee and thank him for all his work in putting together this bill and making it a priority. Mr. Dingell.

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

Mr. DINGELL. Mr. Chairman, first, this is a very important hearing that we are conducting today. Second, I want to commend you for the hearing but also for your leadership in this very important matter and for the way that we have worked together on a number of other important matters this year. So far this committee has been vigorously investigating whether the Food and Drug Administration has the resources and the authorities that it needs to protect the public health.

I want to say that, as everyone will note, we are not considering introduced legislation today but rather a staff draft which will enable us to gather information about the feelings and concerns of our people and about industries' concerns about the situation that we confront. With the assistance of Mr. Stupak and Mr. Shimkus, we have had seven hearings to report and to investigate on tainted foods, with causes ranging from intentional adulteration to poor manufacturing processes. We found that there are enormous amounts of foods and other commodities coming in which the Food and Drug Administration cannot even begin to investigate. The consequences of this have been severe risk, danger, and hurt to our people.

I want to observe that from what we are going to learn at these hearings, it is my intention to work with you, Mr. Chairman, and other members of this committee, first, to meet the concerns of the members, second, to perfect the legislation, and third, to see to it that legislation is introduced upon which we may commence moving with great speed and vigor in the full committee, and I want to observe that we have in this committee this year and last year been working very closely together across the aisle. My colleagues on the Republican side have made enormous contributions to the public interest and I am proud of the way that we have worked together in these matters. It is my intention that we shall continue to do so on this legislation.

We have found in our investigations, and this has been confirmed by FDA's own Science Board, that FDA lacks the resources and the authorities to adequately oversee the Nation's food supply in the 21st century. I would note that they have similar inability in the areas of prescription pharmaceuticals and other areas of the concerns of that agency.

Now, it must be observed the agency has been less than forthcoming about its funding needs. It is evident to almost everyone else, however, from the experts to our constituents and people who are being sickened and killed by the inadequacies of that agency, that the agency is starved for resources and that it cannot meet its

basic responsibilities. The discussion draft that we are considering today will focus on our efforts to seek real legislative concerns to what is in fact a public health crisis.

First, the discussion draft aims to increase the resources that the FDA needs to do its job. As the FDA Science Board found as a result of years of chronic underfunding, and I note this did not start this week, FDA does not have the capability to ensure the safety of the food for the Nation. The Science Board goes on to call the rate at which FDA inspects food facilities appallingly low and notes that FDA has been forced not to increase food inspections but to cut them by 78 percent over the past 35 years, at precisely the same time that food importation has increased exponentially. FDA estimates that at most it inspects domestic food manufacturers once every 10 years. Once every 10 years. The Department of Agriculture can inspect dog food manufacturers more often than Food and Drug can inspect the producers and makers of foods for our people, a curious and indefensible situation. For foreign food facilities, the situation is even worse. At its current rate of inspection, FDA would need more than 2,000 years to visit every plant. This system must change.

Second, because we can't just inspect our way out of the problem, the draft provides FDA with resources and authorities to prevent food safety problems before they occur. Building on legislation introduced by you, Mr. Chairman, we ask those who supply Americans their food to ensure the safety of their product, and when prevention fails, FDA must have strong enforcement tools including authority to order recalls, as our colleague, Ms. DeGette, and others have suggested. Many are reaping the benefits of globalization but we must make sure that all parts of the food chain here bear some responsibility as well.

Finally, the draft provides a range of incentives for good acts in the global system. Many companies with reputations to protect are on the cutting edge of food safety. In the absence of effective FDA oversight, they are using their purchasing power to urge improvements in safety from their suppliers. Those who do this must be rewarded and we must work to assist them so that they can build preventive and protective measures into their products. At the same time, we must ferret out the bad actors who seek to game the regulatory system and pass off contaminated products as safe for consumption, as we have learned from tragic events caused in the not too distant past. E. coli contaminated spinach and pet foods spiked with melamine and lack of regulatory diligence have led to the deaths of people and pets, and these are only a couple of small examples of what is going on.

Mr. Chairman, food, drug, device, and cosmetic safety are not partisan issues and it is our intention that they cannot be so. I look forward to working with all my colleagues on the Committee, especially our ranking member, Mr. Barton, and my Republican colleagues and also other members, as we have previously worked together on legislation important to the American people, such as the Consumer Product Safety Modernization Act, the National Institutes of Health Reauthorization, and I hope that we can work together to craft good, sensible legislation that provides the necessary resources and authority for the Food and Drug Administration to

fulfill its critical mission to protect the American people. And I want my colleagues here in the Committee to know that it is my intention to work with them to see that their concerns, whatever they might be, are addressed and that we can come forward with a bill that will be supported by the Committee with great enthusiasm.

Mr. Chairman, I thank you for your courtesy.

Mr. PALLONE. Thank you, Chairman Dingell.

Next, the gentleman from Indiana, Mr. Buyer, is recognized for an opening statement.

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

Mr. BUYER. Thank you, Mr. Chairman, and I will pick up right where Chairman Dingell left off.

We are really going to get serious about focusing on the safety and efficacy of the food, drug, and medical devices. I have received numerous assurances from Chairman Dingell of his willingness to work with me on legislation that Jim Matheson and I have been drafting. That bill has now been introduced, and I think Chairman Dingell and others are very concerned about the safety of not only the food but also the access of America's drug supply.

Our delivery systems have changed dramatically with the globalization of food and the drug markets, and we no longer have the luxury of monitoring only the operations within our borders. We now have the challenge of ensuring the safety of facilities in areas of the world where criminal interests are high and the regulatory systems are very weak. Over the past year I have focused on the safety of drugs coming into our country and completely diverting our highly regulated drug supply chain, and I understand next week we will turn our attention to the drug and device sections of the discussion draft before us. I look forward to working with you, Chairman Dingell, and Chairman Pallone, and what I am asking is on behalf of Jim Matheson and I, that when you offer this discussion draft that you take what Jim Matheson, Gene Green, Mike Rogers, and I have introduced. It is H.R. 5839, and what we have done, Chairman Pallone, is, we have built off of the good work that Chairman Dingell had done when he created the paper pedigree back in 1988, and so much has advanced since 1988 with regard to technology and we need to take advantage of that and move from the paper pedigree, Chairman Dingell, that you created that can be easily adulterated, and move into the electronic pedigree, and Jim Matheson and I have worked hard with all industries in the supply chain and worked to do the very best, and I think what would be very prudent, what I am asking both chairmen of the full committee and the subcommittee, that this be considered next week for hearing so we can receive input.

Chairman Dingell, you understand it was very complex when you laid out this framework. It hasn't gotten any simpler and it is a very difficult subject to explain to someone who knows nothing about it. It takes a lot of time and investment, and I think it would be very prudent for us to incorporate that in our hearing next week and I would ask for your indulgence and consideration.

With that, I yield back.

Mr. PALLONE. I am going to ask the subcommittee's indulgence because of his time constraints and being on the same subject as Mr. Buyer if we could ask—I will ask unanimous consent to let Mr. Matheson go out of order. So ordered.

The gentleman from Utah is recognized.

Mr. MATHESON. Actually, Mr. Chairman, if I could waive my opening statement and use that during my question time, that is what I would like to do.

Thank you very much, Mr. Chairman.

Mr. PALLONE. Thank you.

Ms. DeGette.

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

Ms. DEGETTE. Thank you very much, Mr. Chairman. I ask unanimous consent to put my full statement in the record.

I want to commend you and Chairman Dingell as well as Chairman Stupak and Ranking Member Barton for the way the Committee has conducted itself with regards to food safety over the last year. This is a really complex issue and it is one that demands a thoughtful and reasoned response, and that is why we have had all the number of hearings we have had in the Oversight and Investigation Subcommittee. Now we have the draft legislation and the hearing today and so I think it is really wonderful the process we are using.

I also want to thank Chairman Dingell and his staff for incorporating the provisions of my legislation granting the FDA mandatory recall authority in the case of an outbreak. I often talk to my constituents about the fact that when there is tainted food on the shelves, the FDA has absolutely no authority to order a mandatory recall, and I think that a mandatory recall can give us two good results. The first one is obviously that if you have a recalcitrant producer who will not voluntarily recall products, then you can mandatorily recall it, but in addition, I think the threat of a potential mandatory recall actually will put pressure on food manufacturers and distributors to make the food safe in the first place, because in truth, while mandatory recall is important, we want to have the food safe before it is recalled to begin with, and so I think that that is an important provision of this bill. It was kind of an edgy leap to put it in there and I think it is important that that be part of any strong food safety legislation.

The second thing I would like to discuss which is not in the draft legislation and I think also would be very effective is legislation I have introduced, H.R. 3485, the TRACE Act, and what that does is, it sets up a food traceability system. We all remember the outbreak of E. coli in spinach a couple of years ago and there was a voluntary recall, but it took weeks and weeks to discover the source of the problem. In the meantime, spinach producers all around the country with perfectly fine facilities and good produce lost tremendous profits. What we learned in our hearings in the Oversight and Investigation Subcommittee is that in fact we have the ability to trace food. In fact, some of the organic food producers and other small family producers do have traceability systems. And if con-

sumers could walk into a store and see a lot number or some kind of a number where we could trace that food back to the source, we would have an ability then to make sure that our food products, we could find where the problem was, we could identify it, and then we could do the recall or whatever we needed to do right away.

So I am hoping I can work with you, Mr. Chairman, and the rest of the Committee to include the provisions of that legislation as well in any final bill that we introduce. Thank you very much.

[The prepared statement of Ms. DeGette follows:]

Hearing on draft legislation, the "FDA Globalization Act"
Subcommittee on Health
Committee on Energy and Commerce
Rep. Diana DeGette
April 24, 2008

Thank you, Mr. Chairman. I want to commend you as well as Chairman Dingell, Ranking Member Barton, and Chairman Stupak for the way this committee has conducted itself with regards to food safety over the last year. I think it is a very good example of how well this Committee can work together when we put our minds to it.

I would like to welcome our witnesses, in particular Mr. Dooley on behalf of GMA, as well as Caroline Smith DeWaal from the Center for Science in the Public Interest. Caroline has been a tireless advocate for safer food for many years, and she has lent her expertise to me and my staff on countless occasions.

I'd like to focus my comments this morning on one provision of the draft bill, Section 113. I want to thank Chairman Dingell and his staff for incorporating the text of my legislation granting the FDA mandatory recall authority in the case of an outbreak.

Obviously we need to focus our efforts on building quality and safety into the food system, so we don't need to recall adulterated food in the first place. That being said, we must also have effective recall procedures in place to deal with an outbreak.

This bill takes a two-pronged approach to get contaminated food out of distribution. First, it sets up voluntarily procedures by providing the company the opportunity to cease distribution of the food, recall it immediately, and notify consumers of the outbreak. The vast majority of companies would surely cooperate with federal officials if it becomes clear that their products are causing people to get sick.

However, if there are bad actors that do not comply with a voluntary recall in a timely manner, this bill provides the FDA with the authority to issue a mandatory recall.

It is shocking to me that the government has never had this authority. I am pleased that Mr. Dooley and food industry has come around as well, supporting mandatory recall after years of opposition.

I also believe that the government cannot arbitrarily issue a recall and cause consumer panic without sound, scientific evidence linking the food to an outbreak of illness. We must provide companies with due process. The language in the bill provides the opportunity for a company to have a hearing within two days, after which a mandatory recall would be ordered immediately if the FDA still believes the food is adulterated.

This bill also addresses how to notify consumers after a mandatory recall is issued. Currently unless a consumer happens to watch the news or read it in the paper, they may not know that the food in their freezer has been recalled. The language in my bill, and as included in the draft bill before us, requires

the FDA to notify state and local public health officials immediately upon discovery of the outbreak.

And because we need to partner with the private sector to get products quickly removed from warehouse and store shelves, notification would also be provided to all companies along the supply chain.

While I am pleased that mandatory recall has been included in this draft, I would like to mention a couple of items that are not in this bill but are essential to food safety reform nonetheless.

First, because our Committee only has jurisdiction over the FDA with regards to food safety, we need to work with our friends on the Agriculture Committee to make sure that mandatory recall authority extends to the USDA as well.

Additionally, I believe that our recall system will not be as effective as it can be unless we are able to trace food products from the "farm to the fork." I have introduced legislation, H.R. 3485, the "TRACE Act" which sets up a food traceability system.

We all remember the outbreak of E.coli in spinach a couple of years ago. While a voluntary recall took place, it took weeks and weeks and weeks to discover the source of the problem. In the meantime, spinach farmers and processors in Colorado and across the nation, with perfectly sanitary facilities and fine produce, lost their entire season's profit because consumers everywhere panicked.

Mr. Chairman, this is just one example of how a food product traceability system would have proved valuable. By using advanced but increasingly cost-effective technology, we could have immediately traced the outbreak to the source of the problem, recalling only the product causing a threat and notifying consumers and retailers directly impacted.

Not only would a traceability system identify the source of contamination in real time, it would allow us to inform businesses along the supply chain, cease distribution of other tainted products, and notify potential consumers and business owners who may have this food in their homes and restaurants.

This is not a pie-in-the-sky idea; in fact many companies are already able to track their food at all stages of farming, processing, packaging, and distribution.

It's time to expand this nationwide so consumers can finally have some confidence in our food system again.

I am grateful to Mr. Dingell and his staff for pledging to work with me on traceability as we move forward. I hope we can include something in the final version of the bill.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

I recognize Mr. Murphy of Pennsylvania for an opening statement.

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

Mr. MURPHY. Thank you, Mr. Chairman.

This Congress we have had six Oversight and Investigation hearings regarding food safety, and this is the second hearing in this subcommittee looking at potential legislative remedies for food safety. I think these hearings have given us substantial evidence of the need to increase the safety of our food supply when you look at some of the things that have occurred, such as 76 million people who contracted foodborne illness in the United States each year and about 325,000 require some hospitalization; about 5,000 die, according to a 2007 GAO study. In the first 2 months of this year alone, the Department of Agriculture has issued 5 recalls on top of 58 in 2007 and 34 the previous year. This number increases substantially when you factor in FDA recalls, and of course, we just experienced the largest beef recall in U.S. history of 143 million pounds, including 50 million pounds that have been sent to federal nutrition programs, including school lunch programs. We continue to have problems ensuring the safety of food imports. In July of last year, California issued a recall of imported Chinese ginger after discovering it had been treated with a dangerous pesticide. With a shaky track record on products ranging from tires to toothpaste, I think we can all agree allowing imported Chinese food with lax oversight is a substantial problem.

Although America is an envy of other nations in terms of what we have in food and farm safety, the question remains, how do we remedy the problem with our food supply without unduly taxing the near 300,000 food facilities in this country? I have serious concerns about the legislation before us today, but it begins the process of finding a legislative solution and I welcome the debate.

I have toured many facilities in my district and I know the tight profit margins many of them operate under. Registrations and the additional regulations could severely impact these local businesses. Let us also keep in mind the expense to them and the expense passed on to consumers with food. U.S. food prices rose 4 percent in 2007, and in 2008, it is expected to be even worse. Eggs cost 25 percent more in February than they did a year ago. Milk and dairy products are up 13 percent. Poultry is 7 percent higher, according to the USDA. Flour used to make bread was selling at $16 a hundredweight last summer and it is up to the 40s and expected to go to some $60.

Keep in mind also these overlap with our energy issues. The grain needed to fill a 25-gallon tank with ethanol would, according to Lester Brown, feed one person for a year, and filling that tank every two weeks would feed 26 people. So any impact we have upon cost of U.S. food supplies and other food supplies are affected around the world.

Keeping all these challenges in mind, I look forward to working on a bill that addresses the weaknesses of our food inspection net-

work without unduly burdening small businesses, and most importantly, without unduly burdening every family and the cost of their grocery basket.

I look forward to the testimony of today's witnesses, and I yield back.

Mr. PALLONE. Thank you.

Next is the gentlewoman from Wisconsin, Ms. Baldwin, recognized for an opening statement.

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

Ms. BALDWIN. Thank you, Mr. Chairman, and thank you very much for holding this important hearing. I want to commend you and Chairman Dingell and Chairman Stupak for putting forward this discussion draft that addresses the very serious challenge we face with respect to food and drug safety.

The fact that our Nation faces a very serious food safety concern is not in question. We all know about many of the incidents that have been related by previous speakers—tainted spinach, peanut butter, and just recently in March of 2008 we had salmonella-tainted cantaloupe in several states, including my home State of Wisconsin, that caused several people to fall ill.

But there are questions that do need to be asked and they include, what additional authorities does the FDA need to ensure the safety of our food supply? Does the FDA have sufficient resources to carry out appropriate food safety measures? What steps can we take to prevent food contamination incidents before they occur? And in an increasingly interconnected world, how do we ensure that food coming in from other countries is safe? And I think that the Dingell-Pallone-Stupak discussion draft addresses these questions in a thoughtful and constructive manner. I strongly agree that the FDA is in critical need of increased resources to ensure the safety of our Nation's food supply. We must take steps to make sure that this need for resources is met, and I support the draft provisions that provide those much-needed resources.

I am also pleased that the discussion draft includes a provision that would allow the FDA to partner with accredited third-party laboratories to perform testing. This partnership will expand the FDA's laboratory testing capacity and will result in more food being tested. This is a smart way to harness the abilities of the private sector and a smart way to expand the FDA's food safety efforts without draining the already very scarce resources of the FDA.

Lastly, Mr. Chairman, I would like to extend a special welcome and thank you to James Lovett, who is one of our witnesses today. Mr. Lovett is testifying on behalf of Covance, a company that has more than 60 years of food testing experience, among other things that they do, and it has a very large and impressive facility in my home district and hometown of Madison, Wisconsin. I am pleased that they will be able to communicate with us today and share their unique perspective in this debate and the role that they play in ensuring the safety of our Nation's food, and I look forward to today's discussion.

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

Mr. PALLONE. Thank you.

Next for an opening statement, the gentleman from New York, Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman. I would like to place my opening statement in the record.

[The prepared statement of Mr. Towns follows:]

Statement of Congressman Ed Towns (NY-10th) to the Subcommittee on Health at the April 24th hearing regarding Food Safety

Chairman Pallone and Ranking Member Deal, thank you for having this very timely hearing concerning, **"Food and Cosmetic Provisions of the 'Food and Drug Administration Globalization Act" Discussion Draft Legislation."** Mr. Chairman and Ranking Member, Congress has a duty to protect citizens from harmful food products in the stream of commerce. It is our central charge for this Subcommittee to be fully engaged on the issue of food safety. Recent incidents of accidental pet and human food contamination – including the largest recall of beef in U.S. history this past February, preceded by the GAO's 2007 determination that Federal oversight of food safety is a high-risk area prompted this Discussion Draft, from the collective bills, as introduced, respectively, by my honorable colleagues, **Representatives Dingell, Pallone, Stupak and DeGette**. I applaud each of you for your wise leadership on teeing up the relevant issues, especially as it relates to the adequacy of FDA funding and authority to ensure the safety of our Nation's food supply – a consistent concern of mine. As a Representative from New York, I want to point out that New York is where licensed food inspection actually began in our nation and remains a major point of entry for foreign imported foods. The Draft's proposal to create an up-to-date registry of all food facilities serving American consumers and other matters is an important and laudable effort. I welcome the dialogue and look forward to hearing from our witnesses.

I wish to welcome **Dr. Stephen Sundlof**, FDA Director of the Center for Food Safety and Applied Nutrition, and our other witnesses who represent industry, academia and consumer perspectives. Lastly, although this matter is separate, I urge this Subcommittee to consider holding a markup on **H.R. 1232: "To establish a competitive grant program to build capacity in**

veterinary medical education and expand the workforce of veterinarians engaged in public health practice and biomedical research." Passing this bill, as introduced by the Honorable Representatives Baldwin and Pickering, of which I am a co-sponsor, is a necessary means of ensuring food safety, and security. Again, thank you Mr. Chairman and Ranking Member. I yield back.

Mr. PALLONE. Thank you.
The gentlewoman from Oregon, Ms. Hooley.

OPENING STATEMENT OF HON. DARLENE HOOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Ms. HOOLEY. Thank you, Mr. Chair. Thank you for holding this hearing and for providing this discussion draft of the Food and Drug Administration Globalization Act legislation.

Mr. Chair, I think it is safe to say that everyone in this room and, for that matter, everyone listening to or watching this hearing, wants our food system to be safe and safer than it currently is. It is clear to me that the first order of business is to increase the resources available to the FDA. As this committee has pointed out on a number of occasions, FDA's own Science Board refused to address the role of science in the agency's work without first addressing the historic lack of resources for the agency as a whole. I do, however, have some issues with the user fees as set up by this legislation, which I will get to in a minute.

I am also pleased that the bill tries to direct the FDA and the food industry to prevent problems before they occur. That makes sense from the point of view of the consumer who does not want to get sick to prove anyone's point, as well as from the point of view of the industry that does not want to go bankrupt facing a major product recall.

The third item in this bill that I am pleased about is the attempt to provide flexible authorities for the enforcement of food safety standards. That is going to help improve industry standards and ensure compliance without the need for overbearing enforcement provisions.

I do, however, have a few concerns about the discussion draft that I think need to be addressed. Let me sum them up. This bill as it currently stands would competitively disadvantage small food producers and processors, leave Oregon in the position of having zero ports of entry for imported foodstuffs and inadvertently increase energy usage to get out food. But let me emphasize the issue is so important and your work on it to date is so laudable that I want to work hard to resolve these issues and arrive at a bill that I can support and that we can pass out of committee.

First, if we must go the road of user fees, then the fees must be on a sliding scale, or processors below a certain size should be exempt altogether from the fee. Two thousand dollars is cost-prohibitive for many of my small food processors. Many people in Oregon are turning toward local food producers and processors to get the freshest, best food while using the least amount of energy to get it. The way this user fee is set up puts those producers at a disadvantage. I also believe that registration of these facilities may already be required by other federal legislation, for example, the Bioterrorism Act of 2002, and I wonder about duplicating efforts.

Second, I have concerns about the country of origin labeling provisions. I want to thank you for changing the COOL provisions from unworkable to workable. We are almost there but not quite. We need to work on the definition of processed food since it varies from the Bureau of Customs and what is proposed in the Farm Bill. We also need to clarify who is responsible for listing ingredi-

ents on whose Web site and is the ingredient listed per the time of year it is available or is it tied to a particular package. There are lots of details to be worked out and I look forward to working with them and with you and your staff.

Third, I am extremely concerned about the provisions that limit eventually the importation of food only through ports with an FDA or FDA-certified inspection and testing facility. Oregon does not have one, not even at the Port of Portland, which would mean that all of our food importation business would be sent to California or Washington. That means the loss of business to Oregon ports but it also means in this time of ever-increasing gas prices that the cost of food will include the increased use of gas to get that food from California and Washington to Oregon. I thought we were supposed to be encouraging the decrease of energy, not passing a policy that requires the unnecessary increased use of gas.

Lastly, I am very concerned that these policies combined, the registration fees, the importation requirements, the labeling requirements, will work against my small food producers. In Oregon, folks pride themselves on innovation, and I would not want the pursuit of food safety to be the death knell for locally produced, locally consumed fresh foods. I have more details from the food safety division of the Oregon Department of Agriculture that I would submit for the record.

I look forward to working with you, Mr. Chair, and my colleagues to resolve these concerns. Thank you.

Mr. PALLONE. Thank you, and I believe that concludes the Members' opening statements so we will now turn to our witnesses, and I would ask the first panel, which is the FDA representatives, to come forward please.

Thank you for being here today. On our first panel, we have Dr. Stephen Sundlof, who is director of the Center for Food Safety and Applied Nutrition at the FDA, and accompanying him is Dr. Steven Solomon, who is deputy director of the Office of Regional Operations in FDA's Office of Regulatory Affairs.

Let me mention that we have 5-minute opening statements. Is just one of you going to speak? OK. So a 5-minute opening statement is from the witness, and that becomes part of the hearing record. The witness may in the discretion of the Committee submit additional brief and pertinent statements in writing for inclusion in the record, and I would now recognize Dr. Sundlof.

STATEMENT OF STEPHEN SUNDLOF, D.V.M., PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

Dr. SUNDLOF. Good morning and thank you, Chairman Pallone and members of the Subcommittee. I am Stephen Sundlof, director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration, and I appreciate the opportunity to discuss our legislative proposals as well as proposals developed by you and your colleague on the Committee to enhance FDA's ability to carry out its important public health mission.

Food can become contaminated at many different steps along the path from farm to fork. In recent years, FDA has done a great deal to prevent both deliberate and unintentional contamination of food

at each of these steps. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that require us to adapt our current food protection strategies.

To address these challenges, last November, Secretary of Health and Human Services Michael Leavitt presented to the President an Action Plan for Import Safety which reflects the input of 12 departments and agencies and provides recommendations to enhance the safety of imported products. In conjunction with the Action Plan, FDA released a Food Protection Plan which provides a framework to identify potential hazards and counter them before they can do harm. Together these plans provide an updated and comprehensive approach to ensure that the U.S. food supply remains one of the safest in the world. The plans encompass three core elements: prevention, intervention, and response. The prevention element means promoting increased corporate responsibility so that food problems do not occur in the first place. The intervention element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The response element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency.

Consistent with the goals of the Action Plan, in December, HHS and the People's Republic of China signed a Memorandum of Agreement to enhance the safety of food and animal feed products exported from China to the United States. The Memorandum of Agreement establishes a bilateral mechanism to provide greater information to ensure products from China meet U.S. standards for quality and safety. The key terms of the agreement include enhanced registration and certification requirements, greater information sharing, faster access to production facilities, and the implementation of key benchmarks to evaluate progress. The first formal bilateral meeting under the Memorandum of Agreement was held in Beijing last month.

FDA has also made a commitment to station inspections and other agency representatives in China to increase our ability to carry out foreign inspections and to facilitate cooperation between FDA and its counterpart regulatory authorities. FDA is considering endeavors similar to this in other countries.

In the plans we identified several new legislative authorities needed to help us fully implement them. For example, FDA is requesting the authority to require entities in the food supply chain to implement measures solely intended to protect against intentional adulteration of the food supply by terrorists or criminals.

We are also requiring explicit authority to issue regulations requiring preventive food safety controls for high-risk foods. Such authority would strengthen FDA's ability to require manufacturers to implement a risk-based Hazardous Analysis and Critical Control Point, or HACCP, or equivalent process to reduce foodborne illnesses from these foods.

Some of the other legislative proposals include authorizing FDA to accredit and use highly qualified independent third parties to evaluate compliance for voluntary inspections, allowing the FDA to move the inspection of high-risk products of concern upstream by requiring the exporting country's regulatory authority or a third-

party inspector to certify each shipment for compliance with FDA's standards prior to shipment, giving FDA authority to issue mandatory recalls if a voluntary recall is not effective, authorizing the FDA to refuse admission of imported food if inspection access has been delayed, limited or denied, and giving FDA enhanced access to food records during emergencies

We commend the members of this committee and their staff for developing the discussion draft entitled "The Food and Drug Administration Globalization Act of 2008." We recognize and appreciate the Committee's efforts to include new authorities requested by the Administration in support of the Action Plan for Import Safety and the Food Protection Plan.

We are in the process of reviewing the discussion draft in detail, and we look forward to working with you on this legislation. At this time, however, we can make some general comments that guided the development of the Action Plan for Import Safety and which we believe should also guide the development of product safety legislation.

First, any legislation should allow FDA to set requirements and priorities based on a strong scientific risk assessment. Given the breadth and scope of the food products imported into the United States, FDA cannot rely on inspections as its primary means of ensuring food safety. Any legislation should build on the framework in the plans to build in safety measure to address risks throughout the product's life cycle and focus efforts on preventing problems first and then use risk-based interventions to ensure preventive approaches are effective coupled with a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

The Federal Government should be striving to address food safety concerns while minimizing the potential effects on the increasing costs of food. While the Administration is supportive of user fee programs in which regulated industries provide funding for additional performance and efforts or programs designed to recoup the costs of enforcement actions such as reinspections, the Administration will carefully review any proposed user fee to ensure that it is being assessed against identifiable recipients for special benefits derived from federal activities beyond those received by the public.

Any legislation should be carefully designed to avoid creating real or perceived barriers. Any legislation should empower robust, voluntary private sector efforts already underway.

With these in mind, we believe that the proposed legislation should be more closely targeted and prioritized according to risk. Several of the legislative sections are not exclusively targeting high-risk products. Some of these requirements would require such substantial resources that they would not be feasible. Further, such resources could detract from more important food safety and food defense priorities.

In addition, the legislation should more explicitly incorporate the Administration's strategy of leveraging efforts underway by certifying bodies and foreign nations. Finally, several provisions of this bill may need to be reviewed in light of U.S. agreement obligations, and we are reaching out to the United States Trade Representative for further insight on these.

Thank you again for the opportunity to discuss FDA's legislative proposals as well as the proposals developed by the Committee. We look forward to working with you to obtain passage of the requested legislative authorities identified in the Food Protection Plan and the Action Plan for Import Safety, and I would be happy to answer any questions at this time.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Sundlof follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

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

DIRECTOR

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

APRIL 24, 2008

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INTRODUCTION

Good morning, Chairman Pallone and Members of the Subcommittee. I am Dr. Stephen Sundlof, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). FDA appreciates the opportunity to discuss our legislative proposals, as well as proposals developed by you and your colleagues on the Committee to enhance FDA's ability to carry out its important public health mission.

FDA is the Federal agency that regulates almost everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed. Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission.

Food can become contaminated at many different steps – on the farm, in processing or distribution facilities, during transit, at retail and food service establishments, and in the home. In recent years, we have done a great deal to prevent both deliberate and unintentional contamination of food at each of these steps. FDA has worked with other Federal, state, local, tribal, and foreign counterpart food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry and academia to significantly strengthen the nation's food safety and food defense system across the entire distribution chain.

This cooperation has resulted in greater awareness of potential vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and the ability to respond more quickly to outbreaks of foodborne illness. However, changes in consumer preferences, changes in industry practices, and the rising volume of imports have posed challenges that required us to adapt our current food protection strategies. Recent outbreaks underscored the need to develop multidisciplinary and integrated product safety strategies.

ACTION PLAN FOR IMPORT SAFETY AND FOOD PROTECTION PLAN

To address these challenges, last November, Secretary Leavitt presented to the President an Action Plan for Import Safety (Action Plan) which reflects the input of twelve Departments and Agencies and provides recommendations to enhance the safety of imported products. In conjunction with the Action Plan, FDA released a Food Protection Plan which provides a framework to identify and counter potential hazards. To achieve the food safety enhancements identified by these plans will require the involvement of all our food safety partners – Federal, state, local, tribal, and foreign governments; industry; academia; consumers; and Congress.

I would now like to describe some of the highlights of the Food Protection Plan (the Plan) and Action Plan and some recent food safety and food defense activities. The Plans build in safety measures across a product's life cycle, from the time a food is produced to the time it is distributed and consumed. FDA's integrated approach encompasses three core elements: prevention, intervention and response. The *prevention* element means promoting increased

corporate responsibility so that food problems do not occur in the first place. The *intervention* element focuses on risk-based inspections, sampling, and surveillance at all points in the food supply chain. The *response* element bolsters FDA's emergency response efforts by allowing for increased speed and efficiency. In these Plans, we identified several new legislative authorities needed to help us fully implement the Plans. As we discuss each subject area, I will briefly summarize those proposed authorities.

MOA with China

Consistent with the goals of the Action Plan, on December 11, 2007, HHS and the General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of food and animal feed products exported from China to the U.S. The MOA establishes a bilateral mechanism to provide greater information to ensure products exported from China to the United States meet U.S. standards for quality and safety. The key terms of the agreement include enhanced registration and certification requirements, greater information-sharing, faster access to production facilities, and the implementation of key benchmarks to evaluate progress. The first formal bilateral meeting under the MOA between FDA and Chinese regulators was held the week of March 17, 2008, in Beijing.

FDA has also made a commitment to station inspectors and other Agency representatives in China to increase our ability to carry out foreign inspections and to assist the Chinese government officials in their regulatory work associated with FDA-regulated products that are to be exported to the U.S. FDA is considering similar endeavors in other countries.

Prevention

Prevention is the first essential step for an effective, proactive food safety and defense plan. FDA's plan implements three key prevention steps: (1) promote increased corporate responsibility to prevent foodborne illnesses, (2) identify food vulnerabilities and assess risk, and (3) expand the understanding and use of effective mitigation strategies. The prevention steps are risk-based and will be implemented as appropriate to particular segments of the industry, taking into account that some foods are inherently safer than others.

To promote increased corporate responsibility, FDA must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. This will require close interaction with growers, manufacturers, distributors, retailers and food service providers, importers, and other critical components of the food supply chain. For example, in December 2007, FDA released self-assessment tools to minimize the risk of intentional contamination of food and cosmetics. The tools enable industry to get a quick and detailed assessment of the security measures they have in place and to identify areas in which improvements are needed.

FDA requests authority to require entities in the food supply chain to implement measures *solely* intended to protect against the intentional adulteration of food by terrorists or criminals. This authority would allow FDA to issue regulations requiring companies to implement practical food defense measures at specific points in the food supply chain where intentional contamination has the greatest potential to cause serious harm, such as requiring locks on

tanker trucks transporting food. The authority would only apply to food in bulk or batch form, prior to being packaged, which have clearly demonstrated vulnerabilities (e.g., short shelf-life), and where it would affect multiple servings and there is a high likelihood of serious adverse health consequences or death from intentional adulteration. These regulations would take into account the best available understanding of the uncertainties, risks, costs, and benefits associated with alternative options. The requirement would utilize industry best practices and would not apply to raw produce or food on farms, except for milk.

FDA is also seeking explicit authority to require preventive food safety controls for high-risk foods (those that have been associated with repeated instances of serious health problems or death to humans or animals from unintentional contamination). Such authority would strengthen FDA's ability to require manufacturers to implement risk-based Hazard Analysis and Critical Control Point (HACCP) or equivalent processes to reduce foodborne illnesses from these foods.

FDA also requests statutory changes that would require facilities to register every two years and authorize FDA to establish food categories within the registration system. These categories would allow FDA to tailor registration categories based on up-to-date food safety information. Under current law, FDA must use preexisting food categories that were not designed for registration purposes and therefore are of limited usefulness for evaluating potential threats to food protection. This change would ensure accurate, up-to-date registration data from facilities. Facilities whose registration remains unchanged would be able to file a simplified renewal registration or affirmation to that effect.

To identify food vulnerabilities and assess risk, FDA will work with the food industry, consumer groups, and Federal, state, local, tribal, and international partners to generate the additional data needed to strengthen our understanding of food safety and food defense risks and vulnerabilities. FDA has developed an internal steering committee to address the various components of an Agency-wide risk-based approach to FDA-regulated food and feed products. In order to expand the understanding and use of effective mitigation strategies, FDA will initiate risk-driven research about sources, spread and prevention of contamination. A comprehensive, risk-based approach allows FDA to maximize the effectiveness of its available resources by focusing on food products that have the potential to pose the greatest risk to human and animal health.

Working with the Centers for Disease Control and Prevention (CDC), FDA will also build the capacity to attribute pathogens to specific foods and identify where in the production life cycle the foods became contaminated. FDA will also continue to work with the Department of Homeland Security on identifying emerging risks and developing rankings so that we can more effectively allocate our available resources to manage these risks.

To enhance the safety of lettuce and leafy greens, FDA is continuing to work with officials in California and with industry to assess the prevalence of factors in and near the field environment which may contribute to potential contamination of leafy greens with *E. coli* O157:H7 and the extent to which Good Agricultural Practices and other preventive controls are being implemented. In the fall of 2007, in cooperation with

industry, state and local governments, and academia, FDA conducted assessments on farms. FDA is also continuing its collaboration with state health and agriculture officials from Florida and Virginia, the produce industry, and several universities to prevent foodborne illness associated with tomatoes from those states. By identifying practices and conditions that can lead to product contamination, FDA and its food safety partners hope to improve guidance and policies intended to minimize the potential for future disease outbreaks.

Intervention

Because no plan will prevent 100 percent of food contamination, FDA is also focused on having targeted, risk-based interventions to provide a second layer of protection. These interventions must ensure that the preventive measures called for are implemented correctly. The Plan includes ways to focus on inspections and sampling based on risk, enhance risk-based surveillance, and improve the detection of food system signals that indicate contamination.

However, the universe of domestic and foreign food establishments subject to FDA inspection is immense. To expand its capacity for the regulation of food and other FDA-regulated products, FDA's Beyond Our Borders Initiative includes increased collaboration with foreign regulators and the use of third parties to provide information about industry's compliance with FDA standards. Legislation to authorize FDA to accredit and use highly qualified independent third parties, or to recognize entities that accredit, to evaluate compliance with FDA requirements for food would be an effective way to further meet the heightened

inspection demand. FDA would not be bound by the information from these third-party organizations in determining compliance with FDA requirements. Use of accredited third parties would be voluntary and might offer more in-depth review and possibly faster review times and expedited entry for imported goods manufactured in facilities inspected by accredited third parties. Use of accredited third parties may also be taken into consideration by FDA when setting inspection and surveillance priorities.

On April 2, 2008, FDA published a notice in the *Federal Register* to solicit public comments on the use of third-party certification programs for foods and feeds, including pet foods. The comment period extends until May 19, 2008. As part of the Agency's response to problems with Chinese aquacultured seafood contaminated with unapproved drugs, FDA worked with the Chinese government to establish a pilot program to demonstrate how aquaculture companies can implement preventive controls that will minimize the risk of unapproved drug residues in the product.

In order to enhance the Agency's risk-based surveillance, FDA plans to focus on improving its ability to target imported foods for inspection based on risk through the use of advanced screening technology at the border and enhanced information sharing agreements with key foreign countries.

As part of the 2009 budget process, the Administration proposed a new user fee requiring manufacturers and laboratories to pay the full costs of reinspections and associated follow-up work when FDA reinspects facilities due to failure to meet current

Good Manufacturing Practices (cGMPs) or other FDA requirements. Where FDA identifies violations during an inspection or issues a warning letter, FDA conducts follow-up inspections to verify a firm's corrective action. The proposed reinspection fee ensures that facilities not complying with health and safety standards bear the cost of reinspection.

Further, FDA should have the option of moving the inspection of high-risk products of concern "upstream" by entering into agreements with the exporting country's regulatory authority. That authority (or an FDA-recognized third party inspector) would certify each shipment or class of shipments for compliance with FDA's standards *prior* to shipment to the U.S. FDA would apply this requirement *only* for imported products that have been shown to pose a threat to public health for U.S. consumers. While FDA would retain the authority to verify the safety of imported products, this approach shares the burden of ensuring the safety of food products with the exporting country. For such a system to be effective, FDA will have to establish an in-depth collaboration with the relevant foreign government authority to ensure that the standards, processes, and criteria by which the foreign authority or third party is certifying products are consistent with those of FDA.

As part of the 2009 budget process, the Administration proposed a new export certification fee for the issuance of export certificates for foods and feeds to those situations where exportation is restricted without this type of certificate. Private sector exporters would bear the cost of the program, but would reap its benefits through the FDA's enhanced ability to facilitate product exports. Importantly, collection of these user fees will enable the FDA to

issue certificates without redirecting resources from other critical food and animal feed safety programs devoted to protecting the public health. Such fees are currently collected by FDA for export certificates for drugs and devices.

In addition, while FDA can pursue an inspection warrant or criminal prosecution if it is denied access to inspect facilities here in the U.S., foreign firms can often deny U.S. officials access to their facilities without any adverse consequence. In particular, although FDA can refuse admission of food that appears to be adulterated or misbranded, the Federal Food, Drug, and Cosmetic Act does not explicitly provide for FDA to refuse admission of food if FDA is hampered in making this determination because its efforts to conduct a foreign inspection were unduly delayed, limited, or denied at a facility where the product was manufactured, processed, packed, or held. Having the authority to prevent entry of food from firms that fail to provide FDA access will enable FDA to keep potentially unsafe food from entering U.S. markets.

FDA can better detect and more quickly identify risk "signals" in the food supply chain by deploying new rapid screening tools and methods to identify pathogens and other contaminants and by enhancing its ability to "map" or trace adverse events back to their causes by improving its Adverse Event and Consumer Complaint Reporting System. This additional information will serve as a supplemental warning indicator for emerging food protection problems. FDA microbiologists recently received training from CDC on a new molecular method for rapidly and accurately identifying *Salmonella* serovars. FDA has

purchased the necessary equipment and will be training its field laboratory personnel in upcoming months.

The pet food recalls showed us that we need to also increase our efforts on animal food and feed, as well as human food. To provide the information necessary to allow for early detection of, and intervention with, contaminated animal feed, FDA is working with the veterinary community, veterinary hospitals, and other private U.S. sources to develop an early warning surveillance and notification system to identify problems with the pet food supply and alert veterinarians and others. FDA also is developing a modernized risk-based Animal Feed Safety System (AFSS) that describes how animal feed production, distribution, and use can be designed to minimize risks to humans and animals.

To implement a requirement in the Food and Drug Administration Amendments Act of 2007, FDA is developing ingredient, processing, and updated labeling standards for pet food. To assist us in this endeavor, FDA is holding a public meeting on May 13, 2008, to obtain input from stakeholder groups on such standards. At this meeting, we are also asking for input on ingredient and processing standards for animal feed generally.

Response

During the past year and a half, FDA responded to food safety problems with contaminated spinach, lettuce, vegetable proteins, and peanut butter, among other foods. While FDA's response to these outbreaks was swift and effective, there is always a need

to respond faster and communicate more effectively with consumers and other partners. During emergencies, important messages must be communicated clearly and through multiple forms of media to consumers and retailers. FDA will enhance its risk communication program through aggressive, targeted campaigns that disseminate clear and effective messages and provide regular updates to help get contaminated products off the retail shelf and out of homes more quickly. FDA has sought expert advice in the field of risk communications from the recently formed Risk Communication Advisory Committee.

To improve our immediate response, FDA is currently reaching out to various organizations to gain a better understanding of best practices for traceability and the use of electronic track-and trace technologies to more rapidly and precisely track the origin and destination of contaminated foods, feed, and ingredients. In addition, FDA plans to issue a Request for Applications this year to provide funding to six states to establish Rapid Response Teams to investigate multi-state outbreaks of foodborne illness, perform traceback of implicated foods, and evaluate data from investigations to identify trends.

Another key component of improving FDA's response is additional authority for emergency responses. FDA is requesting authority for mandatory recall authority and enhanced access to food records during emergencies. Although FDA has the authority to pursue seizure of adulterated or misbranded food through a civil judicial action, this is not a practical option when contaminated product has already been distributed to hundreds or thousands of locations. And while FDA has been able to accomplish most recalls through voluntary

actions by product manufacturers or distributors, there are situations in which firms are unwilling to conduct an effective recall. In such situations, public health would be best protected if FDA has the ability to require a firm to conduct a recall to ensure the prompt and complete removal from distribution channels of food that presents a threat of serious harm to humans or animals. This authority would be limited to foods that the Secretary has reason to believe are adulterated and present a threat of serious adverse health consequences or death. It would be imposed only if a firm refuses or unduly delays conducting a voluntary recall. An order to recall food could only be issued by the HHS Secretary, Deputy Secretary, or Commissioner of Food and Drugs, and would be accompanied by appropriate due process rights.

FDA is also seeking a modification to our records access authority that would give FDA more complete and streamlined access to records necessary to identify the source or cause of foodborne illness and take needed action during food related emergencies. Improved access to information, including records related to an article of food or related articles of food that may present a threat, will enhance FDA's ability to identify problems, respond quickly and appropriately, and protect public health.

Currently, emergency access to records is limited to instances where, for an article of food, FDA has a reasonable belief that the food is adulterated *and* presents a threat of serious adverse health consequences or death. FDA proposes to expand access to records of *related* articles of food, such as food produced on the same manufacturing line. FDA also proposes, in food-related emergencies, to remove the adulteration requirement to allow its inspectors

access to records in emergency situations where FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death. The recent melamine situation in which FDA had early clinical evidence that a specific food was causing illness in pets but did not have clear evidence of a specific adulteration is an example of such a scenario. The records access would relate only to safety or security of the food and would not apply to records pertaining to recipes, financial data, pricing data, personnel data, research data, and sales data. The requirement would not impose any new recordkeeping burdens, and would maintain the current statutory exclusions for the records of farms and restaurants.

We are moving forward to implement the Food Protection Plan and are working with other Federal agencies; state, local, tribal, and foreign governments; as well as with industry to develop the food science and tools necessary to better understand the current risks of the food supply, and develop new detection technologies and improved response systems to rapidly react to food safety threats.

To provide a forum for local, state, and Federal partners to exchange information and ideas about implementing the plan and enhancing food safety, FDA is planning to host a meeting on August 12-14, 2008, with regulatory, epidemiology, and laboratory officials from the departments of health and agriculture from all 50 states. We also recently established a docket and solicited comments from our stakeholders on the Food Protection Plan and on specific questions related to its implementation. The comment period will remain open until July 31, 2008. We have numerous other outreach activities underway to engage our stakeholders in implementing the Food Protection Plan.

FDA GLOBALIZATION ACT OF 2008

We commend the Members of this Committee and their staff for developing the discussion draft entitled, the "Food and Drug Administration Globalization Act of 2008." We recognize and appreciate the Committee's efforts to include new authorities requested by the Administration in support of the Action Plan for Import Safety and the FDA Food Protection Plan.

We are in the process of reviewing the discussion draft in detail and we look forward to working with you on this legislation. At this time, we can, however, make some general comments that guided the development of the Action Plan for Import Safety and Food Protection Plan, which we believe should also guide the development of product safety legislation.

- Any legislation should allow FDA to set requirements and priorities based on a strong scientific FDA risk assessment.
- Given the breadth and scope of food products imported into the U.S., as well as those produced domestically, FDA cannot rely on inspection as its primary means of ensuring food safety. Any legislation should build on the framework in the Plans: build in safety measures to address risks throughout a product's life cycle and focus efforts on preventing problems first, and then use risk-based interventions to ensure preventive approaches are effective, coupled with a rapid response as soon as contaminated food or feed is detected or when there is harm to people or animals.

- The Federal government should be striving to address food safety concerns while minimizing potential effects on the increasing costs of food.
- While the Administration is supportive of user fee programs in which regulated industry provides funding for additional performance and efforts or programs designed to recoup the costs of enforcement actions (such as reinspections), the Administration will carefully review any proposed user fee program to ensure that it is being assessed against identifiable recipients for special benefits derived from Federal activities beyond those received by the general public.
- Any legislation should be carefully designed to avoid creating real or perceived trade barriers.
- Any legislation should empower robust voluntary private sector efforts already underway.

With these in mind, we believe the proposed legislation should be more closely targeted and prioritized according to risk. Several of the legislative sections are not primarily focused on high-risk products. Some of these requirements would require such substantial resources that they would not be feasible. Further, such use of resources could detract from more important food safety and food defense priorities.

In addition, the legislation should more explicitly incorporate the Administration's strategy of leveraging efforts underway by certification bodies and foreign nations.

Finally, several provisions of this bill may need to be reviewed in light of U.S. agreement obligations, and we are reaching out to the United States Trade Representative for further insight on these.

CONCLUSION

Together, the Food Protection Plan and the Action Plan for Import Safety provide an updated and comprehensive approach to ensure that the U.S. food supply remains one of the safest in the world. FDA remains committed to working closely with all of its partners to implement the Plans' measures to protect the nation's food supply. We commend this Committee for its work and look forward to working with Congress to obtain passage of the necessary legislative authorities identified in the Food Protection Plan and the Action Plan for Import Safety. Thank you for the opportunity to discuss FDA's activities to enhance food safety. I would be happy to answer any questions.

Mr. PALLONE. Thank you, Dr. Sundlof.

I will recognize myself for 5 minutes for questions. I have two questions. I am going to try to get in one about the funding and one about your authority, so just bear with me so we can get both of those in.

The draft legislation incorporates some of the suggestions your agency made in its recently released Food Protection Plan, and those are strong concepts and things the FDA should be doing to protect the American people. But we know for a fact that the FDA is underfunded. Commissioner von Eschenbach even recently stated in an interview that you have requested more than the 2.95 percent overall increase for the FDA that was proposed by the Administration, and former FDA Commissioner and CMS Administrator Mark McClellan stated, and I quote, "The President's fiscal 2009 budget barely gives FDA enough funds to operate at last year's level and does little to make up for the steady loss of staffing that the agency has endured for the past decade."

So my first question, in your professional judgment, how much money does the FDA need to carry out the tasks laid out in your plan and also in this bill?

Dr. SUNDLOF. Thank you, Mr. Chairman. Well, first of all, a lot of it has to do with the authorities that we are going to be given. If we do acquire some of these authorities, it will make a big difference on the amount of revenues and resources that we are going to need. For instance, if we have the authority to recognize third-party inspectors, then we would expect that the number of inspections that would be required by FDA, we would be relying on those third parties to do a lot of the inspection work for us. That doesn't mean that there aren't costs associated with that. We would have to certify those third parties to make sure that they are inspecting in accordance with our regulations. But it is very difficult at this point to say exactly how much additional revenues we will be needing until we have a clearer picture of what new authorities that we have already declared we need in order to——

Mr. PALLONE. Well, do you want to make a distinction between your plan versus this bill? I mean, I know this bill you are just seeing in the last few days, but do you want to talk about the cost of additional money under your plan at least?

Dr. SUNDLOF. Well, under our plan, again, we would have—it depends again on the amount of inspection that is going to be required. Under this particular plan, the Globalization Act, it would basically require that every food manufacturer in the world that exports to the United States would have to be inspected at a fairly regular frequency, either 2 or 4 years.

Mr. PALLONE. Do you have cost estimates for your plan anywhere in the agency at this point you could give us?

Dr. SUNDLOF. We don't have cost estimates at this time. The plan that we were talking about said that we would take a tiered approach, that we would have more frequent inspections for those high-risk plants and fewer inspections for plants that——

Mr. PALLONE. Well, let me just ask you this because I want to get to the second question. If you can at some point—I am sure at some point you are going to put some kind of cost on your plan—

get back to us because obviously the amount of funding is a big issue here in terms of how we pay for it.

In your testimony, you mentioned three core elements that are vital to ensuring a safe food supply including concepts like prevention, intervention, and response and, while prevention is very important to me and is a central theme in my bill on food safety, I don't think we should be just reacting to instances of contaminated food but instead we should make sure things—we should make sure those instances never happen in the first place. And yet at the same time, in your testimony you are only asking for authorities in specific areas such as the power to protect against the intentional adulteration of food and for high-risk foods. However, the recent outbreaks have not been intentional nor have they solely affected high-risk products, and yet Americans are still dying from foodborne illnesses. So my question is, does the FDA currently have the authority to protect the American people from low-risk, non-intentional outbreaks, and if not, what authorities do you need to do so, to provide those protections?

Dr. SUNDLOF. Thank you, Mr. Chairman. We do have the authority to protect the public against both high and low risk. What we are requesting in the Food Protection Plan and Import Safety Action Plan is the authority to explicitly require that companies that have higher-risk foods that they are producing have plans in place, written plans in place that we can audit against to make sure that they are following a preventive program so that contaminated food does not get to the public. Now, for lower-risk plants, we would encourage those low-risk plants to also have similar preventive measures in place. We think that in order to make the maximum use of our resources, that we should be targeting those firms that produce high-risk products.

Mr. PALLONE. So essentially you have the authority, in your opinion, for both right now but you are focusing on high risk?

Dr. SUNDLOF. We are focusing on, we would like to have explicit authority to require firms that produce high-risk foods to have plans in place and documented so that we can inspect against those particular plans. Right now that authority is explicit for seafood and I believe at least seafood and other high-risk products there is no explicit authority for that.

Mr. PALLONE. Thank you.

The gentleman from Georgia.

Mr. DEAL. Thank you.

Dr. Sundlof, one of the concerns that you have already heard expressed from members here in opening statements and one that my State would have a concern about too is the lack of FDA inspection facilities adjacent to our ports of entry. Would you briefly address that concern and how would you propose to deal with the concern about having inspection facilities available at ports of entry?

Dr. SUNDLOF. Yes, so laboratory facilities at ports of entry.

Mr. DEAL. Yes.

Dr. SUNDLOF. Well, I can just say that depending upon what kind of food is imported into the United States, it may not make a difference whether or not there is a laboratory there because that laboratory may not be doing the types of analysis that we would require. For instance, if it was seafood and the particular labora-

tory was only looking at things like pesticide residues, it wouldn't—there would be no effect on having a laboratory right there. We believe that with the rapid transportation that is available today that products can be shipped from the port of entry to any of our laboratories within 24 hours, and that really doesn't represent a problem for us.

Mr. DEAL. Well, obviously, as you have already heard, States are very concerned about their own competitiveness in terms of what may be mandated for inspections that will dictate laboratory analysis. I think that is one of those concerns that all of us are going to have to be very aware of in terms of anything legislatively mandated in that regard. My State, for example, as I understand, does not have a laboratory except in Atlanta, Georgia, which is very much inland from our ports. So that will be a concern that you are going to continue to hear, I think, and something that as a practical matter all of us both at the legislative level and at the enforcement level need to look at very carefully and have a more thorough understanding.

In that regard, could you expound just a little bit about the existing agreements with other countries in terms of, you indicated that the authority to rely on the exporting country to certify safety is an important element in this whole process. How successful do you think that currently is? What needs to be done? If we need to beef up that end of it, what needs to be done there?

Dr. SUNDLOF. Thank you. Currently the only agreement that we have underway is with China and we have just begun that process, and we have identified certain high-risk foods, seafood being one of them, that we would require that the Chinese government certify to our standards that those products were safe before they ever left the port. We are considering similar agreements with other countries for which we have concerns about their ability to ensure that the food is safe. What we have asked for in the Import Safety Action Plan is the explicit authority to require certification from other countries as a condition of them being able to export to the United States.

Mr. DEAL. Obviously that could potentially impact trade agreements and other matters, and you indicated that consultation with the U.S. Trade Representative Office was one of the areas that needs to take place, and I agree with that. Would you, after you and your staff have consulted with USTR, would you be willing to come up and brief us staff-wise and members who are interested on what those kind of trade implications might be and areas of concern that we should be aware of in that regard?

Dr. SUNDLOF. Certainly.

Mr. DEAL. I think that would be very helpful for us to have a pretty detailed understanding of the interaction between all of these things as it relates to what we are trying to legislatively achieve here.

Thank you, and I would yield back my time.

Mr. PALLONE. Thank you, Mr. Deal.

Recognize Chairman Dingell for 5 minutes for questions.

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy.

These questions to the Food and Drug Administration. The Science Board estimated that over the past 35 years your inspec-

tion capability has fallen 78 percent because of cuts in funding. In addition, they estimated that you inspect food manufacturers once every 10 years. They also estimated that you made only 96 overseas food inspections last year out of a potential for 180,000 or more facilities that needed inspection. Are these statements true?

Dr. SUNDLOF. I believe they are, sir.

Mr. DINGELL. All right. Now, let us look at your situation. You have the unfortunate situation that you have received huge cuts so your ability has declined enormously over that period of time. You now do not know what the additional burdens imposed on you by this bill will do. I am asking you at this time to submit to us in writing at your earliest convenience a statement of what you need to carry out your current responsibilities, and second, what you will need under this bill to carry out the responsibilities imposed upon you. Can you give me a quick and dirty answer as to what you will need to bring yourself current with your present responsibilities under law in terms of inspecting food-producing establishments? How much?

Dr. SUNDLOF. I don't have a number for you.

Mr. DINGELL. Then we will send you a letter and I will expect that you will give us a response.

Mr. Chairman, I ask unanimous consent that the record remain open for that to be inserted.

Mr. PALLONE. Without objection, so ordered.

Mr. DINGELL. Now, tell us, please, about what the additional responsibilities will be as asked about by our very able chairman.

Dr. SUNDLOF. Well, the additional responsibilities both in the Food Protection Plan and the Import Safety Action Plan and in the bill that we are discussing today is going to be that we will take on a new role and that is as a certifying body, that we will certify other, whether it is a foreign government, whether it is a State agency, or whether it is a private industry, private sector industry, to inspect to our standards.

Mr. DINGELL. In order to enable us to make a proper appraisal, we will also include that question and you give us a more detailed and thoughtful answer on that.

Now, I would like to address risk-based systems and information and structure. According to the Science Board, FDA lacks information science capability and information infrastructure to fulfill its regulatory mandate. They found that there is insufficient capability in modeling risk assessment and analysis. Are you familiar with that statement?

Dr. SUNDLOF. I am familiar with the statement, sir.

Mr. DINGELL. The report goes on to state FDA IT infrastructure is obsolete, unstable, lacks sufficient controls to ensure continuity of operations or to provide effective disaster recovery services, and they go on to observe that, given the lack of dependable IT infrastructure, an eroding science base, and a dwindling workforce, they raise questions about whether FDA can effectively model risk to evaluate food shipments entering the interstate commerce currently. Are you familiar with that?

Dr. SUNDLOF. Yes, sir, I am.

Mr. DINGELL. Do you agree with that or disagree with it, yes or no?

Dr. SUNDLOF. Well, I don't completely agree with that. We have put a lot of emphasis in fact when we announced——

Mr. DINGELL. Just simply, because our time is limited, do you agree or disagree?

Dr. SUNDLOF. I disagree with the entirety of the statement, not with the—let me restate that. I don't disagree with the entirety of the statement. There are certain statements within that that I do disagree with.

Mr. DINGELL. Now, you have down there two different systems of handling your data and information, do you not?

Dr. SUNDLOF. I am not sure what you are referring to.

Mr. DINGELL. Please submit the answer to that for the record. I believe you do.

Now, Commissioner von Eschenbach stated before the National Press Club in February of 2008 that he will continue to make his staff available day or night to work with Congress on food safety legislation. Tell me when the Administration will have its comments to us regarding the discussion draft.

Dr. SUNDLOF. I don't have a time frame. I know that we are working——

Mr. DINGELL. I would like it at your earliest convenience.

Mr. Chairman, just one more question.

You state in your testimony that any legislation should empower robust, voluntary, private sector efforts and that such is already underway. Is that correct?

Dr. SUNDLOF. That is correct.

Mr. DINGELL. My time is expired, but I want you to submit to us a clear statement of what that means and what you are in fact doing to give us these robust voluntary private sector efforts that are already underway.

Mr. Chairman, I thank you for your courtesy.

Mr. PALLONE. Thank you, Chairman Dingell.

Ranking Member Barton is recognized for questions, 5 minutes.

Mr. BARTON. Thank you, Chairman Pallone. I have been watching the hearing on my television set as I was in a series of private meetings so I somewhat kept up with the hearing although I haven't been here in person.

Dr. Sundlof, has the FDA taken any kind of an official position on the bill that is the subject of this hearing today?

Dr. SUNDLOF. No, the Department has not taken an official position.

Mr. BARTON. If you read your testimony, one could interpret that the FDA would prefer, instead of a strict regulatory approach, more of a risk-based approach. Is that a fair statement?

Dr. SUNDLOF. Yes, it is a fair statement that we would prefer to use our resources to apply to the highest risk areas rather than a broad, across-the-board inspection program.

Mr. BARTON. Do you see a possibility, since this is a discussion draft, to have a meeting somewhere in the middle between the approach in the bill before us and the approach where you have limited assets and you apply those more risk-based approaches? Is there a possibility to meld those two together?

Dr. SUNDLOF. I would certainly hope so.

Mr. BARTON. I would too. Would you care to comment on the use of third parties for certain functions as opposed to having everything be done directly by paid employees of the FDA?

Dr. SUNDLOF. Well, sir, I think it is impractical, especially when we are talking about foreign inspections, to think that the FDA could possibly cover 150 different countries and somewhere between 140,000 and 180,000 different manufacturers. First of all, it would require that we had agreements with all those foreign governments to go in and inspect but the reality of that situation is that if everybody took that approach, then every country would be inspecting every other country and it would be a continuous string of inspections that would go on and I don't see how a company could actually produce food under those conditions because they would be constantly inspected by every country. So we believe, and I think it is consistent with the proposed legislation, that we rely on either foreign governments to certify according to our standards or third party independent folks to certify to our standards and that we would have an auditing function to make sure that they are in compliance with our standards.

Mr. BARTON. Is it fair to say that the approach you just outlined, if I understand correctly, is used right now on the drug side? Don't you have that same approach for inspecting drugs and drug ingredients?

Dr. SUNDLOF. We do with a few countries under mutual recognition agreements, not all countries but more and more. We are looking to other countries if we believe they are equivalent to our system, and utilizing the information that they gather from their inspections.

Mr. BARTON. But there would be a precedent on the drug side in some countries?

Dr. SUNDLOF. Yes.

Mr. BARTON. All right. What is your view of the proposal that all food imports have to come into certain ports that already have an FDA laboratory?

Dr. SUNDLOF. Well, again, our food laboratories are scattered throughout the United States, not always associated with ports of entry, and that different types of testing and sampling occur in various parts of the United States. So even if the import did come to a port where there was a laboratory, there is no guarantee that that laboratory could actually run the analysis that we would want and so we would still have to ship that sample to another laboratory in the United States that specialized in that particular testing. So at least from my view is that it doesn't gain us very much, requiring that the particular port have a laboratory.

Mr. BARTON. My time is about to expire. My last question, if I understand the bill correctly, it also restricts the ability of the FDA to reorganize or relocate any of these food inspection laboratories. In the 21st century, do you think that is good public policy to put that kind of a restriction into law?

Dr. SUNDLOF. Mr. Chairman, I think that we always want to preserve our flexibility in the FDA to put our resources where we think they will serve in the best interest of the public.

Mr. BARTON. Thank you, Chairman Pallone.

Mr. PALLONE. Thank you, Mr. Barton.

Next is our vice chair, Mr. Green, recognized for questions.

Mr. GREEN. Thank you, Mr. Chairman, and I think some of the questions I have may have been answered, but Doctor, you heard my opening statement. I have the Port of Houston and we don't have a lab. In fact, we don't have one in the State of Texas, even though we have the biggest land port I guess in the world, in Laredo and Nuevo Laredo, Texas, for goods including foodstuffs. Do you happen to know what the lab in Arkansas's specialty is? Is it really food testing or is it something else the FDA may be doing?

Dr. SUNDLOF. I am going to ask Dr. Solomon to respond to that.

Dr. SOLOMON. They do do food in the Arkansas lab, among other areas, but food testing is one of their areas.

Mr. GREEN. And I don't know who put the lab there but I can imagine if it was a Member of Congress, somebody from southern Arkansas many decades ago, and I understand how that works and that is why if the bill makes some changes, it should recognize that there are ports that have a great deal of foodstuff coming in, and I know you can oversight stuff and I know the bill hopefully will call for alternative certification at independent labs that are certified and would not pick winners and losers in a bill based on the 13 lab locations.

The FDA's use of voluntary registration or certification before they regulate food and drugs, and are these labs able to handle the current workload or with this increased workload that you would have? Now, I have to admit, I have been on the docks at the Port of Houston and had FDA inspectors there with me, so we have inspectors on the docks.

Dr. SUNDLOF. Again, I am going to ask Dr. Solomon to respond to that.

Dr. SOLOMON. We are always looking at our laboratories and other activities to see their capacity, their capability, their timeliness of doing work, and we are continually evaluating how we can improve that because testing is one component of trying to get assurances about the safety of food, so we are handling our current workload. We understand that there is more work that needs to be done and we are looking to obtain additional efficiencies by trying to improve the laboratory capabilities, capacity, and their timeliness.

Mr. GREEN. And the last thing is, I know this bill provides additional funds for the expansion, and would the FDA, with these funds, intend to add more labs and particularly locations that have a great deal of imports that you would need, and would you consider locating them in areas that have that high food import or trade levels?

Dr. SUNDLOF. Right now I don't believe that we have made any kind of decisions about increasing laboratory capability. One of the things we are considering is recognizing independent laboratories and accrediting those laboratories to conduct analysis that would supplement the work that is currently done in the FDA laboratories.

Mr. GREEN. And I know the cost issue, if it costs so much to do at an independent lab, that it would be maybe cheaper to actually establish an FDA lab in a location if you have enough business to do it.

Dr. SUNDLOF. It is certainly something that we would consider.

Mr. GREEN. Thank you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you, Mr. Green.

The gentleman from Indiana, Mr. Buyer, for questions.

Mr. BUYER. Thank you.

To either of you, do you think it is important to have a non-delegation clause when it comes to the authority to issue a mandatory recall?

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

Mr. BUYER. Do you believe it is important to have a non-delegation clause when it comes to the authority to issue mandatory recall?

Dr. SUNDLOF. OK. Thank you. Let me just say that in virtually every situation where we have asked for a recall, we have gotten compliance from the regulated industry. So it would be a very rare event if we asked for a voluntary recall and we were denied that recall. And in those extraordinary circumstances, I don't have concerns that that delegation would be given to the Commissioner or even the Secretary because I believe these would be fairly extraordinary circumstances.

Mr. BUYER. Why is it an important issue for you?

Dr. SUNDLOF. Why is it an important issue? It is an important issue because we believe that there could be circumstances where the public's health was at risk and where we were not given—our request for voluntary recall was denied and we would never want to find ourselves in that situation, where we couldn't go out and ensure that we could remove any potentially risky food products from the marketplace.

Mr. BUYER. Regarding your risk-based approach to, I don't care whether the issues are in drugs or here in food, when you set forth the model or the paradigm to do that, there are acceptable levels of risk that you have to take. So when you articulate to us that you prefer risk-based approaches, can you elaborate a little bit further on why that is the preferable approach?

Dr. SUNDLOF. It is the preferable approach because we want to make sure that with—the universe of food out there is obviously vast. We have limited resources and we want to use those resources as judiciously as we can to target those products that we believe have the greatest potential to cause harm to public health. So it is purely from the standpoint that we first of all want to have systems that we can identify what is a high-risk food, why is it high risk, and then make sure that we are paying adequate attention to those high-risk foods to ensure that they are safe and not ignoring the lower-risk products because we are finding that some of the products that we thought were low risk in the past actually turned out to be higher risk than we thought. We are really targeting our efforts to make sure that we are addressing the food that has the highest potential to cause harm to the public health.

Mr. BUYER. When you come to judgment, do you have interagency cooperation or interdepartmental cooperation with the Department of Homeland Security?

Dr. SUNDLOF. We do have frequent interactions with the Department of Homeland Security and we do discuss these issues.

Mr. BUYER. When you say "and we do discuss these issues," so with regard to interfacing of targeting systems in your risk-based approach with regard to countries, localities, territories, companies that are on certain lists, is that what we are talking about?

Dr. SUNDLOF. With Homeland Security, we have come up with a risk paradigm to identify which products have the greatest potential for causing a catastrophe should the food become adulterated intentionally, and I think Dr. Solomon has some more information on that.

Dr. SOLOMON. The prior notice submission for food entries were located with Customs and Border Protection and Homeland Security at the National Targeting Center and our staffs along with USDA work side by side in looking at the assessment of entries coming in and particularly from a concern about bioterrorism concerns making those assessments jointly and sharing information so that co-location is very valuable to us. Other examples on Homeland Security relate to the pet food contamination, when we worked to stop product coming in from China, the wheat gluten and the rice protein concentrate, Customs and Border Protection and Homeland Security went out and did a nationwide blitz to see was there any evidence of this product, this contaminant coming in from any other country. So we focused on the initial product and Homeland Security focused on the rest of the border issues.

Mr. BUYER. Thank you very much.

Mr. PALLONE. Thank you.

The gentlewoman from Wisconsin, Ms. Baldwin, for questions.

Ms. BALDWIN. Thank you, Mr. Chairman.

Dr. Sundlof, you have already addressed a couple of questions relating to the third-party system that is being proposed in this discussion draft to enhance and augment FDA's food testing capabilities. As I understand it, FDA currently works with independent testers like Covance, who will be represented in the next panel. So I wonder, from your experience with independent testers, do you agree that they do sound, independent scientific testing, and also, can you speak to what sort of accreditation process you would envision FDA undertaking to ensure that the testing done by third parties is rigorous and in accordance with the highest scientific standards?

Dr. SUNDLOF. Thank you. We currently do rely on independent third-party laboratories when, for instance, we have an import alert against a product coming into the United States. We require that those importing firms have their product tested upon entry to the United States and that they pay for that their through an independent third-party laboratory and then we review the results of that so we do have some good relationships. We do rely on them right now. In terms of accrediting, there are certain laboratory accreditation standards that I believe we would be relying on in officially accrediting. Right now we don't accredit. We would like to accredit. We rely on the testing results of certain laboratories that we have confidence in but we want to take that to the next step and actually be able to accredit them. There would be—there are very good accreditation standards in place and we would most likely rely on what is already out there.

Ms. BALDWIN. What sort of accreditation processes are in place that you don't currently use but you might?

Dr. SUNDLOF. I think there are some ISO standards. I think there are other standards. I am not familiar with all of them right now.

Ms. BALDWIN. The other question I have is, sort of trying to move FDA from basically being in a reaction mode for food safety issues and looking at what actions the FDA should be taking to prevent food contamination, food safety incidents before they even occur, and what could the FDA be doing right now to prevent future food safety threats? What additional authorities do you think the FDA needs to be more proactive and preventive, and what are your comments on the draft legislation's provisions that seek to enable FDA to act more proactively by requiring foreign and domestic food facilities to have safety plans in place to identify and mitigate hazards?

Dr. SUNDLOF. Thank you. What we asked for in our Food Protection Plan and Import Safety Action Plan is somewhat similar to what is in the proposed legislation. Under both of those plans, we would require two things. First, for intentional contamination, we would want our high-risk food areas to have certain preventive measures documented and in place that we could inspect against so that is a preventive measure. The other one that we asked for is for high-risk food production facilities, that they would have HACCP-like plans in place that we again could—mandatory—that we could inspect against to ensure that they were—that they did have effective preventative programs in place.

Ms. BALDWIN. Thank you.

Mr. PALLONE. The gentleman from Pennsylvania, Mr. Pitts, is recognized for questions.

Mr. PITTS. Thank you, Mr. Chairman.

Dr. Sundlof, do you think requiring the labeling of the country of origin of every ingredient in a product will improve the safety of that product, and if so, why?

Dr. SUNDLOF. The safety of the products that come into the United States from other countries should be as safe as the domestically produced products. We are asking for these new authorities to help ensure that but I don't want people to feel that relying on a country of origin label is going to give them information about the safety of that particular product. It should meet the United States' standards.

Mr. PITTS. And what is your primary concern about supporting the country of origin labeling?

Dr. SUNDLOF. I don't have—I don't think I have a position on whether or not to support or not support country of origin labeling, only that it should not be viewed—if there is country of origin labeling, that it should be viewed as a way for consumers to make judgments on the safety of the product. We don't believe that country of origin labeling in any way should be associated with the safety of foods imported from other countries.

Mr. PITTS. What is it related to then?

Dr. SUNDLOF. Well, it would be something other than that and again, we have not taken a position on anything else. From the point of view of the FDA, that is the thing that we are concerned

about the most is that food that is imported conform to the same standards as domestically produced food and therefore country of origin labeling does not provide any additional information.

Mr. PITTS. Are you concerned about possible confusion with a requirement for labeling to the public and the concern about the difficulties of a manufacturer to comply and the cost for changing ingredients? For instance, if you have a product with 22 ingredients, and one of them is from Brazil, and, let's say Brazil has a drought. The company may gave to go to Argentina for that particular ingredient. Are you concerned about the constantly changing label, the requirements?

Dr. SUNDLOF. Again, since the FDA has not asked and the Administration has not asked for country of origin labeling, that is not something that we even consider at this point.

Mr. PITTS. Do you think it would be a mistake if food safety legislation tried to undo what many food manufacturers have already put in place in regards to food safety and replace it with a system that relies on inspections of all facilities and testing of all food shipments?

Dr. SUNDLOF. Certainly we don't believe that inspection or sampling and testing of all food shipments is a feasible approach, considering that we receive somewhere on the order of almost 10 million import entries per year, at least at this time, not even feasible to try and test our way into safety.

Mr. PITTS. If we are going to have the safest food supply system possible, don't we have to rely or put more onus on the manufacturers to prevent food safety issues?

Dr. SUNDLOF. Yes, absolutely, and that is one of the principles of both the Import Safety Action Plan and the Food Protection Plan is to put especially the prevention responsibility on the suppliers, manufacturers that are——

Mr. PITTS. Do most corporate food manufacturers have safety systems in place to prevent both intentional and unintentional food contamination?

Dr. SUNDLOF. Many of them have excellent systems in place, not all of them.

Mr. PITTS. Would you say most of them?

Dr. SUNDLOF. I don't have a figure on that. It becomes a matter of, you may have many, many small companies that produce a small percentage of the food versus large companies that produce a much larger—a few large companies that produce larger percentage but we are aware of many good plans already in place.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

Next is the gentleman from Utah, Mr. Matheson, recognized for questions.

Mr. MATHESON. Well, thank you, Mr. Chairman. Mr. Chairman, I would like to work with you on another issue, which is not currently included in the discussion draft before us but I think it is an issue that is very much within the purview of the FDA and food safety and I think it should be included in legislation that we move here in the House. This is a problem that stems from the lead content of certain ceramic or decorative food ware such as plates.

In my home State of Utah, and I am sure in districts throughout the country, consumers are unaware that lead is component of glazes and can leach out of ceramic ware if the glaze is improperly fired or worn down from daily use. Children are at particular risk of lead exposure and this risk is compounded when we are talking about food containers because kids frequently consume acidic juices that leach lead from ceramics. Now, this issue recently hit home for me. A young mother in Utah who was breastfeeding her baby used ceramics plates to heat her food in the microwave. Her infant became very sick and ultimately her doctors discovered that the baby was suffering from lead poisoning because of the plates used in the food preparation for her mother. This mother was completely unaware of the potential health risk posed by certain ceramic ware products, as I suspect many, if not everyone in this room, as well would be aware of that risk.

Mr. Chairman, I brought with me a brief video clip of news coverage which I think will give my colleagues on the Committee as well as our panel a better snapshot of this issue just as brief background. In November of 2007, over 400 people lined up at the Salt Lake Country Government Center to have bags and tubs filled with dishes along with toys and jewelry tested for lead levels. Once they found out that this is a problem, the public has responded with great concern. You will see lines of people in the video, which showcases the magnitude of interest in the problem. This runs for less than a minute but it helps highlight the story of this mother and her baby. Could we run the video?

Mr. PALLONE. And I will mention the gentleman actually has an additional 3 minutes from what it is up there, because you had 8.

[Video shown.]

Mr. MATHESON. Well, as I said, I wanted to give a brief clip just to show how I found out about the issue and show how compelling it is when you see Chloe and her mom, who were subjected to this.

Dr. Sundlof, what I wanted to ask you, first of all, I first want to just confirm, are you aware of the cases of lead poisoning among children that have been traced to ceramic dishes?

Dr. SUNDLOF. No, sir. The last one that we are aware of in which ceramic ware was involved, and we don't know if that was actually the cause of the increased blood lead levels in a child, was in 2004, and that was, I believe, in New York and there was a ceramic plate that was imported from France. That child did have elevated levels of lead in the blood but it is not clear as to whether the plate was the source or not. We do have standards. The FDA does have standards for lead in ceramic ware and we test at the borders for that.

Mr. MATHESON. What percentage of plates coming in do you test?

Dr. SUNDLOF. I will ask Dr. Solomon for input.

Dr. SOLOMON. We actually do several different tests. One is a quick swab test, because the issue with lead——

Mr. MATHESON. Just how many do you test though? I guess that is what I am interested in. I mean, I can't believe it is many of the plates coming in. Is it a small percentage that actually get tested?

Dr. SOLOMON. We would have to get back to you for the record.

Mr. MATHESON. I understand there is a Memorandum of Understanding that the FDA has signed with the state administration of

entry, exit, inspection and quarantine in China, and in that Memorandum of Understanding, you established a certification system that ceramic ware made in China that is imported to the United States would carry an inspection stamp. On the box it has a CCIB stamp for the Chinese organization. It also carries an FDA stamp. So when consumers go and buy these plates, and I have seen them in the stores in Utah, there is an FDA stamp on the box, but that stamp doesn't necessarily provide any information to the consumer about lead content. What protections does that stamp indicate to consumers when they see the stamp on a ceramic plate that is being sold in the United States?

Dr. SUNDLOF. This may not be the authoritative answer and I will get back to you if it is not, but what I believe that means is, we have assurances from the Chinese government that ceramic ware that is exported to the United States will meet our standards for lead. That doesn't mean that they don't have any lead in them but they will meet the low levels of leachable lead that we have established.

Mr. MATHESON. See, what I think is, consumers, when they see an FDA label on a box, assume it is safe. That would be what I would assume. I think that is what most people would assume. And I think most consumers have no idea that lead exists in ceramic ware at all. Wouldn't it be more useful at least to have a label on the box that mentions that this product may contain lead? I mean, I have got a plate right here. I can't tell that it has lead but it has been tested. It has all kinds of lead in it. I have a plate right here that was sold by another company where they have stamped on it that it lead-free so you have some manufacturers that will tell you that they don't have lead in their product but both of these that came from overseas are going to have that FDA label on the box and that doesn't give me as a consumer much information at all. So it seems to me it might be helpful if we could maybe at least inform consumers that there is lead in the product. Would FDA be open to something like that?

Dr. SUNDLOF. Well, the way that we—rather than declaring something to be lead-free, we have established levels at which we don't believe that there is any harm to public health, that the levels of lead are extremely low that leach from these ceramic utensils. One of the other things that—what we are concerned about is the lead that can actually leach out of the plates. Many of the glazes do contain lead but if they are fired correctly in the process of manufacturing these plates, then that lead should be sealed there into the plate and not be available for ingestion.

Mr. MATHESON. I am not here to argue about the level that is safe or not safe. I would suggest that in the testing that was done for hundreds of people in Utah, the levels were all over the map. Some of them were well in excess of FDA's standards. And secondly, we don't know if the glaze has been fired correctly, and as a consumer, I can't tell you if the glaze is right on this plate. I have no idea if the glaze has been fired correctly. As a consumer, until I saw this story on the news back in Utah, I didn't know there was lead in this.

So Mr. Chairman, I am very anxious to see if there something we can do in this bill to make sure consumers are better informed

about the possibility of lead being in these plates so they can make their own decisions about using this type of plate to microwave food, and I appreciate you working with the Committee on this and I appreciate your indulgence with the extra time for questioning. I yield back my time.

Mr. PALLONE. Thank you, and we will certainly follow up on your request.

Next is the gentlewoman from North Carolina, Ms. Myrick for questions.

Ms. MYRICK. Thank you, Mr. Chairman.

I just have one question, Doctor. What would you say is the most cost-effective way in broad terms to improve food safety in this country without dramatically increasing the price of food, which is already very high right now and moving up?

Dr. SUNDLOF. Well, if I look at all of the legislative authorities that we have requested in the Food Protection Plan and Import Safety Action Plan, I believe that third-party certification, where we can multiply our inspectorate by the use of independent third parties is the most effective way to improve the safety.

Mr. PALLONE. Thank you.

The gentlewoman from Oregon, Ms. Hooley, for questions.

Ms. HOOLEY. Thank you, Mr. Chair. I have a question for Dr. Sundlof. Actually I have lots, but I am going to try to narrow this down.

You mentioned in your testimony that FDA recently signed a Memorandum of Understanding concerning food safety and facility registration with China. Were you aware, and this may be happening in other States as well, that Oregon Department of Agriculture has been working for the last couple of years with China on food processing facility inspection protocols? What is your opinion of the role of States in food safety?

Dr. SUNDLOF. I was not aware of that, and I don't have a position on that. We can get back to you on that.

Ms. HOOLEY. OK. That would be helpful.

Several years ago, I was very involved in passing country of origin food labeling that actually made it through the House and the Senate and signed by the President and yet it has really never taken place. The question is, is that ever going to happen, number one. And number two, as we look at food processing and in talking to at least some of my food processors in my district, they were talking about, there are examples where they may get garlic that is a mixture of garlic from several companies that they put into whatever food they are making or they may have a bad year for broccoli one place and so you get it someplace else the next year. What do you think, and how do you do this if you are going to label that can or put it on a Web site? I mean, whose Web site, what do they have to list? Is it the final manufacturing where it is put in the can or put in the containers or whatever they put it in? Is that going to work, first of all? And will the public have more assurance that that will in fact make our food safer?

Dr. SUNDLOF. Again, the FDA did not ask for country of origin labeling. I believe the U.S. Department of Agriculture does have that authority as well as the Treasury, I believe. We do not. We didn't ask for it. As you indicated, there are complications in trying

to do that with the many ingredients that may make up a food and the fact that those sources of ingredients can change overnight. We certainly, as I said earlier, do not want or believe it is in the best interest of the public to be viewing country of origin labeling as a way of determining whether or not a product is safe because those products need to meet the U.S. safety standards just as domestically produced food.

Ms. HOOLEY. Thank you very much.

Mr. PALLONE. Thank you, and I think that concludes our questions. Thank you very much for your input, and in those cases where we asked for follow-up questions, if you could get back to us in writing as quickly as possible. Thank you again. Thank you both.

Dr. SUNDLOF. Thank you, Mr. Chairman.

Mr. PALLONE. And I would ask the next panel to come forward. I want to welcome our second panel, and let me introduce each of you. Starting on my left is Mr. Michael Taylor, who is research professor of health policy for the Department of Health Policy of the School of Public Health and Health Services of George Washington University. Next is Mr. Michael Ambrosio, who is vice president for food safety and quality assurance of the Wakefern Food Corporation in Elizabeth in my home State of New Jersey. And then we have Mr. James Lovett, who is a corporate senior vice president of Covance Laboratories. This says based in Princeton, New Jersey, but I know you mentioned—oh, OK. I know you mentioned Wisconsin as well. And then we have our colleague, the Honorable Cal Dooley, a former Congressman and president and CEO of the Grocery Manufacturers Association. Good to see you again, Cal. And finally is Ms. Caroline Smith DeWaal, who is the food safety director for the Center for Science in the Public Interest, who has been working on these issues for many years. Good to see you as well.

As I mentioned, we have 5-minute opening statements from each of the witnesses. Those statements will be made part of the hearing record. Each witness may in the discretion of the Committee submit additional brief and pertinent statements in writing for inclusion in the record, and I will start again on my left with Mr. Michael Taylor, who is recognized for 5 minutes. Thank you.

STATEMENT OF MICHAEL R. TAYLOR, RESEARCH PROFESSOR OF HEALTH POLICY, DEPARTMENT OF HEALTH POLICY, SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, GEORGE WASHINGTON UNIVERSITY

Mr. TAYLOR. Thank you very much, Mr. Chairman, Ranking Member Deal and members of the Committee. I appreciate the opportunity to testify today on the discussion draft of the Food and Drug Administration Globalization Act. Last year, as I think we have already heard this morning, the Government Accountability Office declared the Federal Government's food safety program at high risk of failure due to its outdated laws, fragmented structure, and inefficient use of resources. This came after a decade of recommendations from GAO and the National Academy of Sciences to modernize the system legislative and organizationally so that it can be effective in preventing food safety problems instead of simply reacting to problems after the fact.

So Mr. Chairman, I applaud the subcommittee for tackling this critical issue and for focusing first on the obsolete food safety laws under which the Food and Drug Administration operates. FDA's legal tools for addressing foodborne illness and the safety of imported foods were enacted in 1938. They may have been suitable for their time but they focus more on reacting to problems rather than preventing them and they are plainly inadequate to deal with today's globalized food supply.

As we embark on modernizing these laws, I urge the subcommittee to be clear first on the basic policy principles that should guide reform, and I think you will find good agreement among experts on the following five principles, and in fact, we have heard most of them embraced in varying ways already this morning.

First, it is critically important to treat food safety as a farm-to-table systemwide problem. This simply recognizes that hazards can be created and minimized at many points across the food system. Second, we must make prevention of food safety problems the central focus of the system because this is the only way to protect public health and maintain public confidence. Third, we must recognize that the primary duty for prevention falls on the food industry, as we have heard this morning. It is the industry, not government, that produces food, and only the industry can make it safe. Fourth, we must focus FDA on setting and enforcing standards that make the food industry accountable for prevention. Ensuring accountability by setting and enforcing standards is the unique and most essential government role on food safety. Fifth and finally, we must strengthen FDA's mandate for providing national leadership and international leadership on food safety and bolster the agency's tools for managing a science- and risk-based regulatory program. This includes a stronger research mandate and working with State and local governments to build a nationally integrated food safety system that makes good use of all its resources.

Now, I think that the discussion draft that is on the table for discussion today embraces most of these principles to varying degrees. First and foremost, the discussion draft is, I believe, on the fundamentally right track in mandating safety plans and preventive controls for all food facilities, domestic and foreign. Importantly, it also recognizes in order for food safety plans and preventive controls to be effective in improving food safety and enhancing public confidence, the plans must be linked to food safety outcomes in the form of performance standards set and enforced by FDA. To me, this coupling of preventive controls with objective measures of performance is the most essential element of meaningful food safety reform.

The discussion draft also addresses the important issue of food safety at the farm level with what I think is a very judicious approach to establishing standards for fresh produce and it includes some innovative ideas for enhancing oversight of imported foods. Overall, I think the discussion draft is the right starting point.

As outlined in my written testimony, however, I do have questions about some provisions, such as the proposal for certification of food facilities. While I see its potential value for imports if done by credible third parties, I think we have to focus first on strengthening the accountability of importers themselves for ensuring the

safety of the food they import, and further, I do not think that FDA should be in the business of certifying food facilities.

In moving forward with this legislation, I hope the subcommittee will also consider measures to strengthen food safety oversight at the retail level in collaboration with State and local agencies and to give FDA the research mandate and resources it needs to restore its scientific leadership on food safety. Mr. Chairman, restoring FDA's capacity for leadership is critical to food safety and to public confidence in food safety. We need to get FDA's food safety policies right and then we need to back them up with the resources to do the job.

Thank you again for the opportunity to testify, and I look forward to questions.

[The prepared statement of Mr. Taylor follows:]

STATEMENT OF MICHAEL R. TAYLOR *

Mr. Chairman, Mr. Deal, members of the subcommittee, I appreciate this opportunity to testify on the food and cosmetic provisions of the Chairman'sFood and Drug Administration Globalization Act" discussion draft.

INTRODUCTION

I applaud the subcommittee for tackling the modernization of our food safety laws. For over a decade, the Government Accountability Office (GAO) and expert committees of the National Academy of Sciences (NAS) have been documenting fundamental problems in the nation's food safety system—a system that has evolved over many years without a coherent plan or strategy and that now includes some 20 components of FDA, USDA, EPA, and CDC, and 3,000 state and local agencies.

Among all these agencies, FDA has long been looked to as the natural focal point for food safety leadership in the United States and internationally. It oversees 80% of the U.S. food supply (including an even greater share of imported food) and is the steward of a long tradition of effective, science-based regulation to protect public health.

Unfortunately, FDA's current ability to provide food safety leadership, or even meet its basic food safety responsibilities, is badly constrained by:

- Obsolete statutes that date back to the 1930s and focus more on reacting to problems than preventing them;
- Inadequate resources that are dwindling in the face of an increasingly complex, global food supply; and an
- Internally fragmented and ineffectual organizational structure that makes FDA incapable today of providing effective food safety leadership.

Certainly, FDA could be doing more with its present tools to address some of today's pressing food safety problems. I believe, however, that FDA will continue to fall short of what the public needs and expects from this critical public health institution until Congress provides a modern statutory mandate, an adequate and stable resource base, and an institutional structure capable of national and international leadership on food safety.

And that is why it is so timely and important for this subcommittee to be focusing on how to improve FDA's food safety program. Getting food safety right at FDA is essential to the public's health, to the confidence people want to have in the food they feed themselves and their families, and to the economic success of the food system. The subcommittee's leadership will be essential to achieving these outcomes.

In my testimony today, I will outline what I believe are the core policy elements of a successful strategy for improving food safety, and I will comment on how these elements are addressed in the discussion draft of the "Food and Drug Administration Globalization Act of 2008" released on April 18 by Chairman Dingell. I will also touch on the need to provide FDA an adequate and stable funding base for its food safety program and to unify and elevate the organizational elements of the program

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so that FDA can once again provide food safety leadership, nationally and internationally.

In general, I find the discussion draft to be very much on the right track. It recognizes that food safety is a farm-to-table and global challenge and that FDA's program must be based not only on reacting to problems but on enforcing the duty of the food industry to prevent them. The draft legislation's core requirement that companies have food safety plans—and that the plans be based on the concept of preventive process control and be designed to satisfy government-established performance standards—is central to any meaningful modernization of the food safety system. The draft also contains innovative provisions to address the safety of imported food.

I will offer some suggestions for improving these and other provisions of the draft, and I will note some additional legislative needs I recommend the subcommittee consider.

CORE POLICY ELEMENTS OF A SUCCESSFUL FOOD SAFETY STRATEGY

The following are the five core policy elements that I consider essential to a successful FDA food safety strategy.

1. Treat food safety as a farm-to-table, system-wide problem.

For most of the 20th century, food safety regulators focused largely on basic sanitation in processing plants, chemical contaminants in food, and the safety of chemical additives. It was possible then for FDA to focus on a relatively narrow set of establishments, commodities, and decision processes through which those concerns could be addressed. Over the last twenty years, however, the problem of foodborne illness caused by microbial pathogens has emerged as a central food safety concern and one that requires a broader, "farm-to-table" approach to ensuring food safety.

A farm-to-table approach is required due to the simple reality that dangerous bacteria and other pathogens can enter the food chain at almost any point, from production on the farm through processing, retail sale, and final preparation for consumption; they can grow; and they can be killed. Thus, whether someone gets sick depends not on any one contamination event but on a wide range of events and behaviors that occur across the entire farm-to-table food system and that, in combination, determine the likelihood dangerous levels of an organism will be present at the point of consumption.

This expanded understanding of food safety makes everyone—from farmers to consumers, as well as government food safety agencies—actors in the food safety system. It creates the opportunity and need for integrated action to minimize food safety risks at points all across the farm-to-table system—wherever pathogens can enter the food and grow or be reduced. FDA's food safety program must recognize and act on this reality, as recommended repeatedly by GAO and NAS.

This broader understanding of the food safety challenge—and the need to act in a comprehensive, integrated way to meet it—applies with full force to the growing volume of food imports.

2. Make prevention of food safety problems the central focus of the system.

Prevention is the core principle of public health and should be the central focus of the food safety system. Prevention of problems is certainly what consumers expect of the system, and it's the core principle that drives modern approaches to food safety. Most notably, HACCP (Hazard Analysis and Critical Control Points) is a system of preventive process control that was developed originally by the food industry as a method for anticipating and preventing food safety hazards in particular food production and processing operations.

FDA has adopted HACCP as a regulatory requirement for seafood and juice, but prevention is not an explicit part of its statutory mandate. In fact, FDA's food safety legal authorities are designed primarily for reacting to and correcting problems after they occur, not for preventing them. In an on-going outbreak of foodborne illness, swift reaction and containment measures are important and can reduce the number of illnesses associated with that outbreak, but, to protect public health and meet public expectations for food safety, preventive measures such as HAACP need to be built in to the system so that the risk of food safety problems occurring in the first place is minimized to the greatest extent reasonably possible.

FDA currently pursues prevention of this kind only on a selective and ad hoc basis. A comprehensive, systematic approach to prevention should be a core principle and central focus of the food safety system.

3. Recognize that the primary duty for prevention falls on the food industry.

This may be the most crucial point to emphasize in getting roles and relationships between government and industry right. The unavoidable reality is that government does not make food, and government cannot make it safe. That's the food industry's

job, and making food safe—doing everything reasonably possible to prevent food safety problems—is the most fundamental duty food producers and processors owe to America's consumers.

Many of our Nation's leading food processors and retailers take this duty very seriously, and they make extensive efforts to fulfill it. They know food safety doesn't just happen; it's the result of a plan. So they impose safety specifications on their suppliers to be sure their raw materials and ingredients are safe, they implement HACCP and other preventive control measures within their processing plants, and they test their finished products to verify that their control systems are working. In fact, over the years, much of the food safety innovation in the United States has come from companies that take food safety seriously and have plans for achieving it.

The problem is that many of the nation's 44,000 food manufacturers and processors, 114,000 food retailers, and 935,000 restaurants do not have effective food safety plans. And, at the farm level, systematic planning for prevention of food safety problems is in its relative infancy. This must change.

Any business involved in producing, processing, and marketing food must have a plan for making it safe, based on modern preventive controls. This does not mean a one-size-fits-all approach. It does not mean HACCP per se for every commercial participant in the food system. But it does mean that anyone producing food for today's marketplace should know how they are going to make it safe and should do that consistently, every day.

4. Focus FDA on setting and enforcing standards that make the food industry accountable for prevention.While the food industry is inherently responsible for making food safe by acting preventively, FDA's job as a public health regulatory agency is to set and enforce standards that make the industry publicly accountable for prevention, in accordance with a defined standard of care. Setting standards for prevention means defining the responsibility of food producers, processors and retailers to have and implement food safety plans based on modern preventive controls. It also means establishing performance standards that define the level of protection, or food safety performance, that is to be achieved through preventive controls, such as the levels of chemical residues or microbial contaminants that are deemed acceptable.

Standards protect food safety, however, only if companies comply with them, and it is FDA's job to ensure compliance through inspection and enforcement. For many leading companies, compliance is not an issue: if the government sets a food safety standard, they will organize their systems to comply. In fact, many will go beyond what the government requires in response to the demands of their customers expressed in the marketplace. The food industry is, however, highly diverse, with some companies lacking the market incentive or an internal culture that ensures they meet high food safety standards. That's why government standards and government enforcement are needed, and it's why they are in the interest of both consumers and those in the industry who take their food safety job seriously and do it well.

Government regulation of food safety is essential, but it has to be smart regulation. We have learned that old fashioned "command and control" regulation—in which the government specifies not only the outcome to be achieved but how industry must achieve it—can impose unnecessary costs and stifle innovation. Instead, modern regulation is clear in setting performance standards for companies and flexible in how companies can achieve the standard. Thus, as a regulatory tool, HAACP sets a standard of care for implementing preventive process control but is inherently flexible in allowing companies to tailor their preventive controls to the particular hazards and circumstances in their operations. Performance standards for microbial contamination say what level and incidence are acceptable, but they do not dictate the interventions needed to achieve them.

In a food safety system based on holding the industry accountable for prevention, regulators have a duty not only to avoid stifling innovation but to affirmatively encourage it. This means among other things ensuring that regulatory review of new food safety technologies is done promptly and with an appreciation of the food safety benefits of technological innovation.

5. Strengthen FDA's mandate and tools for providing national leadership on food safety and managing a science- and risk-based regulatory program.While FDA's core role on food safety is to set and enforce standards, it will be effective in this role only if it operates from a position of strength as the nation's leading science-based, public health regulatory agency. To this end, FDA should have a clear mandate to drive research aimed at understanding food safety problems and solutions and setting science-based standards. It should work closely with CDC, other federal food safety agencies, and state and local agencies to build an integrated, national system of food safety protection. And it should provide scientific and policy leadership to

develop workable approaches to risk-based priority setting and resource allocation across the food safety system.

COMMENTS ON THE DISCUSSION DRAFT

The five core policy elements outlined above reflect current thinking about the attributes of a modern, effective food safety system, as that thinking has evolved through the work of NAS, GAO and other experts. I will organize my major comments and suggestions concerning the discussion draft around these five elements.

1. Treat food safety as a farm-to-table, system-wide problem.

As I understand section 102 of the discussion draft, it would apply the requirements for a food safety plan and preventive controls to all facilities that process or store food for the U.S. market, whether domestic or foreign. It thus strengthens and modernizes standards for food safety in these critical facilities and recognizes, properly, that U.S. food safety standards should apply to imported food just as they do to domestically-produced food.

The discussion draft also takes an important step in section 103 toward bringing agricultural producers more fully into the food safety system by making the food safety plan and preventive control requirements applicable to the production of fresh produce, subject to FDA being able to spell out how producers can comply for specific types of produce. I agree that, within FDA's jurisdiction, produce deserves the highest priority in setting standards for on-farm prevention of food safety problems. I also agree that the measured approach taken in the discussion draft is appropriate, given the wide range of large- and small-scale growers involved and the relative inexperience of many in this sector with preventive process control.

My only suggestion with regard to the produce provisions of the discussion draft is to include a clear directive to FDA to prioritize the types of produce that are most in need of preventive controls to ensure food safety and to move forward promptly with the needed regulations. In addition to produce, FDA has jurisdiction over on-farm food safety practices for eggs and has proposed regulations that would require preventive measures for egg safety. FDA should be directed to finalize those regulations.

The subcommittee should also take note of the fact that animal production practices can be an important risk factor for produce safety, as well as the safety of meat and poultry products. In the case of produce, failure to prevent access of animals to fields where crops are grown or to manage manure in a way that prevents water- or air-borne transmission of pathogens increases the risk of contamination with E. coli O157:H7 and other dangerous bacteria. USDA and FDA both have roles to play in addressing animal production practices that affect food safety, but USDA has no authority to regulate on the farm for food safety purposes, and FDA's mandate and authority in this area are at best murky. Congress thus needs to take a comprehensive look at how to improve the government's ability, working in collaboration with the agricultural community, to strengthen food safety practices on the farm.

While the discussion draft addresses the on-farm and processing segments of the farm-to-table spectrum, it does not address the critical retail sector, which includes both restaurants and grocery stores. State and local agencies play the frontline role in setting and enforcing standards at the retail level, and there is a long history of collaboration between these agencies and FDA, through the FDA's Food Code and other efforts, to help ensure that state and local oversight reflects up-to-date science and is reasonably consistent nationally. This collaboration needs to be strengthened through training, technical assistance, and federal incentives for state and local agencies to adopt updated standards for retail food safety and implement them effectively.

2. Make prevention of food safety problems the central focus of the system.

The central strength of the discussion draft is that it would direct and empower FDA to implement a food safety system that is based on the public health principle of prevention. That is what the food safety plan and process control requirements in section 102 are all about, and I hope the subcommittee and Congress will adopt this essential reform.

3. Recognize that the primary duty for prevention falls on the food industry.

The discussion draft embraces the key principle that the primary duty for prevention rests with the food industry by requiring in section 102 that the operators of all facilities have food safety plans based on preventive controls.

The draft also reflects the modern understanding of the key elements of preventive process control for food safety, which include hazard analysis, validation of the specific controls selected to address the hazards, monitoring and verification that the controls are working as intended, proper recordkeeping, and procedures for cor-

recting problems when they do occur. It is important that, in codifying the food industry's prevention duty, Congress spell out these basic principles.

As section 102 recognizes, in-process and end-of-process testing can be important tools for verification that preventive controls are working properly. The nature of the company testing that is appropriate and useful for this purpose will vary substantially, however, based on the nature of the food and process involved. I believe the role of testing as a process control verification tool deserves serious discussion, with the goal of fostering such testing by companies when it can contribute to food safety, while preserving the flexibility for companies to adopt testing approaches that make sense in their particular operations.

Section 107 calls specifically for end-of-process testing of food shipments to ensure compliance with applicable food safety standards, with the approach to testing depending on whether facilities are certified or not under the discussion draft's certification provision in section 106. I interpret section 107 as being intended, at least in part, to provide incentives for facilities to seek and gain certification. I have some concerns and suggestions concerning the draft's approach to certification, which I will note below. I see a need for discussion, however, of how section 107 testing relates to testing conducted under a food safety plan. Among other things, care needs to be take to ensure that the nation's testing infrastructure is not swamped with testing—such as for baked bread, dry cereals, and low-acid canned foods—that may not contribute to food safety.

4. Focus FDA on setting and enforcing standards that make the food industry accountable for prevention.

From a public health and consumer protection perspective, food safety plans and preventive controls are valuable only to the extent they are designed and implemented to achieve acceptable food safety outcomes. Section 102 of the discussion draft adopts this principle in two critically important ways: (1) it explicitly directs FDA to examine food safety plans to ensure they meet "relevant regulatory and food safety standards," and (2) it authorizes FDA to establish by regulation and to enforce performance standards that define for specific hazards the level of food safety performance a facility must meet. These are essential elements of the needed modernization of FDA's food safety legal authority.

I have one suggestion with regard to FDA's role in setting standards. I recommend FDA be given an affirmative directive to identify the most significant hazards in the food supply, prioritize hazards with respect to the need for performance standards to prevent food safety problems, and to implement a program to systematically develop and adopt standards for the highest priority hazards. Without a mandate to set priorities and act preventively, the crisis-of-the-day reality in which FDA operates will keep it mired in reaction, rather than leading on prevention.

While I think the discussion draft is basically sound in authorizing FDA to set standards, I have some concerns and suggestions about how the draft approaches FDA's ability to hold companies accountable for meeting the standards. And standards benefit food safety only to the extent compliance is achieved. I'll touch here on the basic enforcement mechanism for food safety plans, preventive controls, and performance standards; the role of civil penalties; and the proposed certification program.

I see no enforcement provision in the discussion draft for the requirement that facilities have food safety plans based on preventive controls and that they meet hazard-specific performance standards. I assume this is a drafting oversight. I recommend that the legislation make it a prohibited act for a facility to fail to have a food safety plan that complies with the new requirement or to ship a product that fails to meet a hazard-specific performance standard. Products that fail to meet a hazard-specific standard should also be deemed adulterated.

I support the availability of civil penalties as a tool for holding companies accountable for prevention. The prevention value of food safety plans and preventive controls depends on their being implemented successfully on a continuing, daily basis. This will happen only if a facility's managers have in place not only a satisfactory written plan but the systems to ensure the plan is implemented properly. Many companies need no incentive from government to have such systems, but many do. For the shift to prevention to work in practice and be credible to the public, FDA needs accountability tools that provide incentives for these companies to work in this new way.

Under current law, FDA's most commonly used remedies for dealing with food safety problems are voluntary recalls and judicial seizure actions. In both cases, FDA is able to act only against the food itself, rather than the behavior that gave rise to the food safety problem. FDA can also seek court-ordered injunctions to control future behavior and criminal penalties to punish past conduct, but pursuing these remedies is extremely cumbersome and costly.

Civil penalties provide FDA an efficient remedy for situations in which companies have failed to act preventively by having and successfully implementing a proper food safety plan. A civil penalty provision should be crafted carefully to recognize that the implementation of a food safety plan is never perfect and that the success of a plan lies not in preventing every problem, but in minimizing problems as much as reasonably possible and responding well to contain problems when they do occur.

I think the discussion draft's approach to certification of food facilities in section 106 deserves careful consideration and thought. I see the value of certification in the import situation as a way to bolster the assurance that products offered for import to the United States have been produced under conditions that meet U.S. standards. I think this can help compensate for the reality that the United States cannot possibly provide the same level of inspection and compliance oversight in foreign facilities that it can provide in U.S. facilities. I think it is even more fundamentally important, however, to clarify and strengthen the duty and accountability of U.S.-based importers for ensuring the food they import meets U.S. food safety standards.

I also see the potential value of certification for domestic facilities as an element for FDA to consider in guiding the risk-based allocation of its inspectional resources, which I think is critical to the long-run effectiveness and efficiency of the federal food safety program.

I have a number of specific concerns and suggestions about the certification proposal in the discussion draft, of which I will mention two here.

First, certification should be done only by independent third parties, which, in the case of imports, could include foreign governments. I do not think FDA should be the certifying party. FDA should accredit certifiers, but not grant certifications itself.

I base this view largely on my experience at USDA, where the granting of the government stamp of approval creates a commonality of interest between the agency and the company and erodes the independence and objectivity of the agency in assessing the company's future problems and behavior. I'm also concerned that, if FDA is put in the certification business, that will become a dominant focus of the agency's food safety managers, rather than setting and enforcing food safety standards. This is a particular concern because certifications are based on a snapshot in time, while the preventive approach to food safety depends on the continuing successful implementation of food safety plans and compliance with performance standards.

Second, the discussion draft is not clear on how "compliance with applicable requirements" is to be determined for purposes of granting certification. Is it sufficient to have an adequate written plan? Does the plan's successful implementation have to be demonstrated in practice over time? Does compliance with applicable performance standards have to be demonstrated?

5. Strengthen FDA's mandate and tools for providing national leadership on food safety and managing a science- and risk-based regulatory program.

The discussion draft directs FDA to conduct research on testing methods, with a priority to be accorded development of methods to detect intentional contamination. This is good as far as it goes, but, as outlined earlier, I recommend that FDA be given a broader mandate to drive problem-solving food safety research; build a more integrated, national food safety system; and provide system-wide leadership for risk-based priority setting and resource allocation, as called for by GAO and NAS.

RESOURCES AND STRUCTURE

Beyond a modernized statute, the other key ingredients for FDA's future success on food safety are adequate and stable resources and a unified and elevated organizational structure.

Provide FDA an Adequate and Stable Resource Base

FDA's resources for food safety have been eroding for years as the agency's food safety challenge gets larger. Staffing levels are declining, and the total operating budget for FDA's Center for Food Safety and Applied Nutrition—the resources available to take action after the staff and rent are paid—is down to around $25 million, which is a paltry sum for an organization charged with driving food safety progress across 80% of the American food supply, while also regulating dietary supplements and food labeling, ensuring the safety of infant formula and food additives, and attempting to provide food safety leadership internationally. An agency with all these responsibilities that can't conduct or commission research, adequately equip its staff, or travel simply can't do its job.

FDA needs an adequate and stable resource base for its food safety program. The discussion draft addresses this need primarily through annual facility registration fees. This is, obviously, a controversial topic. I am one of many who believe that

public health and regulatory programs of the government should, ideally, be financed through normal appropriations rather than fees. The primary value at stake here, however, is that FDA must have an adequate and stable funding base. If appropriated funds are not realistically going to meet this need, registration fees are probably the least objectionable alternative, because they spread the cost widely and do not involve a direct quid pro quo between FDA and the industry.

Unify and Elevate the Organizational Elements of the FDA Food Safety Program

The third key ingredient for the success of any agency—after an appropriate statutory mandate and adequate resources—is an organizational framework suitable for its purpose. For food safety, FDA needs a framework that enables it to provide national leadership on food safety and run a coherent, well-planned program that makes the best use of available resources to improve food safety. For several reasons, FDA lacks such a framework.

First, within FDA, the food program has historically taken a back seat to the drug and medical device programs in the competition for management attention and resources. This is due in part to the intense interest that drug and device companies, health professionals, and patients all have in FDA's "gatekeeper" role for therapeutic products and is reflected in the fact that most FDA commissioners come from a biomedical or health care background. This strong tilt toward drugs and devices was exacerbated by the drug and device user fee laws, which have further focused FDA management attention, accountability, and resources on the therapeutic side of the agency. History has taught that the job of providing effective national leadership simultaneously on both therapeutic products and food safety is too big a job for any one person.

Second, FDA's organizational structure for food safety is fragmented and lacks a clear focal point for leadership. CFSAN ostensibly has the lead on food safety at FDA, but CFSAN actually shares food safety jurisdiction with the Center for Veterinary Medicine, which regulates pet food and animal drug and feed additive residues in human food, and with the Office of Regulatory Affairs, which manages the majority of FDA's food safety resources through its field force of inspectors, compliance officers and laboratory personnel. The recent appointment in the Office of the Commissioner of an Associate Commissioner for Food Safety does not solve the problem. This position lacks budget or line authority for programs and thus in some ways further clouds responsibility and accountability for food safety within FDA.

Finally, food safety leadership at FDA rests at least two bureaucratic layers removed from the Secretary of Health and Human Services. As decisionmaking in the executive branch continues to be centralized at higher and higher levels, with OMB having enormous influence on regulatory policy, the full time leader of the nation's premier food safety program needs to have the greater clout in the system that comes from being presidentially appointed and reporting directly to the Secretary.

I recognize that these organizational issues are beyond the scope of the discussion draft and that solving them requires careful thought and planning, but I hope that the subcommittee will see the need to tackle them as part of a continuing effort to equip FDA to do its food safety job. In my view, the solution lies in unifying the food-related components of FDA into a single organization and elevating that organization within HHS under the leadership of a presidentially appointed official reporting directly to the Secretary.

CONCLUSION

Thank you again, Mr. Chairman, for the opportunity to testify on these important issues. I look forward to answering your questions and the questions of your colleagues on the Committee. And I would be happy to discuss with your staff further details on the discussion draft.

MAJOR POINTS

- The discussion draft is on the fundamentally right track in mandating food safety plans and preventive process controls for all food facilities, domestic and foreign.
- The establishment and enforcement of performance standards is a key element of prevention oriented reform, as contemplated by the discussion draft.
- The process for setting and enforcing performance standards needs to be strengthened, including the judicious use of civil penalties as an incentive for compliance.
- The application of the food safety plan and preventive controls requirement to fresh produce is a positive and important step toward a "farm-to-table" food safety system, but the legislation should also address improving oversight at the retail level.

• Certification can be useful to bolster confidence in imports and guide risk-based resource allocation of domestic inspection resources, but FDA should accredit certifying bodies, not grant certifications itself.
• To ensure FDA's success, Congress needs to address not only its legislative authority but also FDA's resources and organizational structure.

Mr. PALLONE. Thank you, Mr. Taylor.
Mr. Ambrosio.

STATEMENT OF MICHAEL AMBROSIO, VICE PRESIDENT OF FOOD SAFETY AND QUALITY ASSURANCE, WAKEFERN FOOD CORPORATION

Mr. AMBROSIO. Chairman Pallone and members of the Health Subcommittee, I am honored to appear before you today to present our views and suggestions on the Food and Drug Administration Globalization Act and legislation. I am Mike Ambrosio, vice president of quality assurance, Wakefern Food Corporation, and have been in charge of food safety programs at Wakefern for the past 28 years.

Founded in 1946, Wakefern Food Corporation has grown from a small, struggling cooperative into a strong regional player with significant operations in the New York metro area. Headquartered in Keasbey, New Jersey, Wakefern, along with ShopRite stores, has become one of New Jersey's largest employers with approximately 32,000 associates in New Jersey and 47,000 overall.

In 2007, retail sales totaled $10 billion. Wakefern operates 2.5 million square feet of warehouses and logistical distribution centers supplying over 200 stores in New Jersey, New York, Pennsylvania, Delaware, Connecticut, Massachusetts, and Rhode Island.

The Wakefern organization is the Nation's largest retailer-owned non-farm cooperative in the United States and is comprised of 44 members who independent own and operate supermarkets under the ShopRite banner.

Mr. Chairman, I applaud you, your ranking member and the subcommittee for your efforts to improve food safety. We too believe that improvements will best be achieved through a three-tiered program that emphasizes prevention, intervention, and response. This morning I will present several of Wakefern's recommendations for revising the bill, but I ask that my entire statement be included for the record.

Media coverage of recent outbreaks, recalls, and food safety scares have contributed to a decline in consumer confidence and reveal new challenges for ensuring the food supply is safe in an ever-changing marketplace. I am pleased to note that in 2008 with the Federal Government and the private sector working together to improve food safety, consumer confidence has rebounded.

Our retail industry trade association, the Food Marketing Institute, working with Wakefern and its other members, has outlined a number of retail industry food safety efforts and goals in a report being released today. Mr. Chairman, I would like to submit this paper, the FMI Food Safety Paper: the Supermarket Perspective, for the record.

Enhancing the safety of the food supply requires the active effort and strong support of suppliers, food wholesalers, and retailers, as well as government. This includes our commitment to train our

own people, our efforts to implement best food safety practices, and our outreach to consumers. It is a farm-to-table challenge that needs a farm-to-table solution. It is both a domestic and an international problem we must address together.

Wakefern is committed to working with the supply community to constantly improve the safety of the food they manufacture, process, and to this end participate in the Safe Quality Food program, SQF.

Within the domestic retail setting, training store managers and workers in food safety is an important tool. Currently Wakefern makes extensive use of the SuperSafeMark program.

The final link is the supply chain is the consumer. Wakefern has long provided consumers with practical, science-based guidance on the safe food handling at home through the Partnership for Food Safety Education. Our customers expect the foods they purchase to be safe, whether it is store produced, manufactured, or farm grown.

As retailers, we have an obligation to make sure we are sourcing from suppliers who have food safety plans in place. Accredited third-party certification companies are objective, independent bodies that are highly qualified to evaluate manufacturing facilities and to test, if warranted, that the supplier meets or exceeds all federally mandated food safety standards.

One such program is SQF, which is managed by FMI and recognized by the Global Food Safety Initiative, which also recognizes several other certification programs. Wakefern uses SQF because SQF is a well-documented, validated food safety management system. We are pleased to see that your bill recognizes this concept but we would ask that you work with us to ensure that accredited third-party programs do not become a substitute for FDA inspection and regulation. These programs are best used to supplement and leverage FDA resources since FDA will never have sufficient resources to inspect every facility. In recognition of rigorous infrastructure currently in place, we encourage Congress and FDA to examine how other countries are using certification as part of the overall risk assessment plan.

We believe that the FDA should be given the authority to mandate a recall in those cases where a company responsible for adulterated food does not act properly to recall a food. We also believe that suppliers should be required to give retailers immediate notification when a recall action is taken.

In addition, there are several other initiatives we would like to support: global sourcing safety, rapid testing, safety standards for produce. Here again, as a retailer, Wakefern will be using SQF in a vigorous appeals process. There are several other food safety initiatives that Wakefern supports but were not included in your draft: traceback systems and designating a lead food safety agency.

Mr. Chairman, there are also proposals in the legislation that Wakefern would not support and we have asked our industry trade association to examine more closely. These are registration fees, user fees, and country of origin labeling.

Mr. Chairman, thank you for the opportunity to testify. I remain available to the subcommittee for further discussion and information should you need it.

Mr. PALLONE. Thank you, Mr. Ambrosio.

Mr. Lovett.

STATEMENT OF JAMES LOVETT, CORPORATE SENIOR VICE PRESIDENT, COVANCE LABORATORIES

Mr. LOVETT. Thank you, Mr. Chairman and members of the subcommittee. I am James Lovett of Covance, one of the world's largest and most comprehensive contract research organizations. Headquartered in Princeton, New Jersey, Covance has operations in more than 20 countries and more than 8,700 employees, two-thirds of whom are in the United States. We conduct research and development for new medicines and provide laboratory testing services to food and other industries. One of my responsibilities at Covance is our food testing business. I thank you for inviting me to participate in this discussion on food safety. We strongly support the subcommittee's efforts to advance food safety in our country and we also support the third-party testing provision in the draft discussion bill.

Covance is a full-service laboratory to the food industry offering comprehensive testing services. Our facility in Madison, Wisconsin, is one of the largest food testing laboratories in the world. Our lab routinely analyzes more than 50,000 samples per month. It operates 24 hours a day, 7 days a week. It serves not just industry customers but also State and federal labs including the FDA. I would like to thank Congresswoman Baldwin for her support of our Madison facility, and she has actually toured our facility there, and I would also like to note that we operate food testing laboratories in Battle Creek, Michigan, and Singapore that have similar capabilities.

Let me turn to the current status of food safety testing at the FDA. You know, the sheer volume, variety and complexity of FDA-regulated imports coming into this country is stunning. FDA agrees in its Food Protection Plan that "increases in the volume and complexity of imported foods have taxed the limits of FDA's approach to handling imports." So FDA has recommended a new approach that includes the use of highly qualified third parties.

We agree with the vision of the FDA and of this subcommittee about the potential contribution of third-party testing labs. This will provide several benefits. First is faster implementation. This country currently has significant private laboratory capacity capable of ramping up quickly to meet any new testing requirements desired by Congress and the FDA. Second is efficient use of limited resources, as we noted earlier. It is not necessary for FDA to dramatically increase its own laboratory testing capabilities. The capability exists already in the private sector, and we can quickly meet new requirements. Third is access to state-of-the-art testing facilities. Covance and many other qualified laboratories maintain highly trained staff and state-of-the-art equipment with a high level of automation, ensuring rapid and high-volume sample throughput. And then fourth is the ability of the FDA to maintain adequate oversight and control. FDA has worked effectively with Covance and other labs for many years on a variety of issues. Authorizing FDA to accredit third parties builds on the success but it should entail very strict accrediting requirements.

Let us face it. It is essential that the American public have a high level of confidence in their food safety and the testing of their food. Food testing laboratories, whether private or public, should be held to high standards. We have some suggestions for appropriate accreditation standards for consideration.

First is FDA Good Laboratory Practices, or GLPs. FDA already has published GLPs for third-party laboratories for many years. We are not starting from scratch with third-party lab standards. FDA should continue to use this highly reliable standard which is respected across the globe.

Second is the International Standards Organization, as was noted earlier, the ISO 17025 standard. ISO standards generally are used in manufacturing and the chemical and petroleum industries and in food processing and other areas. Requiring ISO certification, together with the FDA GLP program, would help ensure stringent recordkeeping requirements.

Third is AOAC International official methods. The majority of testing methods actually used today for food testing have been fully validated and standardized by AOAC International. AOAC provides validation services for testing methods and AOAC official methods are considered the gold standard of test methods around the world. FDA laboratories themselves use an AOAC method when it is available, as does Covance.

So in conclusion, Covance applauds the Committee for including provisions of its draft bill authorizing the FDA to accredit third-party labs. We believe there is an appropriate role for independent third parties to improve the safety of our food supply and this use of third parties will also permit FDA to quickly and easily alter resource requirements based on changing needs and circumstances.

So I thank you for the opportunity to testify and I would be pleased to answer any questions.

[The prepared statement of Mr. Lovett follows:]

STATEMENT OF JAMES LOVETT

INTRODUCTION

Mr. Chairman and members of the subcommittee, I am James Lovett, Corporate Senior Vice President for Covance Inc., one of the world's largest and most comprehensive contract research companies, with global operations in more than 20 countries, and more than 8,700 employees worldwide (approximately two-thirds in the United States). Our company conducts research and development for pharmaceutical companies and provides laboratory testing services to the chemical, agrochemical, and food industries. I am responsible for Covance's food testing business. We are pleased to have been invited as part of this discussion on food safety, and look forward to working with the Committee as this process continues.

OVERVIEW OF COVANCE'S WORK

Covance is a full service laboratory to the food industry, offering comprehensive testing services for both food safety and food nutrition. The food testing organization originally grew from a research branch of the University of Wisconsin over 75 years ago. This testing facility in Madison, Wisconsin, is now one of the largest food testing laboratories in the world. The total Covance campus in Madison covers nearly one million square feet of laboratories and employs almost 2,000 scientists and technicians, and food testing is an important part of our operation. In addition to the Madison laboratory, Covance operates food testing laboratories in Battle Creek, Michigan, and in Singapore.

The food testing laboratory in Madison can routinely analyze over 50,000 samples per month. It operates 24 hours a day, seven days a week. It provides rapid accurate

test data to industry customers, as well as state and federal government agencies. The food safety testing programs employed at Covance cover testing protocols for chemical contamination, microbiological contamination, pathogen detection, and detection of other deleterious contaminants. The testing profile includes detection of the contamination, identification of the chemical or microbe, quantification of the contamination, and confirmation of all positive test data. Our laboratories in Michigan and Singapore feature similar capabilities. Covance has provided food testing support to FDA for many years on a wide variety of projects.

CURRENT STATUS OF FOOD SAFETY TESTING AT FDA

FDA regulates roughly 80 percent of the U.S. food supply, which is $417 billion worth of domestic food and $49 billion in imported food annually.[1] FDA has oversight of more than 136,000 registered domestic food facilities. Approximately 189,000 registered foreign facilities manufacture, process, pack, or hold food consumed by Americans.

FDA plays a critically important role in ensuring the safety and public confidence in the food we eat. Foodborne illnesses are caused by more than 200 different foodborne pathogens of which we are currently aware. These include viruses, bacteria, parasites, and toxins, plus a vast number of potential chemical contaminants and metals.

FDA's Food Protection Plan outlines many of the factors complicating its mission of protecting the safety of the U.S. food supply. Changes in demographics, convenience trends, and consumption patterns are converging in a way that poses new challenges for ensuring the safety of the foods we eat. In addition, the sheer volume, variety, and complexity of the FDA-regulated products arriving at U.S. ports makes it nearly impossible for FDA to adequately oversee compliance with food safety standards and FDA regulations. According to FDA's report, over 300 U.S. ports receive products from the more than 150 countries and territories with whom the U.S. trades.[2]

FDA concedes in its plan that "increases in the volume and complexity of imported foods have taxed the limits of FDA's approach to handling imports."[3] In response, FDA has recommended a new approach for addressing potential safety issues with imported foods, including increased intervention in the form of targeted, risk-based inspections and testing. FDA's plan supports the concept of accrediting highly qualified third parties to assist with this effort. FDA acknowledges it lacks the resources to adequately perform this function on its own. Furthermore, it understands that using qualified third parties will allow this new approach to be implemented more quickly and efficiently than by simply increasing FDA's infrastructure and staff resources.

Covance believes that FDA is doing the best it can with the resources it has. However, the reality is that less than 1 percent of U.S. food imports are tested. This does not compare favorably to the 25 percent that is tested in Canada or the even higher percent that is tested in Japan. We believe a risk-based plan, as suggested by the FDA, offers the best general approach to improving food safety without having to test every last article of imported food. However, even under a risk-based approach, our nation should clearly be testing much more food than it currently does.

Even where good processes are believed to be in place to assure food safety, testing is the only way to be confident that those processes are actually working to produce and ship food that is safe for consumption by the American public. If you think about it, all food is tested—either in a laboratory before a human eats it or by the consumer at the actual time of consumption. We believe it is only prudent to have a robust testing program to ensure that the ultimate test—what happens when a human being eats the food—consistently results in a passing grade.

BENEFITS OF A THIRD PARTY SYSTEM TO THE AMERICAN PUBLIC

Covance applauds the Committee for including within its draft bill a provision authorizing FDA to accredit third party laboratories. Authorizing FDA to accredit third parties to assist in the efforts to institute a more rigorous, risk-based approach to food safety testing will provide the following benefits:

(1) Faster Implementation of New Food Safety Objectives
(2) Efficient Use of Limited Government Resources
(3) Access to State-of-the-Art Testing Facilities

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[1] FDA Food Protection Plan, Nov. 2007, p. 6.
[2] Id., p. 8.
[3] 3 Id., p. 8.

(4) Ability of FDA to Maintain Adequate Oversight and Control

(1) Faster Implementation—This country currently has significant private laboratory capacity capable of quickly ramping up to meet any new testing requirements desired by Congress or FDA. There is no need for FDA to do this alone—with longer timelines to ramp up and higher cost to the U.S. taxpayer—when capable private laboratories can help.

(2) Efficient Use of Limited Resources—It's not necessary for FDA to dramatically increase its laboratory testing capabilities. This capacity currently exists in the private sector and we would be able quickly meet any new testing requirements.

(3) Access to State-of-the-Art Testing Facilities—Covance and many other highly qualified laboratories maintain "state of the art" equipment providing a high level of automation, ensuring very rapid and high volume sample through put. These sophisticated instruments provide the very highest level of sensitivity and selectivity, allowing our laboratories to provide extremely sensitive and precise test results. Our highly trained staff is able to report results faster than most other laboratories, including those currently operated by FDA.

(4) Ability of FDA to Maintain Adequate Oversight and Control—FDA has worked with independent laboratories for many years in the human and animal drug approval process, the new cosmetic approval process, and in the submission of new food additives. In our experience, this process has worked well. Expanding some of the existing relationships by providing FDA with authority to accredit third parties to expand food testing capacity would rightfully entail very strict accrediting requirements. Only laboratories able to demonstrate the ability to comply with very strict standards established by FDA should receive accreditation. FDA should conduct compliance audits to ensure all accredited laboratories maintain these high standards. By placing control within the FDA for accreditation on the front end, while providing auditing authority to ensure third party laboratories maintain the required standards, FDA will have the tools it needs to maintain adequate oversight of this new authority.

How a Comprehensive Third Party Testing System Would Work

For a typical food shipment that FDA has determined must receive testing at a port-of-entry, we believe the process might work as follows:

- When a food shipment arrives at a U.S. port, FDA or the importer would determine whether it should be subject to testing under FDA's new risk-based testing requirements. If a shipment is chosen for testing, the food would be sampled according to a strict sampling plan determined by FDA to arrive at a "statistically" valid sample. These samples could be taken by third party, independent sampling companies, several of which already exist.
- Samples would then be transferred to the third party laboratory—with the collected samples maintained under a "chain of custody" while they are transported.
- Samples would arrive at the laboratory and be "logged in" to the laboratory data system. At the same time, FDA and the private food company would be notified of sample arrival and given an estimate for data completion. Within hours of sample receipt, the laboratory could initiate testing.
- When test data is complete, results would be simultaneously transmitted to FDA and the food company. If any data show a presumptive positive for a pathogen or poisonous chemical, an investigation would be initiated immediately to confirm these results. Once again, notification would be sent simultaneously to FDA and the food company.
- The testing company would conduct the investigation to confirm the test data and final reports would be issued to FDA and the food company.

FDA Accreditation and Oversight of Third Party Labs

It is essential that the American public have a high level of confidence in accredited third party laboratories. Therefore, I would like to expand upon the FDA accreditation requirements that will be critical to an effective and efficient third party testing program.

The data produced by the independent laboratories will be used to make critical decisions about the quality of the U.S. food supply. Therefore, FDA must require rigorous standards and accreditation requirements for third party laboratories. We fully support the provisions in the draft FDA Globalization Act which provide for the Secretary to accredit laboratories, monitor laboratory performance and conduct annual audits. I will discuss some of the requirements we would expect FDA to include within its accreditation standards. FDA might include other requirements as well.

FDA Good Laboratory Practices

In order to become a qualified third party testing laboratory, FDA must provide for laboratory accreditation and certification, and the laboratory must be able to produce acceptable data in the proficiency testing program. FDA should standardize the test methods being used so that comparable procedures would be used by all testing facilities. FDA already has published Good Laboratory Practices (FDA GLP) for third party laboratories and this protocol has been followed by a multitude of laboratories in their data submission to FDA for many years. FDA should continue to use this highly reliable standard, which is respected across the globe.

International Standards Organization (ISO) 17025 Standard

Another standard FDA might require as part of the accreditation process is ISO—the International Standards Organization—a European-based organization with a mission to standardize practices in a number of industries. ISO standards are used in manufacturing, in the chemical and petroleum industries, and in food processing. ISO's published test methods are often similar to AOAC, which I will discuss in a moment. In particular, the ISO 17025 standard was developed for laboratories and requires comprehensive documentation of laboratory activities in the form of Standard Operation Procedures (SOP). The standard also requires a Quality Manual that describes overall business conduct. Companies are required to submit to an inspection for this accreditation, and must demonstrate acceptable testing performance in the form of an external sample evaluation program. Although not as comprehensive as the FDA GLP program, ISO 17025 is very effective in ensuring a laboratory keeps good records. Requiring ISO certification, together with the FDA GLP program, would be very effective in ensuring stringent recordkeeping requirements and the high standards for the measurement of the data quality.

AOAC International Official Methods

The majority of the testing methods currently used today have been fully validated and standardized by AOAC International and these methods would provide a uniform framework for the industry. Founded in 1884, AOAC provides validation services for testing methods including laboratory evaluation, proficiency testing, and validation of test methods which are globally recognized. AOAC Official Methods are considered the "gold standard" of test methods around the world, and are recognized by regulatory agencies and courts of law. FDA laboratories themselves use an AOAC method when it is available, and these standards are already used extensively in the food and dietary supplement industries. This aligns the FDA and third party laboratories very well. We recommend FDA require use of AOAC methods whenever they are available. FDA might also be encouraged to establish priorities for development of additional AOAC methods to meet new testing needs as they are identified.

Sampling Protocol

The draft bill indicated that the sampling and testing for a non-certified food company will be handled by an accredited testing laboratory. Currently a number of different models exist for conducting sampling. In order to ensure the efficacy of the test results, it is important that the sampling protocol be uniform and clearly established.

Conclusion

In conclusion, Covance applauds the Committee for including provisions in its draft bill authorizing FDA to accredit third party laboratories. We believe there is an appropriate role for independent third party laboratories in improving the safety of the U.S. food supply. Proper oversight by FDA will guard against any perceived conflicts of interest. Use of third parties will also permit FDA to more quickly and easily alter resource requirements based upon changing circumstances and needs. Other benefits as discussed above include the following:

(1) Faster Implementation of New Food Safety Objectives
(2) Efficient Use of Limited Resources
(3) Access To State-of-the-Art Testing Facilities
(4) Ability of FDA to Maintain Adequate Oversight and Control

I hope my testimony will prove useful as the Committee considers measures to enhance FDA's food safety testing capabilities. Thank you for the opportunity to testify and I would be pleased to answer any questions the Committee may have.

Mr. PALLONE. Thank you, Mr. Lovett.
Congressman Dooley.

STATEMENT OF CALVIN DOOLEY, PRESIDENT AND CEO, GROCERY MANUFACTURERS ASSOCIATION

Mr. DOOLEY. Well, thank you, and I am delighted to be joining all of you today and I am testifying on behalf of the Grocery Manufacturers Association, the National Fisheries Institute, the Snack Food Association, the American Frozen Food Institute, and the American Bakers Association. We are all committed in representing our members to be partners with you and others to ensure that we can advance reforms that will enhance the safety of our food supply.

In particular, as we move forward with considering what should be included in reforms, we have several measures.

One, we urge you to give FDA the power to establish safety standards for fruits and vegetables. Two, we urge you to require that every food company has a food safety plan that is based upon food safety risk analysis, that documents appropriate food safety controls, and that is available for FDA to review. Three, we urge you to require every food importer to police their foreign suppliers and document for FDA review their food safety controls. And four, we urge you to give FDA new powers to address bad actors who have declined to recall contaminated food products posing a risk of severe health consequences. We are pleased that a bipartisan piece of legislation embodying these components was introduced just yesterday by Congressman Costa and Congressman Putnam.

When we turn to the issue of the provisions that are in the discussion draft bill, we think there are many in there that are constructive but we do have some serious concerns about others. We have strong objections to the registration fees, the import fees, and other fees that will essentially result in $1 billion in taxes on food products which will show up in increased costs at the grocery store shelves. You put this on top of the energy legislation that was passed by this committee that is also diverting 25 percent of our corn crop from food to fuel, you are further compounding the rapid escalation in food prices that we have never seen in recent times.

We are also very concerned about some of the prescriptive and regulatory approaches that would allow FDA inspectors to second-guess food safety decisions from many of our member companies that are really embodying the latest in technology and science to ensure that they have the most effective systems in place. What you would be effectively doing would be something that is analogous to asking the DMV inspector to be questioning whether or not the engineer that was designing the brakes for the Ford auto were the best. This is not the route that we should be doing down.

And when we come to the issue of the third-party certification, I think we have to be very concerned about basically having FDA give the authority and the power of effectively a government agency to pass judgment on whether or not suppliers or manufacturers are in compliance with FDA regulations. Again, if you turn this around, what we are going to be effectively doing is saying to any producer of food or an ingredient product, regardless of where they are in the world, could be France, could be Canada, could be Soma-

lia, is that we are going to require them to be certified by a third-party entity that we have supposedly sanctioned to pass judgment on whether or not they are complying with our defined set of regulations and rules. What are we to expect is going to be the response to this? Do you not expect that Canada, that France, that the U.K., that China, that Japan will also put in place similar protocols that would require every exporter of a food product in this country to be accredited or certified by a group that they have sanctioned? I really ask the Committee to give serious consideration about going down a path that will inevitably invite a response that will have great harm on our ability to access international markets, which are so important to our industry.

The food industry is willing, though, to accept that there are some needs for reform to ensure that we are allowing FDA to have the appropriate enforcement provisions when you have an instance of a need for a mandatory recall. You know, we support some of the provisions that include this for when you have a Class I need for a recall.

The other provision I would like to touch on in closing is the provision that would allow for a $500,000 civil penalty to be assessed on a daily basis. Right now, what happens when you have a potential food safety problem that is occurring, is that there is a very collaborative interaction between the manufacturer and FDA and CDC, the Centers for Disease Control. If you put in place a threat of a $500,000 civil penalty, you are going to really undermine that collaboration, that discussion that really leads to the most efficient and quickest determination of what products pose a risk and getting them out of the market as quickly as possible. Our member companies do not need a threat of a civil penalty to ensure that they are deploying the best practices, and I would ask the Committee to give serious considerations whether or not that would in fact be an effective reform to enhance the safety of our food products.

[The prepared statement of Mr. Dooley follows:]

Written testimony of the Honorable Cal Dooley

Grocery Manufacturers Association

President and CEO

Before the Health Subcommittee

Of the House Committee on Energy and Commerce

April 24, 2008

Thank you, Mr. Chairman.

My name is Cal Dooley and I am President and CEO of the Grocery Manufacturers Association.

We commend and share your commitment to ensuring the safety of our nation's food supplies and agree that a strong, adequately funded Food and Drug Administration (FDA) is fundamental to achieving this goal.

Food and beverage companies already implement a variety of food safety measures and controls to ensure the safety and quality of our products and ingredients. Ensuring the safety of our products is our most important priority. We agree that

Congress must take steps to help FDA and the food industry address new challenges posed by rising food imports and changing consumer preferences. We believe that a risk-based approach to the prevention of contamination should continue to be the foundation of nation's food safety strategies.

We are grateful for your willingness to work with us to craft food safety legislation. While we share the broad goals of the Discussion Draft of the *Food and Drug Administration Globalization Act of 2008,* we believe that many of the provisions of the Discussion Draft, if adopted, would place enormous new burdens on FDA, farmers, food importers, and the food industry and would dramatically increase food prices without addressing the sources of contamination or significantly improving food safety.

In particular, we strongly oppose placing a $2,000 annual tax on each food facility and a $10,000 annual tax on each food importer to finance FDA operations. All Americans, not simply food companies, benefit from improvements to our nation's food safety programs. We believe the costs of FDA inspections and research should be financed from general tax revenue, not from taxes imposed on food importers or facilities. While we support increased resources for FDA, we strongly oppose food taxes and "fees" that are not tailored to provide a government service to our industry and that will likely compound food costs at a time of record food inflation.

We are also very troubled by your proposal to privatize much of our food safety system. In particular, we are concerned that a proposal to require that all foreign and domestic food facilities obtain certification from FDA-accredited certifying agents would

exhaust FDA resources and would improperly delegate FDA responsibilities. Because importers who fail to seek certification would face severe import limitations and testing requirements, the "voluntary" program outlined in the Discussion Draft is effectively mandatory.

A massive across-the-board certification requirement that ignores risk is unworkable and wasteful of public and private sector resources. While there is a role for third party audits in our food safety system, we believe this role should be linked to demonstrated need, such as the certification of imports of certain high risk foods. Effectively requiring all domestic and foreign facilities to obtain certification would demand the creation of an unprecedented private army of third-party certifiers that would drain talented staff from FDA and would be tantamount to creating a "shadow" government.

We also strongly oppose costly new regulatory requirements, including provisions that provide FDA inspectors with broad authority to review the adequacy of food safety plans, to mandate specific controls for each facility, to establish performance standards for each facility, and to require broad new labeling requirements. While we support the requirement that all food companies have a food safety plan, we believe food companies should be given the discretion to identify appropriate safety controls and measures beyond those controls and measures already required by regulation. Prescriptive, across-the-board new regulatory requirements will stifle innovation, divert resources from

proven food safety measures, and will increase food costs at a time of record food inflation.

While we believe that some facilities deserve greater scrutiny than others, we oppose rigid inspection schedules and instead believe that FDA inspections should be based upon risk. We also strongly oppose needless civil penalties and reinspection fees. Food companies have powerful incentives to ensure the safety of food products and ingredients and current law already provides a wide range of enforcement tools, including seizure, injunction, and civil and criminal penalties. Giving FDA the power to assign massive fines and fees will dramatically alter the cooperative relationship between FDA and the food industry and will create a powerful incentive for FDA to find violations regardless of merit. We also oppose giving FDA the power to suspend registration.

We instead propose that Congress modernize our food safety system by making risk and the prevention of contamination the focus of our food safety strategies. In particular, we propose the following reforms:

- One, we urge you to give FDA the power to establish safety standards for fruits and vegetables. In particular, give FDA the power to establish food safety standards for particular fruits and vegetables – when risk and science demonstrate standards are needed. Under this proposal, FDA should be given the power to work with USDA and states to ensure standards are being met, and FDA should

be given the power to work with states to tailor standards to meet local growing conditions.

- Two, we urge you to require food companies to have a food safety plan. In particular, every food company selling food in the US should conduct a food safety risk analysis that identifies potential sources of contamination, identifies appropriate food safety controls, verifies that those controls are effective, and documents those controls in a food safety plan subject to FDA review.

- Three, require every food importer to police their foreign suppliers. In particular, Congress should require that all food importers, subject to FDA guidance, document the food safety measures and controls being implemented by their foreign suppliers and should require food importers to make their foreign supplier food safety plan available to FDA. Food importers who demonstrate their products pose no meaningful risk should be eligible for expedited entry at the border so FDA can give greater scrutiny to high risk imports.

- Four, build the capacity of foreign governments and enlist the help of the private sector. In particular, Congress should direct FDA to develop a plan to help build the scientific and regulatory capacity of major exporters to the U.S. and should create a registry of private laboratories that meet FDA standards. In addition, FDA should enlist the help of accredited third party auditors to ensure that high risk imports meet federal safety standards, to verify the contents of foreign

supplier safety plans, and to help identify those imports eligible for expedited entry.

- Five, give the Secretary new powers to address bad actors. Although food companies routinely recall contaminated products, we believe Congress should give the FDA the power to order a recall, subject to due process protections, when a product poses the risk of severe health consequences or death and the company has refused to conduct a recall.

Mr. Chairman, we are grateful for the opportunity to work with you to promote a risk based approach to food safety regulation and to allow FDA the flexibility to respond to emerging risks in the manner that most efficiently uses the agency's precious resources. We look forward to working with you to develop and implement improvements that will make risk and prevention the focus of our nation's food safety systems.

Summary

Food companies support efforts to modernize our food safety system by making risk and the prevention of contamination the focus of our food safety strategies. In particular, we propose the following reforms:

- Give FDA the power to establish safety standards for fruits and vegetables. In particular, give FDA the power to establish food safety standards for particular fruits and vegetables.

- Require food companies to have a food safety plan. In particular, every food company selling food in the US should conduct a food safety risk analysis that identifies potential sources of contamination, identifies appropriate food safety controls, verifies that those controls are effective, and documents those controls in a food safety plan subject to FDA review.

- Require every food importer to police their foreign suppliers and build the capacity of foreign governments. In particular, Congress should require that all food importers document the food safety measures and controls being implemented by their foreign suppliers.

- Give the Secretary new powers to address bad actors. Although food companies routinely recall contaminated products, we believe Congress should give the FDA the power to order a recall, subject to due process protections, when a product poses the risk of severe health consequences or death and the company has refused to conduct a recall

Although we support giving FDA additional resources, we oppose taxes on food facilities and imports and we are troubled by proposals to require that all foreign and domestic food facilities obtain third-party certification. We also oppose prescriptive new regulatory requirements, broad new labeling requirements, and civil penalty proposals that will increase food costs but will not improve food safety.

Mr. PALLONE. Thank you.
Ms. DeWaal.

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

Ms. DEWAAL. Thank you so much, Chairman Pallone, and on behalf of our over 900,000 consumer members of the Center for Science in the Public Interest, I want to thank you for your leadership on food safety, and Representative Deal, Representative Barton, Representative Dingell, the many members of this committee who have worked long and hard on this issue in the last 2 years.

The impact of foodborne disease has been fully described in hearings already before this subcommittee, and with this hearing I see that your committee is really starting the job of solving the problems in our food safety system. But let us not forget the victims, some of whom have testified before this committee, victims like Ashley Armstrong, who at 3 years of age suffered acute kidney failure and months of dialysis after eating E. coli-tainted spinach. Her cost, the costs of her family were unspeakable. Hundreds of thousands of dollars in medical costs. Her parents spent months in the hospital. Or Mora Marshall, who at 86 years of age was hospitalized and will spend the rest of her life in nursing care from eating salmonella-tainted peanut butter. As the Committee moves forward to consider this legislation, these are a few of the victims I hope you remember and the illnesses that we must prevent as you search for ways to empower the FDA with the resources and the authority that it so sorely lacks today.

It seems like every week another food warning sends consumers to their pantries to look for the source of a melon or the production code on a recently recalled can or jar of food. Food outbreaks and recalls in recent years have caused a dramatic loss in consumer confidence and many, many costs to the food industry as well.

CSPI has long advocated that Congress take this step of creating a modern food safety system, and we believe after analyzing 16 years of outbreak data that this system we are operating under, and the proof is in the last few years, is fundamentally flawed. We need a new system. We have supported a unified food agency. We have brought forward many concepts and ideas to this committee and others but it is critically important that the new system be based on public health.

While the FDA Globalization Act does not contain sweeping reform of the nature that we have proposed in the past, nonetheless, the improvements that it proposes are essential to address the gaps and weaknesses in FDA's current food safety programs. It builds upon the improvements of the Bioterrorism Act of 2002 but adds a fundamental new structure to FDA's food safety program. It contains numerous improvements. I will just mention a few: written process control plans utilizing performance standards that create a food safety foundation that has not before existed at FDA. It also contains a voluntary certification program for imported foods but one that has strong incentives to encourage food companies to seek certification and that is modeled on programs already in place in the retail sector and it also has important new enforcement au-

thorities, things like mandatory recall and civil penalties that the FDA needs to do its job.

In the spirit of the draft discussion, CSPI has offered a number of suggestions, the most important of which is the recommendation that you increase the inspection frequency in the bill. The inspection frequencies you have right now of 2 years and 4 years are really not good enough and we would like to see those inspection frequencies increased to ensure that the food companies really know they have to comply.

The FDA Globalization Act, though, really takes many ideas from many stakeholders, people like the Grocery Manufacturers of America, who put out their own plan; CSPI, who put out a white paper in the fall; and the Food and Drug Administration's "Food Protection Plans." It really very successfully weaves many of these ideas together.

This hearing really demonstrates that there is widespread agreement among these entities and also the Committee here on the need to improve FDA's oversight of imports, their inspection capability and their enforcement tools. While each stakeholder may differ on the particulars, the FDA Globalization Act offers an unprecedented opportunity for Congress to pass strong food safety legislation that in fact represents the best ideas for improving the current system. Thank you.

[The prepared statement of Ms. DeWaal follows:]

Food and Drug Administration Globalization Act

Testimony of Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest
before the
House Subcommittee on Health
of the House Committee on Energy and Commerce

Washington, DC
April 24, 2008

My name is Caroline Smith DeWaal, and I am the director of food safety for the Center for Science in the Public Interest (CSPI). CSPI is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by over 900,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you, Chairman Pallone, Chairman Dingell, Ranking Member Deal and the Members of this Subcommittee for the opportunity to comment on the discussion draft of the Food and Drug Administration Globalization Act.

In the past two years, repeated outbreaks, Congressional hearings, and nationwide recalls have turned the tragic statistics of 76 million illnesses, 325,000 hospitalizations and 5,000 deaths annually due to food-borne illnesses into a problem familiar to almost every consumer. Who hasn't checked where their melon was grown or searched their pantries for everything from peanut butter to canned chili?

The impact of food-borne disease has been fully described in previous hearings before this Subcommittee. With this hearing, Congress begins the process of solving problems in our

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food safety system. But I don't want us to forget the victims of our antiquated and broken food safety system. Victims like Ashley Armstrong, who at three years of age suffered acute kidney failure and months of dialysis after eating *E. coli*-tainted spinach. Mora Marshall, who at 86 years of age was hospitalized and will spend the rest of her life in a nursing home after eating S*almonella*-tainted peanut butter. These are individuals we need to remember and the illnesses we need to prevent as we search for ways to assure the Food and Drug Administration (FDA) has the resources and authority it so sadly lacks today.

The loss of consumer's confidence in food safety has been widely documented. For example, last year the Food Marketing Institute documented a 16 percent decline in consumer confidence in the safety of food they purchase at grocery stores.[1] In July, *USA Today* found 83 percent of shoppers were concerned about food from China, and 61 percent about food from Mexico.[2] In December, the Thompson West Research poll found 61 percent of Americans worry about the safety of their food.[3] And consumers are not the only ones affected. The food industry bears substantial costs when the actions of one company results in a nationwide outbreak or recall. After the spinach outbreak in 2006, spinach farmers reported losing $350 million, and had still not recovered when a second leafy green outbreak occurred in August 2007.[4] The Peter Pan peanut butter outbreak cost ConAgra more than $140 million, including $55 million in lost sales.[5] Congress needs to act now to address FDA's deficiencies or risk repeated outbreaks

[1] Food Marketing Institute, U.S. Grocery Shopper Trends 2007, 66.
[2] Elizabeth Weise, *Buying Only U.S. Food is a Tall Order*, USA TODAY, July 10, 2007, *available at* http://www.usatoday.com/news/health/2007-07-10-american-goods_N.htm.
[3] Thompson West Research, *Consumers Worried About Product Safety*, Dec. 18, 2007, at http://west.thomson.com/news/releases/productsafety.aspx.
[4] Elizabeth Weise & Julie Schmit, *Spinach Recall: 5 Faces. 5 Agonizing Deaths. 1 Year Later.*, USA TODAY, Sept. 20, 2007, *available at* http://www.usatoday.com/money/industries/food/2007-09-20-spinach-main_N.htm.
[5] Mike Hughlett, *E. coli Outbreak Kills Meat Company: Huge Costs Seen in Fixing Problems*, The Chicago Trib., ¶ 9-11, Oct. 6, 2007, http://www.chicagotribune.com/features/lifestyle/health/chi-sat_toppsoct06,1,4231570.story.

imposing costs on the public and industry for health care services, business interruption, and lost confidence.

The Food and Drug Administration Globalization Act Advances Food Safety

CSPI has long advocated for Congress to create a modern food safety oversight system in the federal government. We have analyzed 16 years of outbreak data, and reached the firm conclusion that the current system is fundamentally flawed in its approach to food safety, and that far-reaching reform is needed. We have also suggested a unified food safety agency as one mechanism of improvement, bringing together the dysfunctional inspection programs at the FDA and USDA in a new agency focused on public health.

While the FDA Globalization Act does not contain such sweeping reform, nonetheless, the improvements that it proposes are essential to address the gaps and weaknesses in FDA's current food safety program. It builds upon the improvements of the Bioterrorism Act of 2002, but adds a fundamental new structure to FDA's food safety program in the form of new written plans at the producer and processor level. These plans create a food safety foundation that has not existed before at FDA and weaves together the distinct threads of inspection reform, improved oversight of imports and better funding into a coherent whole.

Let me explain. The introduction of HACCP systems, initiated by both FDA and USDA in the 1990s, began the movement to a modern food safety system. HACCP stands for "Hazard Analysis and Critical Control Points" systems, and it puts responsibility and accountability for food safety on the processor of the food, that person or entity that expects to make a profit by selling food to the public. Most important, however, is that it creates a duty for industry to implement systems to prevent problems rather than simply react. USDA's HACCP requirements

covered the entire meat and poultry industries. FDA's approach was much more limited, requiring only the seafood and juice industries to adopt HACCP systems.

While full-blown HACCP systems may not be appropriate for every segment of the food industry, there is an element of HACCP that is appropriate, and it forms the centerpiece of the FDA Globalization Act. The requirement that food processors and producers identify possible hazards linked to their food and outline a control plan provides a core responsibility for industry to know the food safety profile of their products and to have written plans to address those hazards. If FDA determines that certain performance standards are necessary for one type of process, the written plans are the vehicle to determine how the standards are being implemented.

This written plan is the responsibility of the processor or food producer, the entity that knows their process best. Farmers, for example, know the environmental conditions and weather in the area better than any regulator, and therefore should be in the driver's seat when it comes to food safety. But the written plans also create an opportunity for the FDA inspector or a third party auditor to understand the thinking of those in charge of food production at every factory or farm. Instead of starting from zero with every inspection, FDA can begin with an understanding of the process controls that are in use in every facility. If there are gaps in the hazard analysis, these can be pointed out and addressed. If there are failures in the system, they can be understood as being either a failure to execute the written plan, or a failure to fully understand the hazards. Most importantly, failures can be caught earlier, before food gets to the market.

I have toured food facilities in many parts of the world. From Kansas to Colorado, from New Zealand to the Netherlands, I have never encountered a food plant that wasn't excited to show me their food safety plan. These are widely used in most segments of the industry. Sometimes they are full-blown HACCP plans. Other times, they encompass sanitation plans and

tracing systems along with less stringent process control systems. But as you walk through the plant, you see the stations where the employees are checking systems and documenting their findings for review by plant managers. These control systems are fundamental to food production, and should form the core of a modern food safety system for both domestic and imported products, as proposed in the FDA Globalization Act. While written plans provide a platform for the systematic audits of food plants, they will only be effective if FDA has the capacity to inspect the plants regularly.

Voluntary Certification Program Could Improve Import Safety

The FDA Globalization Act takes an approach to improving the safety of imports that is already widely used in the retail sector today. The voluntary certification program for imported food contained in the discussion draft is an important provision, but truly only the minimum Congress should require to assure imported food is safe. CSPI would like to see certification made mandatory and there is strong support for this approach. Congress recently approved mandatory certification for children's toys under the Consumer Product Safety Commission Reform Act.[6] If the safety of imported toys children play with is subject to mandatory certification, why would Congress impose a lesser standard for the imported foods children eat?

Mandatory certification of imports was recommended by the President's Interagency Working Group on Import Safety for certain products.[7] The Grocery Manufacturers Association (GMA) "Four Pillars" plan discusses a Mandatory Quality Assurance Program for Importers that acts as a certification requirement. So, the question is not whether certification has a place, but how it is implemented.

[6] H.R. 4040, 110th Cong. § 10 (2007).
[7] *Action Plan for Import Safety*, Interagency Working Group on Import Safety, Nov. 2007, 23.

The FDA Globalization Act proposes a voluntary certification program for all types of food. It would allow FDA to certify facilities, provides FDA with authority to accredit foreign governments, other governmental bodies, or private agencies as certifying agents of FDA, and establishes incentives to encourage certification. Aspects of the certification model in the Act have already been tested in another statute. The National Organic Program uses certifying agents to evaluate compliance with the Organic Foods Production Act.

While CSPI prefers a mandatory certification program, we are willing to support the voluntary approach put forward in the FDA Globalization Act as long as there are strong incentives to participate and appropriate safeguards to assure that those who don't participate nonetheless deliver safe products to our ports. These elements are both in the discussion draft. Facilities that are certified are rewarded with the ability to come in through all U.S. ports of entry; less frequent inspections; periodic (rather than pre-market) laboratory testing; and access to the Safe and Secure Food Importation Program. Under the program, no products can be denied entry simply because the source is not certified. But consumers are protected by the requirements that uncertified products must enter through ports where they can be inspected closely and must be tested for contaminants.

Key elements to modernizing food inspection for our domestic industry

Aside from proposing process control systems, the FDA Globalization Act provides a number of key provisions for modernizing food safety for the food industry operating in the U.S., including seafood, produce, eggs, dairy and many processed foods.

Annual Facility Registration: First adopted in 2002 in the Bioterrorism Act, the registration of domestic and foreign food facilities that intend to sell food to U.S. consumers is

an essential component of a modern food safety system. Annual registration, as proposed in the discussion draft, would improve the reliability of the current facilities list and assure facilities can be located and are held accountable. A reliable list also gives FDA a true picture of the community of food suppliers it should inspect.

Recommendation *– The Committee could adopt a graduated fee so that smaller facilities or facilities that produce less risky products would pay less than large plants or producers of riskier products.*

Inspections: The FDA Globalization Act sets forth a mandatory minimum FDA inspection frequency of once every two years for uncertified facilities, or once every four years if they are certified. While CSPI would like to see more frequent inspections, with rates double that proposed in the bill, we strongly support the principle that food facilities should have a mandatory minimum inspection rate that at least puts them on par with plants that produce drugs and medical devices.[8] In fact, I have been told by former FDA officials that food inspections are given the lowest priority at the Office of Regulatory Affairs because they lack any statutory mandate for inspection.

Recommendation *–The minimum inspection frequency for food should be changed to once every year for uncertified facilities and once every two years if facilities are certified. In addition, the bill should include a specific proviso that FDA conducts more frequent inspections of high-risk facilities.*

On-Farm Food Safety Programs: The FDA Globalization Act requires producers of fresh fruits and vegetables to have a written plan for implementing process controls and to meet

[8] FDA is required to inspect drug and device establishments at least once in a two year period. 21 U.S.C. § 360(h) (2006).

performance standards established by FDA. This requirement is to be implemented one year after FDA issues regulations on how growers are to comply with it.

Recommendation *– Consider replacing the section with an amendment based on the Fresh Produce Safety Act, H.R. 5620, sponsored by Bruce Braley, which is pending in the Subcommittee on Health of the House Energy and Commerce Committee.*

Mandatory Recall and Civil Penalties: The FDA Globalization Act provides FDA with authority to order a recall of food that is adulterated or misbranded in a manner that may result in injury or illness. It also provides FDA with authority to assess a civil penalty of up to $100,000 (individual) or $500,000 (corporation) against anyone who commits a prohibited act. We strongly support these sections of the legislation, as we believe that stronger recall authority is warranted but should not remain the only solution to food safety problems. Civil penalties are more flexible, and can be used as a substitute for recalls when initiated for solely technical violations.

Key elements to modernizing food inspection for imported food

Certification Program: Voluntary certification solves the bottleneck problem inherent in moving from our existing open entry system to a certification program. The program encourages companies to become certified by providing strong incentives for participation. To better equip FDA with the resources to quickly certify facilities, the program includes accredited third-party certifying agents, including both foreign national governments (i.e. Canada, New Zealand); regional government (i.e. the European Union); and state governments (i.e. California, New York, or Florida). The bill provides some opportunities for private entities to become

certifying agents, but attempts to mitigate the risks by (1) specifying cooperatives as permissible agents and allowing FDA to expand the program to private entities only if they do not present any conflicts of interest issues; (2) conditioning continued accreditation on there being no outbreaks caused by products the agent certified and compliance with FDA requests; (3) providing FDA with authority to double check the agent's work without notice through inspections and audits; and (4) adding the filing of misleading or false food safety reports to the list of prohibited activities.

> ***Recommendation*** *– The Committee should phase in a mandatory certification program by requiring all foreign facilities to be certified within a certain period (such as five or 10 years).*

Other importer specific provisions:

Safe and Secure Food Importation Program: Certified foreign facilities can request recognition as Safe and Secure Food Importers and import food under expedited procedures.

Specific Ports of Entry: After a date specified by FDA, products from uncertified foreign facilities may only enter through ports located in metropolitan areas that have a federal laboratory. Certified foreign facilities can send products to any port.

Enforcement and Recall: FDA can deny entry to food imports from any country that delays or does not consent to an investigation when food from that country is linked to an outbreak of food-borne disease or found to be adulterated or mislabeled.

Registration of Importers: Commercial importers are required to register and pay a $10,000 fee.

Unique Identifier for Importers: FDA is to assign a unique identification number to each registrant (facilities and importers) and may use the number for any purpose.

Dedicated Foreign Inspectorate: FDA is directed to establish a corps of inspectors dedicated to inspecting foreign facilities. The corps must have enough inspectors to inspect foreign facilities at least as frequently as it does domestic facilities.

Key elements addressing funding deficiencies in FDA's Food Program

CSPI strongly supports efforts to increase funding for the food programs at FDA. As I testified last year, FDA's food program is in critical condition.[9] CSPI is working with the food industry and the Alliance for a Stronger FDA to educate members of Congress on the urgent need for greater appropriations.

We agree with the Committee that in any modernization plan, Congress must fully address funding for the new program, which the drafters have done in six separate provisions for raising fees in the discussion draft.[10] However, I have several overarching concerns that I urge the Committee to consider. In developing fees for the bill, the committee must recognize that the start-up costs of a fee-based system are significant. The registration and certification systems carry administrative costs that could be applied to FDA inspection. In addition, there is the

[9] "[I]ndustry and consumers together have estimated that the food program at FDA needs additional funding of approximately $450 million for that agency to meet its basic program requirements [for FY 2008]." *H.R. 3610, The Food and Drug Import Safety Act: Hearing Before the House Subcommittee on Health*, 110th Cong. (2007) (statement of Caroline Smith DeWaal, Food Safety Director, CSPI) *available at* http://energycommerce.house.gov/cmte_mtgs/110-he-hrg.092607.DeWaal-testimony.pdf.

[10] The fees included in the discussion draft are:

- A $2,000 annual facilities registration fee.
- A fee on foreign governments and agents for accreditation in an amount sufficient to generate revenues equal to the accreditation program's costs.
- A re-inspection fee in an amount sufficient to generate revenues equal to the costs of the re-inspection.
- An export certification fee in an amount sufficient to generate revenues equal to the costs of the service.
- A laboratory accreditation fee in an amount to generate revenues equal to the costs of the service.
- A $10,000 annual importer registration fee.

significant risk that OMB will take any fee-based system and use it to reduce overall appropriations to the agency, such that FDA will be no better off with fees than without. Therefore we caution the committee to consider carefully these issues in approving any fees outlined in this bill.

FDA Globalization Act Melds the Best Ideas from Industry, Consumers and Government

The FDA Globalization Act has taken ideas from the range of reform plans submitted by stakeholders from industry, consumer organizations and FDA in the aftermath of outbreaks of 2006 and 2007. Last year, CSPI released its "White Paper: Building a Modern Food Safety System for FDA-Regulated Products," the Grocery Manufacturers Association (GMA) released its "Four Pillars of Public-Private Partnership" plan, and FDA released its "Food Protection Plan." Each plan carried elements for improving food safety that have been crafted into the FDA Globalization Act.

Each of these plans called for changes in the facility registration program, implementation of process controls, better safety standards, improvements to the inspection system, greater oversight of imported foods, and more investment in research. Additionally, the plans by CSPI and FDA sought better enforcement tools such as mandatory recall and the authority to refuse imports from countries that hindered FDA inspections.

While each stakeholder may differ over the particulars of how to implement reform, the FDA Globalization Act offers an unprecedented opportunity for Congress to pass strong food safety reform that reflects the best ideas offered for improving the current system.

Mr. PALLONE. Thank you, and I want to thank all the panel. We will start with questions and I will recognize myself initially for 5 minutes. I am trying to get one question in for Mr. Taylor and then one for Mr. Ambrosio.

Mr. Taylor, you mentioned the need to strengthen the performance standards section in the discussion draft. We have gotten some questions on this provision in particular as there appears to be confusion as to what performance standards are and what they should be. Some even feel that it would be impossible to create performance standards for all foods and would like us to focus only on the top 10 contaminants and those most risky products. In your professional opinion, what should we be aiming for as we expand the performance standards section of the bill?

Mr. TAYLOR. I think this is a really important question to ask and I think Cal Dooley's comments sort of pose the issue. I think I completely agree with Cal that what we are not talking about is standards where the government is going in and telling companies how to produce safe food and how to design the brakes in the car. That is the old-fashioned command and control approach to regulation, which is a failure. I ran the food safety agency as USDA which is based on that principle and I have seen it not working very well. When I use the term performance standards, I am referring to standards that address the outcome that is to be achieved. We have these in the current system today. We have pesticide tolerances, for example, that set a quantitative limit on the amount of a residue that can be present in food and companies then work to meet that outcome. They are not told how to do it. They work to achieve it. We also have standards with respect to microbial pathogens, which is what I think we are really focusing on here today and of course the recent work that FDA has done on Listeria trying to find a health-based level of Listeria that protects public health and that the companies can then work to meet that what I refer to as a food safety outcome that is an acceptable level of contamination so it is not about mandating how they do it, it is ensuring on behalf of the public that these food safety plans are actually designed to achieve an outcome that is acceptable to the public. The modern approach to regulation is performance standards, not command and control mandatory standards.

I would also emphasize that there are many, many hazards in the food supply. I strongly believe that FDA ought to be directed to take a risk-based approach to focus on the most significant hazards in terms of impact on public health and figure out what are the selected commodity and pathogen-specific hazards for which a new performance standard can actually help drive progress on food safety so it should be targeted and it should be done in a way that is not prescribing how the industry does it but defines on behalf of the public what is an acceptable outcome in these high-priority cases.

Mr. PALLONE. Thank you.

Mr. Ambrosio, I would like to follow up on your comments on the concept of certification since your views on the matter seem to be different from Mr. Dooley's. My understanding is that many retailers including most of the largest like Wakefern but also Wegman's, Safeway, Giant, already now ask their suppliers to be certified for

safety by a third-party entity. In fact, that under one particular certification system already being used by major retailers, 30,000 facilities were certified last year alone. Is it your sense that that is where the food industry is heading? Is it your view that certification can play an important role in helping to augment FDA oversight?

Mr. AMBROSIO. Thank you. Certification can play an important and vital role in this. The SQF model, which is recognized by the Global Food Safety Initiative, is an international standard that parallels with the British Retail Consortium and the IFS. When you look at it, it is really, without getting too technical, and I can give you information with regard to the technicality of the program, but it truly is an enhanced HACCP program when you look at it. There are a lot of good things that manufacturers do, but in this particular case, when you look at a certification body that oversees what processes are being performed at those manufacturing facilities, it truly gives you a sense that there is a good management system that is put in place. It really is walking the walk and talking the talk. I mean, essentially when you go in there, it is the manufacturing facility that develops these plans and they live by it. It has been proven, it is worldwide, it has been globally recognized for several years now. It started when the Alar situation happened on the West Coast. So when you look at it from a global perspective, it is recognized. It parallels Dutch HACCP. It parallels many other global food safety initiatives that are out there and it is recognized.

Mr. PALLONE. Well, you mentioned this particular one, the Safe Quality Food program. Do you want to just elaborate a little more on how that operates with you?

Mr. AMBROSIO. Well, SQF is a FMI-managed program and essentially it is what I had said, it is a managed program. It is a really enhanced way of looking at things. They look at it from the grower's level, if you want to look at produce, for that matter, and then they take it all the way to the processing end. There are different levels of SQF where you get into SQF 1000 and 2000 and both address the needs of what you are actually looking at. It is pretty much tailored to the specific discipline of the operation, so if you are looking at a manufacturer, there are disciplines within the body of that program that address that. If you are looking at a farmer, it gives you those disciplines with regards to the growing conditions, and if you are processing spinach, as we had the incident back in 2006, you will see that that will go right into the processing facility in which the spinach is manufactured.

Mr. PALLONE. OK. Thanks a lot.

Mr. Deal.

Mr. DEAL. Thank you.

Dr. Sundlof testified that he thought FDA should be given the authority to promulgate regulations to prevent intentional adulteration of food by terrorists or criminals. Do any of you oppose FDA being given that authority? I see no opposition.

He also testified that FDA should have the authority to require that food facilities register with the FDA every 2 years. Do any of you oppose giving that authority statutorily? I see none.

He also testified that FDA cannot deny entry into the country of a food produced in a foreign facility where the facility operators hampered or denied FDA's ability to inspect that facility. He asked that we change the law to allow FDA to deny entry of foods produced in that facility. Do any of you oppose us changing the law in that regard? Yes, Ms. DeWaal?

Ms. DEWAAL. Mr. Deal, my apologies. Your second question slid by me. We actually support annual registration.

Mr. DEAL. So the 2 years is not often enough?

Ms. DEWAAL. Yes, but more to the point, all of these elements are—they are not opposed but they are not enough. They will not solve the problems we have seen with spinach, with peanut butter, with imported pet food and food ingredients. They will not solve those problems alone. But I don't oppose them per se.

Mr. DEAL. The foreign facility, I assume everybody would generally agree that if they have denied or hampered FDA's authority to inspect, that we should at least give FDA the authority to deny products from those facilities coming in. Anybody opposed to that proposal? OK.

He also requested in his testimony that FDA have the authority to order a mandatory recall in the event that a company does not conduct its own voluntary recall, and I think the indication is that we haven't had that situation develop yet. Would any of you—and that that authority in FDA be non-delegable below the Commissioner of FDA level. Would you all generally support that proposition? I believe I see agreement on that.

OK. Let me move to some of the other issues that we maybe don't have quite as much agreement on. You know, I referenced PDUFA reauthorization in my opening statement, and when we have been dealing with user fees in the past, user fees have generally been considered to have benefit for the people who are paying the fees. In the case of pharmaceuticals, to speed up the process of the FDA review so presumably their product could get to market quicker. What benefit to the payor of these fees do you see in the proposal here? OK. Sort of what I thought. Let me ask you—oh, yes. OK. Yes, ma'am?

Ms. DEWAAL. I think one of the issues of cost that has to be looked at is the price of not having a program, and not having a program today, an effective food safety program, actually costs consumers not to mention the cost to the victims of these outbreaks, which can be quite large, but even if you have a mild case of illness and you are out of work for 2 days, that costs you, your employer. So there are significant societal costs here. In addition though, the industry itself has faced significant costs from the failure and lack of a system. The spinach industry has faced, I think in liability costs alone, it is $100 million, which is what Mr. Dooley and I have been lobbying for as a minimum of what FDA needs next year to do its job for food safety. So the liability costs, the costs to the industry here are huge—business interruption, which occurred for the entire spinach industry. So the fee issues are not—nobody likes them but we need systems in place that are effective as soon as possible.

Mr. DEAL. Well, I think all of us would agree that we would like to avoid these kind of bad situations developing. If any of us had

confidence that we could write a statute that would do that, certainly we would do it. I don't think anybody thinks we have the ability to do that.

Mr. Dooley?

Mr. DOOLEY. Yes, if I can just respond, is that GMA and the related associations which I identified prior to my testimony, totally oppose the user fees that are currently being proposed or most of them that are being proposed in the draft. We would support perhaps a user fee that would be associated with an export certificate because that does provide a proprietary benefit. But again, when we look at this whole issue of public safety, this should be a public charge, much as your public safety on your streets and your communities of your neighborhoods, and that if you move down the path of charging a fee from the people who you are inspecting, you also have the potential to undermine the credibility and the integrity of this inspection service by having those who are being inspected basically funding it.

Mr. DEAL. And as you know, that is one of the concerns that we have had of becoming so dependent on those fees for what is supposed to be an objective analysis.

Thank you all, and my time is expired.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Deal.

The gentlewoman from Wisconsin, Ms. Baldwin.

Ms. BALDWIN. Thank you, Mr. Chairman. I have been focusing a lot in opening statements and previous questioning on the discussion draft's third-party testing provision. I am going to continue to do that with just a couple of quick questions for Mr. Lovett.

The discussion draft contemplates additional food testing over what is currently occurring, and I am wondering, looking forward to ultimate passage of a bill, implementation of a bill, what proportion of additional testing would you see third-party laboratories taking on versus FDA itself?

Mr. LOVETT. Thank you for your question, Congresswoman Baldwin. I think that third-party labs can take on substantial testing. It is not that there are a lot of empty labs sitting out there, just ready to start running tomorrow because obviously, our free enterprise system doesn't work that way. But companies like ourselves can ramp up laboratories very quickly. Just last year the Singapore laboratory that I mentioned, we took an empty building and 6 months later had an ISO 17025 certified laboratory running testing on food, and so, this is ramp-up that can happen very quickly and I think that in the absence of very substantial appropriations to allow the FDA to build the large number of labs that I think will ultimately be needed, the private sector can really make a big contribution here.

Ms. BALDWIN. You mentioned in your testimony that currently your company, Covance, works with the FDA, government at the federal level, State level, and private entities. Can you talk a little bit about the current partnership you have with FDA and then also explain to me how would the testing done by your company or a third party compare to the type of testing that is currently done by the FDA? Is it similar or is it different? Please elaborate.

Mr. LOVETT. Yes. Thank you again. I will take the second question first, if you don't mind. I think the testing is actually quite similar. You know, we both run AOAC methods when that is feasible or when they are available, and we run similar methods on other occasions. So I think the testing between a good government lab and a good private lab is basically the same.

In terms of work we have done with the FDA, it has been myriad work over the years on a multiple of occasions. Often it is something where, for example, in the case of ephedra, when that first became a safety concern several years ago, there wasn't a good method to identify ephedra in food and it was actually Covance that was retained by the FDA to develop a liquid crystal mass spectrometer analysis—I am a lawyer, not a chemist—to identify ephedra in both supplements and food. These were then fully validated by the AOAC and the FDA and they were used together with data that we generated through our own testing to ultimately ban dietary supplements containing ephedra. Another example is acrylamide. When that became a concern, we were contracted by the FDA to conduct a large market basket survey to identify how much acrylamide there actually was in a whole series of different kinds of foods, and I think that is a good example where we were able to ramp up very quickly to do what was a very large volume of testing on short notice that would have been difficult for an existing government lab that is already very busy to take on.

Ms. BALDWIN. Thank you.

Mr. LOVETT. Thank you.

Mr. PALLONE. The gentleman from Pennsylvania, Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. Dooley or anyone else who would like to respond, given all the new requirements, the import choke points, testing of every single import, what could we expect to happen to the price of food if this bill passes?

Mr. DOOLEY. Well, inevitably there would be an increase in the cost or the price of production that would inevitably be passed on to consumers so you would see an increase, but it is hard to quantify just what the magnitude of that would be. We can quantify what the magnitude of the fees would be. I mean, you have in the legislation with the registration fees, that is $600 million. If you look at the $10,000 per importer fee, what does that mean to Mr. Ambrosio's stores that he has. If they are importing directly, maybe it is wine from France or cheese from Europe or someplace, are they going to be liable for a $10,000 fee, or that little boutique store that you might have on Main Street that is an importer directly, are they also going to be $10,000? We look at that as being another magnitude that could be as much as $400 million on top of that. And then if you go into the regulatory side of it, that inevitably is going to increase some prices. But the one thing I want to clarify is, is that there is a lot of our companies today are doing—have in place the best practices, and when it comes to the audit, what we are concerned with is, we have a proposal that would say that every private sector company that has a set of preventive controls in place and if you are importing you have a supplier quality assurance plan, that plan will inevitably include a third-party probably certification or audit. But that is going to be a private

contractual arrangement that they will have with their supplier. Why we are so concerned and what we think will add additional costs here, if you have FDA sanctioning one audit that might be out there, is that you can create a restriction in the marketplace which will drive up the costs of audits that will also be passed on to that consumer, and you also have the threat of again imposing these on other countries and their companies that are manufacturing that they are going to have a new cost there that they are going to respond. And so I think we have to be very careful about going down this path of this certifying these third-party auditors.

Mr. PITTS. Now, you mentioned ethanol, the ethanol mandate for gasoline has dramatically increased the cost of food. Can we estimate the increase in the cost of food for this bill in conjunction with the ethanol mandate?

Mr. DOOLEY. You know, we haven't done the complete analysis on that. We have currently retained an economist that is doing some modeling to get some more precise figures in terms of the increased cost of food that is associated with the ethanol mandate. On this provision we haven't done that work yet.

Mr. PITTS. Can you provide the Committee with the analysis when you——

Mr. DOOLEY. We will do that.

Mr. PITTS. Thank you.

The draft calls for labeling packaged meat and poultry products when it has been packaged using minute levels of carbon monoxide. The rationale is that it may artificially keep the meat red longer and mislead consumers. Are there types of packaging that have the effect of preserving the redness of meat longer?

Mr. DOOLEY. Yes, there are a number of different alternatives that processors can use that can provide for preserving the color as well as in preserving the quality of the product for an extended period of time and this is an example. When I mentioned in my testimony that we are very concerned about prescriptive controls being put in place, this is a classic example of Congress putting a prescriptive control on what type of technology can be used in the packaging of a meat product. They are requiring a separate label that will basically make this very difficult to be used in the marketplace, and the concern that we have is that you have—when I was serving in Congress, of the 435 colleagues that I had there, none of them I think had a Ph.D. in food science, and yet you have Congress promulgating a provision that will impede the adoption and utilization of technology that has benefits to consumers.

Mr. PITTS. Has there been any evidence that the use of carbon monoxide in meat packaging has any adverse health effects?

Mr. DOOLEY. The scientific evidence overwhelmingly points out that this poses no health risk to consumers by its utilization.

Mr. PITTS. OK. I just have one more question. The draft requires country of origin labeling for where the final product was produced along with a requirement to maintain a Web site with a list of all sourced ingredients. Can you comment on that provision in terms of your ability to do it and in terms of what it contributes to food safety, anyone? Go ahead, Mr. Dooley.

Mr. DOOLEY. Well, first off, what the grocery manufacturers are absolutely committed to, it doesn't matter if that food product that

you are manufacturing in the United States or if you are importing a food product or if you are importing ingredients from any country throughout the world that those have to be safe, and that this idea that we are going to be able to develop a Web site where we can put on every ingredient that is in a particular product, it is going to be problematic. I mean, you look at a pound of Folgers coffee on the grocery store shelf. It could have beans coming from 27 different countries. And if you look in the frozen food aisle, you might have a product that has mixed vegetables in it. Well, at different times of the year, that company is going to be sourcing those vegetables from different countries. So are we then to put on the Web site this product could contain vegetables that came from these 50 countries at some point during the year, and what is the value to the consumer by providing that information? We would say there is little to none and it will not provide any significant benefits in terms of—any benefit whatsoever in terms of food safety issues.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. PALLONE. I am going to go to a second round, in part because I think we expect Mr. Dingell to come back so I am going to ask some questions myself and then we will go back and forth again for those who would like to.

Going back to Congressman Dooley again, in your testimony you emphasize that we need to implement a risk-based approach for the prevention of contamination, and in our conversations with industry experts, oftentimes though they sort of indicate that that is not an easy thing to do. Can you elaborate on this idea and explain how it would factor in safety mechanisms for what usually would be considered low-risk products like peanut butter which, as you know, was a recent cause of a salmonella outbreak?

Mr. DOOLEY. Well, I think that—and Mr. Taylor probably can elaborate on this too, is that there are some products that are processed in a manner which they are inherently low risk. There are some products that are going to be more acidic that are going to be a lower risk. There are going to be some products which are fresh and are semi-processed that are going to be of higher risk, and we need to have a regulatory system and an inspection system that is developed where you are allocating more of your scarce resources if you are FDA on those products that pose the greatest risk. And I would even say when you look at the fee structure that you put in place, does it make any sense to charge a flat fee of $2,000 across the board or should that be a risk-based fee? Does it make any sense to have an arbitrary number of inspections saying a plant has to be inspected every 2 years regardless of the risk of that product that is being processed? Once again, you need to have a system which is identifying the inherent risk of a product to consumers to have a foodborne illness and then allocating your resources in a way that is going to make the biggest difference.

Mr. PALLONE. I still don't understand how you would propose to do this risk-based modeling. I mean, I have been having a problem with that in many areas, not just this one, but let me go back to——

Mr. DOOLEY. If I can respond?

Mr. PALLONE. Sure.

Mr. DOOLEY. What you are doing in effect if you are establishing some of the performance standards that Mr. Taylor referenced, you are in fact then identifying that there are some levels in some products that are going to need to have a performance standard because you have identified a risk. This is not that hard to do.

Mr. PALLONE. All right. Following up then, let me ask Ms. DeWaal because obviously this relates to both what Congressman Dooley and Mr. Taylor said, I mean, you heard Mr. Taylor's views on the performance standards and basically this is the same question. What would we look at in terms of performance standards, and given the difficulty, in my opinion, in structuring a risk-based model, how do you factor this all in?

Ms. DEWAAL. Thank you, Chairman Pallone. On this issue of risk-based whether it is performance standards or inspection frequency, one thing that we have seen over the last year is even the U.S. Department of Agriculture, which has a much more robust inspection system, has been unable to develop the data necessary to really catalog their facilities in terms of risk. It doesn't mean they are not going to continue to work on it but the bottom line is, they don't have that system in place today to do it. In terms of performance standards, the way the Globalization Act is structured right now allows for FDA to utilize performance standards where they see it is appropriate. It leaves discretion in the agency itself to use performance standards. The model of using performance standards to evaluate and measure how the process controls are working is an excellent model but again, I would agree with your assessment—we are not there yet. We can't use it for every single food product, but we can use it more effectively than we do today.

Mr. PALLONE. Mr. Taylor?

Mr. TAYLOR. I just might add a point to hopefully clarify and add to this. The provision in the bill that would call for standards for fresh produce is an example, I would argue, of taking a risk-based approach, taking the evidence that we got from the outbreak investigations that have shown that we do have a risk of contamination of fresh produce with certain bacteria and that there is a need to put in place standards to prevent that, and the standards would presumably be crafted scientifically to address a particular hazard, whether it is salmonella or E. coli, and be a way to measure the success of the efforts that were taken, so the risk-based approach is making the decision to focus efforts in terms of standard setting and then inspection on this particular set of commodities because they pose public health risks. I want to underscore, there was some suggestion that somehow the food industry in running its business would take a risk-based approach. Well, in a way that is true, but the food industry has a fundamental obligation which I think most companies take seriously to ensure that every food that they produce is safe. You can make any food unsafe if you allow contamination with pesticides or other chemicals and so there is that foundational duty that the companies have to be sure that the broad standards for safety in the food laws are met, but the risk-based approach is really focused on how we target government efforts to get a public health benefit for the resources that are invested.

Mr. PALLONE. Mr. Pitts, do you want to ask any more questions?

Mr. PITTS. I will ask another one.

Mr. PALLONE. You are recognized.

Mr. PITTS. Thank you, Mr. Chairman.

To anyone, according to the FDA Food Protection Plan, there are over 300 ports in the United States where food is imported into this country. The draft legislation would require a certification for food facilities or the importer would be limited to the ports in which there is an FDA lab in that metropolitan area. Given that some labs are not located at major ports, the number of ports where food could be imported could actually be lower than 13. Is it practical to say that we are going to have the number of ports available to import food to be less than 13, and not have a devastating effect on our food supply? Who would like to comment?

Ms. DeWaal.

Ms. DEWAAL. Thank you so much. In terms of narrowing the number of ports of entry from 300 to 13, I think that the intention of the bill is not the way I read it plainly is to have a system where it is voluntary to get certified but there is a strong incentive. If companies want to continue to operate exactly as they do today, which is they can go to any port of entry they choose, they get certified, and it gives a time frame for allowing that certification to occur. It can't occur overnight because there aren't probably enough certifiers in place. The thing that certainly hit home for me as I listened to the FDA witness today was the fact that today they are not using their laboratories for the most part to check imported food. Very little imported food today is ever checked in a laboratory. I believe it is like two-tenths of 1 percent. So the new system will have to utilize laboratories, whether they are FDA laboratories or private laboratories, to do the testing that is needed for imports and that is not being done today.

Mr. PITTS. Anyone else like to comment?

Mr. Taylor.

Mr. TAYLOR. Well, I think the certification issue is getting a lot of discussion before this legislation moves forward. I think it is a very interesting idea and I think it has significant questions around it. I would urge that we think about certification as an add-on, a way to supplement a system that is based fundamentally on the duty of the importer to be able to document how it was that food they are importing, they are importing into the United States, they should be able to document how it is that that food was produced in a way that meets U.S. standards. As I understand the proposal that the GMA put out last fall on imports, that is what they recommend, and the reason I think that is so important because that is the legally accountable entity here in the United States that FDA can hold responsible and can prevent their ability to bring imports into whatever port if that assurance is not provided. Then there is the question of how those companies meet that—those importers, I should say, meet those duties and I think there are roles for third-party certification and a lot of different ways to sort of provide that assurance but I would build certification on top of a foundation of accountability for the importer to provide assurance that the product produced overseas is being produced in accordance with the same standards that we are able to enforce directly here in the United States.

Mr. PITTS. Mr. Ambrosio?

Mr. AMBROSIO. We like testing, as retailers. However, that is not what I really look at from my standpoint governing where I have to govern. Testing only validates a process. I don't know how many items you would have to test in order for somebody to feel good about it. If you look at Salinas Valley and you look at lettuce in that valley over there, and I have been there several times, how many heads of lettuce do you have to test in order for somebody to feel good about it? It all goes back to the culture of those farmers and how they produce the item and how they harvest the item coming to port. So you can test and test and test but you might not see everything that you are testing. Testing only gives you a snapshot and it validates the program. In the case of the biggest outbreak we have ever had on produce, it was domestic, it wasn't imported. So I think we really have to look at what we are doing domestically first and then think about we can take the good practices that we have learned domestically and then give the importers more of an opportunity to enhance their growing manufacturing procedures.

Mr. PITTS. Mr. Lovett?

Mr. LOVETT. If I could just build on what Mr. Ambrosio said, I totally agree that testing only validates an existing program and it is really the overall program that assures food safety. At the same time, that just begs the question of how much testing is needed to really validate the program, and I am not sure that two-tenths of 1 percent is enough. So I think even to go to 1 percent would be a fivefold increase, which would be very substantial. Without delving into all the details of certification as it relates to the question you first raised about linking ports of entry to the FDA labs, I think that leveraging the resources of private labs, which I think is going to be needed as a practical matter to increase the amount of testing at a rate that we are all going to probably want to see, means that you don't necessarily have to have that linkage to a particular port because there are private labs in all kinds of locations.

Mr. PITTS. Thank you very much for your testimony. My time is up.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

Again, I am just going to ask a few more questions. We are waiting for Mr. Dingell. He should be here any minute.

Let me go back to Mr. Dooley again. In your testimony, you state, and I quote, "Congress should direct FDA to develop a plan to help build the scientific and regulatory capacity of major exporters to the United States." Do you want to develop that? I mean, I know you made that statement, but what do you expect to be done to follow up on that?

Mr. DOOLEY. Well, I think this is where you really have to define that public-private partnership that can really help develop the capacity in many of the developing countries of the world to have the ability not only to establish the appropriate standards and protocols but also the ability to enforce those, and that is where I think, the potential. I don't want anyone to think that I am a critic of a standard for an audit. I think, though, those audits ought to be a

private contractual arrangement between the retailer, the manufacturer, and potentially the companies that are providing those ingredients. So there is the ability to help build out a private sector infrastructure that could see the greater utilization of some of these audits that have higher standards that can be deployed, and in some instances could be sanctioned by those governments to become the standard for that particular country. So there is a lot of work here. I mean, we are all part—the CSPI and GMA and others are part of a coalition to increase the funding for FDA. You know, we want to double it over 5 years. We think there are opportunities to do it. We are not talking about that much money in the grand scheme of things and we want to be a partner with all of you in trying to achieve that.

Mr. PALLONE. Thank you.

Mr. Dingell, Chairman Dingell is recognized for questions.

Mr. DINGELL. Mr. Chairman, thank you.

I would like to welcome my old friend, Mr. Dooley, back and tell him how pleased we are to have him here. Just real quickly, Mr. Dooley, do you think our current system of regulation is working well? Yes or no.

Mr. DOOLEY. Being a former Member of Congress, it is difficult to say yes or no.

Mr. DINGELL. Well, I only have 5 minutes and I have lost 15 seconds of it already.

Mr. DOOLEY. I think the system is working as well as we should expect. You know, we need to modernize FDA.

Mr. DINGELL. I note here that we have had 76 million illnesses, 325,000 hospitalizations, 5,000 deaths annually due to foodborne illnesses. Does that tell you things are working well?

Mr. DOOLEY. You know, we would clearly state that there is room for improvement. We are committed to trying to implement the private sector reforms and the public reforms that can achieve that, and we also have to accept what are the sources of those foodborne illnesses.

Mr. DINGELL. Let us look at this now, Mr. Dooley, because you are one of our experts on this matter. As I understand it, when the food processing industry spends money, they then charge it back against the consumers, for example, when they buy produce, they charge that against the consumers. When they advertise the buildings and food processing machines, they charge that against the consumers. When they have wages and things of that kind, they charge that against the consumers, right?

Mr. DOOLEY. We operate in a manner that is similar to any other private sector business, be it the auto industry or the food industry.

Mr. DINGELL. So you are here complaining, I note, about the fact that the food processing industry is going to be paying a $2,000 annual tax for each food facility and a $10,000 annual tax for each food importer to finance food objectives. That is a major objection of yours, is it not? But that is something that you are going to level against the consumers, isn't it? That is not being extracted from your pocket. That is coming out of the pocket of the consumers, isn't it?

Mr. DOOLEY. It is a cost of doing business.

Mr. DINGELL. Cost of doing business, and you are going to happily assess that against the consuming public. So if the consuming public doesn't complain about that and the consuming public says this is a good idea, we are going to get safer food, your complaint is pretty much vanished because, lo and behold, the people who are going to have to pay the charge happen to like the idea and your folks aren't going to pay it. Now, what, given that circumstance, is your complaint?

Mr. DOOLEY. I would say that I don't subscribe to your assessment that the consumer would have no problem with their food costs being increased, and I also would note that the Consumer Federation of America also objects to user fees.

Mr. DINGELL. Let us look at this thing. Your folks are afflicted by trial lawyers, who start lawsuits against your folks because you sell unsafe commodities and they collect big judgments, don't they?

Mr. DOOLEY. Our folks are totally committed to producing the safest products.

Mr. DINGELL. But the trial lawyers extract large sums of money in most generous settlements paid for by your clients, don't they?

Mr. DOOLEY. On the rare instance where we do have a food safety problem, trial lawyers oftentimes do find profit opportunities.

Mr. DINGELL. And your folks sit there in this very unhappy situation where you are seeing all this stuff coming in from China, dog food that is doctored, catfish, and other fishery products that are coming in that are coming from some of the most contaminated, polluted waters in the world. They are full of bacteria and microbes and all manner of nasty things, viruses, and as we look at it, the Chinese lace these very heavily with antibiotics. Now, I am not sure who they are protecting, the Chinese or us, but our people are getting a lot of antibiotics. Do you like that situation?

Mr. DOOLEY. No, and we are pleased that the legislation that——

Mr. DINGELL. And your people are——

Mr. DOOLEY [continuing]. Congressmen Costa and Putnam have introduced will put in place——

Mr. DINGELL. Let me finish.

Mr. DOOLEY [continuing]. Standards that improve that.

Mr. DINGELL. Your people are selling this stuff to Americans. Your members are doing that. And frankly, I have the view that you need a little protection from that situation, don't you?

Mr. DOOLEY. That is why we have advanced a set of proposals that would enhance the level of food safety.

Mr. DINGELL. So you need Food and Drug to have the money, the personnel to check these matters out, do you not?

Mr. DOOLEY. That is why we are part of the Alliance for a Stronger FDA.

Mr. DINGELL. Yes or no is usually quite sufficient because my time is, regrettably, very limited and I want to hear from you but I have to hear the answers that I need to hear so we have a good record, so we understand what you are really standing for and what you are really telling us.

Now, I was just taking a look here and I found that after the spinach outbreak in 2006, this comes from testimony which you may have heard already, spinach farmers reported losing $350 million, and have still not recovered when a second leafy green out-

break occurred in August 2007. Big lawsuits, spinach market killed, your people inconvenienced, lawsuits filed, fine mess, right?

Mr. DOOLEY. But we have supported FDA being required to develop good agricultural practices for leafy greens and other produce.

Mr. DINGELL. OK. So then we find that Peter Pan, and I like their peanut butter, but all of a sudden they had an outbreak that cost ConAgra $140 million, including $55 million in lost sales. That has gone on forever. Now, it occurs to me that maybe if Food and Drug had a little better capacity to inspect these things, we could all feel a little bit safer. These things might not have occurred and all the other things that are happening with regard to foods and pharmaceuticals wouldn't be transpiring. Am I right?

Mr. DOOLEY. No.

Mr. DINGELL. Now, I am kind of surprised to hear you say that you do not believe that a stronger food safety system would provide service to your industry.

Mr. DOOLEY. No, what I was saying, if I can go beyond the no, is that ConAgra, as you stated, they realize when they have $140 million loss with this one outbreak——

Mr. DINGELL. Well, do you think——

Mr. DOOLEY. —what more incentive do they need to have to put in place——

Mr. DINGELL. Let me ask——

Mr. DOOLEY. —protocols to make sure that won't happen.

Mr. DINGELL. Let me ask a question here. Do you think that we need a stronger food safety system in service to your industry or not?

Mr. DOOLEY. Yes.

Mr. DINGELL. Yes, you do agree? OK. Now, because you are goodhearted folks, make a fine living by putting food on Americans' dinner tables and the result of a good Food and Drug is that your people are protected, they don't get all these nasty lawsuits, they don't lose sales, they maintain customer confidence and a guy comes in and says well, I still want to get Peter Pan peanut butter because I think it is safe, but they lost $55 million on this deal and the spinach people are still not recovered. Now, what we have proposed in the discussion draft are fees. Fees are designed to improve the safety of the Nation's food supply and also to assure that you folks in your industry get safe foods in from places like China where they sell all manner of crap to the citizens of China, unsafe stuff, and if you have been to China, as I have a number of times, I think you have too, you will find that you are going to be damn careful of what you eat over there or you are going to come down with something real nasty, and what we want to do is see that this stuff that comes in is safe. I hope you are supportive of that. Are you?

Mr. DOOLEY. Well, you are supporting—enhancing the food safety system. That is recognized by the work——

Mr. DINGELL. The thing I find most interesting, Mr. Dooley, is, almost every other Food and Drug-regulated industry—pharmaceuticals, medical devices, animal drugs—they have all come forward and said this is a good idea, we want to have strong Food and Drug to protect our people against unsafe commodities, and yet comes my old friend Cal Dooley says we don't need any help, every-

thing is fine while we are poisoning people with bad fish from China, while we are poisoning people with unsafe spinach and peanut butter that is causing huge outbreaks of gastric difficulty to our people. Don't you think that is a little backward approach?

Mr. DOOLEY. I think that was a——

Mr. DINGELL. The food industry has had years of wonderful exemption from regulation. They just don't bother you. They get around to see your folks about every 10 years, look at the plant and say well, maybe this plant is OK, but the other 9 years and three-quarters, there is nobody bothering you. And look at what has happened. People are getting sick, bad commodities are getting on the market, and my old friend Cal Dooley is coming in here and telling us that this industry does not need any help. You are protecting the American people.

Mr. DOOLEY. Mr. Dingell——

Mr. DINGELL. I think we can take a poll in this room today and see how many people agree with you, or if we would walk up and down the street and ask Americans how good a job you are doing, I suspect they wouldn't be in agreement with you. What do you think about that?

Mr. DOOLEY. Will you give me the courtesy of responding?

Mr. DINGELL. I find myself curious. You have never been able to produce the support that it takes in your industry to give Food and Drug the resources that it needs. Nobody else has. So finally we have a way of making Food and Drug be able to finance things of particular importance. Now, it is interesting to note on imports, less than 1 percent of the imports of food are inspected by Food and Drug. You have unsafe fish, you have unsafe vegetables, you have unsafe meats, you have all kinds of stuff coming in. You have unsafe pharmaceuticals coming in. You have counterfeits. You have adulterated, filthy foods, pharmaceuticals and things of that kind coming in from overseas and here comes my old friend Cal Dooley here to tell this poor Polish lawyer from Detroit we really don't need any help, we are doing just fine. How do you feel about that?

Mr. DOOLEY. The industry and GMA back in September of last year advanced our four pillars for enhanced food safety. The basics and the components of those proposals is embodied in legislation that has been introduced by Congressman Costa and Congressman Putnam yesterday. It is a clear demonstration of this industry's commitment to enhance our food safety and further define the public-private partnership which can achieve those outcomes. We also make it very clear that, much like the medical device and the pharmaceutical industry, we will support user fees that provide a proprietary benefit to our members.

Mr. DINGELL. Let us address this. Since this industry all of a sudden became energized by the talk of introduction of legislation, they began doing all these things and yet unsafe foods are coming in from China. People are still getting sick from unsafe foods. Food and Drug doesn't have the resources to do the job and you are here this morning, or this afternoon now, telling us that you don't need any help and everything is fine.

Mr. DOOLEY. Mr. Dingell, that is a clear misrepresentation of my statements. We have consistently stated that we are supportive of, and have been constructively engaged with, your staff, with Mr.

Pallone's staff, with Republicans and Democratic members of this committee in offering our ideas and proposals on how we can enhance the food safety, both domestic as well as international.

Mr. DINGELL. Mr. Dooley, I have the greatest fondness for you, as you well know, but I didn't roll off the cabbage wagon yesterday, and I happen to know that your industry will go to any length to avoid legitimate regulation to protect the consumers. We are going to do that with your help, and I hope we will have your help, and we are going to do it without your help if we don't have your help. I will tell you, it will much easier for you and the industry to work with us than to work against us. I hope you will cooperate with us because the facts, Mr. Dooley, are not with you.

Mr. Chairman, I thank you.

Mr. PALLONE. Thank you, Chairman Dingell.

Mr. Pitts, did you want to add anything? You are done? All right.

First of all, let me thank all the members of the panel. We really appreciate your time and your bearing with us, and as Mr. Dingell said, we really do want your help and your cooperation and your ideas as we move forward, so thank you again.

Let me just say in closing, I want to remind the members that they may submit additional questions for the record to be answered by the relevant witnesses. The questions should be submitted to this committee clerk within the next 10 days so you will find out within the next 10 days if there are additional questions that we would like to have responses from in writing.

Without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 1:17 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. HENRY A. WAXMAN

I want to thank Chairman Pallone for holding this very important hearing today. I also want to commend our colleagues, Chairman Dingell, Chairman Pallone and Chairman Stupak for their efforts in pulling together this very strong legislation to address the very serious and glaring gaps in FDA's authority.

There are few issues that matter more to Americans than the safety of the foods they eat and the drugs and devices they rely upon each day to keep them healthy—or to save their lives.

People want to have the very basic assurance that, when they sit down for a meal, the food they eat won't make them sick. That should just be a given in our country. Americans expect no less.

Unfortunately, we now have far too much evidence that FDA has not been meeting these expectations.

Tainted peanut butter, contaminated fresh produce, uninspected imports about which little is known. I could continue with this list, but I think we have become all too familiar with it. Sadly, Americans have practically become accustomed to hearing these stories in the newspapers and on the nightly news.

So it is critical that we get FDA the authorities and resources it needs to fix this very disturbing and dangerous situation.

This bill takes some significant steps in that direction.

I strongly support the inclusion of a mandatory facility registration along with corresponding registration fees. The fees are minimal—just $2,000 per year per facility. This is a common-sense way to get FDA a desperately needed infusion of resources.

We are asking FDA to take on a great deal of new responsibility here and each aspect of that responsibility demands resources if we want FDA to succeed. The registration fees will provide a critical portion of those dollars and I hope the food industry will get behind them. We all know that giving FDA authority without the necessary resources is tantamount to doing nothing at all.

I also want to briefly address the third party certification program in the bill. As many of you know I've long been opposed to the concept of permitting third parties to fulfill what are essential FDA functions. But in the area of foods, where there are over 300,000 facilities around the world, I understand we are looking at a very different situation from the drug or device context.

So I think that there is a case for considering the use of third parties to supplement FDA's oversight of the imported food supply and to enlist the states in helping us inspect the domestic food supply. But this third party system is far from an ideal system for protecting American consumers, and a far cry from having FDA itself doing this work.

So if we create this kind of system, we have got to proceed with great caution. Ensuring that basic safeguards are in place is absolutely critical.

FDA must be able to maintain careful controls over the use of these third parties. FDA's accreditation process needs to ensure that the certifying agents possess the skills, expertise, and training necessary to act as an effective FDA surrogate. The Agency should be required to issue regulations clearly setting forth who may or may not become accredited. Once a third party is certified, FDA needs to perform frequent spot checks of certifying agent's work to ensure that those third parties are fulfilling their responsibilities—and then have the flexibility to swiftly revoke an accreditation if FDA concludes failures have occurred.

It is also critical that there be no conflicts of interest between the certifying agent and the facility.

I look forward to working with Chairman Dingell, Pallone, and Stupak to make sure these protections are clear and effective. If this program does not have integrity, it will not succeed.

We will need FDA to be our partner in bringing about the change envisioned in this legislation. We need strong leadership from the FDA and from the Administration both in the legislative process and after this bill becomes law.

As we continue the drafting process, we need and expect the Administration's cooperation in giving us full and open access to FDA's expertise and knowledge.

We also must have the best estimates from the Administration for the resources that are necessary to permit FDA to do the job we are asking it to do in this bill-and to do it well.

The time to act is now. I feel confident we have the political will here in Congress to get this done-and soon. The American people are counting on us.

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Food and Drug Administration Globalization Act of 2008".

(b) REFERENCES TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise specified, whenever in this Act an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; references; table of contents.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

Sec. 101. Changes in registration of food facilities.
Sec. 102. Food safety plan; process controls; and performance standards.
Sec. 103. Safety standards for fresh produce.
Sec. 104. Periodic inspections of food facilities.
Sec. 105. Reinspection fee applicable to facilities.
Sec. 106. Food facility certification program.
Sec. 107. Testing of food shipments; accredited laboratories.
Sec. 108. Safe and secure food importation program.

Subtitle B—Intervention

Sec. 111. Imports and commercial food importation through specific ports of entry.
Sec. 112. Research on testing techniques for use in inspections of imported food safety; priority regarding detection of intentional adulteration.

Sec. 113. Notification, nondistribution, and recall of adulterated or misbranded articles of food.

Subtitle C—Response

Sec. 121. Civil penalties relating to food.
Sec. 122. Enforcement and recall.

Subtitle D—Miscellaneous

Sec. 131. Labeling requirement for meat, poultry products, and seafood that contain carbon monoxide.
Sec. 132. Food substances generally recognized as safe.
Sec. 133. Country of origin labeling; disclosure of source of ingredients.
Sec. 134. New food and animal feed export certification fee to improve the ability of United States firms to export their products.

TITLE II—DRUG AND DEVICE SAFETY

Sec. 201. Registration fee applicable to producers of drugs and devices.
Sec. 202. Inspection of producers of drugs, active pharmaceutical ingredients, devices, and device parts.
Sec. 203. Documentation for admissibility of drug imports.
Sec. 204. Origin of ingredients.
Sec. 205. Testing for drug purity and identity.
Sec. 206. Country of origin labeling.
Sec. 207. Recall authority for drugs.
Sec. 208. Destruction of adulterated, misbranded or counterfeit drugs offered for import.
Sec. 209. Administrative detention of drugs that appear to violate the law.
Sec. 210. Civil money penalties for violative drugs and devices and improper import entry filings.

TITLE III—COSMETIC SAFETY

Sec. 301. Registration of cosmetic facilities.

TITLE IV—MISCELLANEOUS

Sec. 401. Registration and fee for commercial importers of food, drugs, devices, and cosmetics.
Sec. 402. Unique identification number for food, drug, and device facilities and establishments.
Sec. 403. Dedicated foreign inspectorate.
Sec. 404. Continued operation of field laboratories.
Sec. 405. False or misleading reporting to FDA.
Sec. 406. Application to biological products.
Sec. 407. Limitation to commercial importation.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.

(a) PROHIBITED ACTS.—Subsection (p) of section 301 (21 U.S.C. 331) is amended by inserting "or section 415, or to pay a registration fee in accordance with section 741" after "the failure to register under section 510".

(b) ANNUAL REGISTRATION AND PAYMENT OF REGISTRATION FEE.—

(1) IN GENERAL.—Section 415(a) (21 U.S.C. 350d(a)) is amended—

(A) in the first sentence of paragraph (1), by inserting "annually" after "be registered";

(B) in paragraph (1), by inserting "and pay the registration fee required under section 741" after "submit a registration to the Secretary" each place it appears in subparagraphs (A) and (B); and

(C) in paragraph (4), by inserting after the first sentence the following: "The Secretary shall remove from such list the name of any facility that fails to reregister in accordance with this section and shall treat such removal as a suspension of the facility's registration.".

(2) REGISTRATION FEE.—Chapter VII (21 U.S.C. 371 et seq.) is amended—

(A) by redesignating sections 741 and 742 as sections 744 and 745, respectively; and

(B) by adding at the end of subchapter C the following:

"PART 3—FEES RELATING TO FOOD

"SEC. 741. FACILITY REGISTRATION FEE.

"(a) IN GENERAL.—The Secretary shall assess and collect a fee for a facility registration under section 415 for food safety activities under this Act.

"(b) AMOUNT OF FEE.—

"(1) IN GENERAL.—Subject to paragraph (2), the amount of the fee under this section shall be $2,000 for the initial registration and each reregistration under section 415 of each facility operated by the registrant.

"(2) ANNUAL INCREASE.—

"(A) IN GENERAL.—Subject to the limitation specified in subparagraph (B), the amount of the fee under this section for registrations and re-registrations for a fiscal year after 2009 shall be the amount of such fee under this section for the previous fiscal year increased by the same percentage as the percentage inflation ad-

justment described in section 736(c)(1) for the fiscal year.

"(B) LIMITATION.—An increase in the amount of the fee under this paragraph shall not be made under this section for any fiscal year unless—

"(i) the amount appropriated for salaries and expenses of the Center for Food Safety and Applied Nutrition within Food and Drug Administration for such fiscal year is equal to or greater than the amount appropriated for salaries and expenses of such Center for fiscal year 2008 multiplied by the adjustment factor applicable to the fiscal year involved under section 736(c); and

"(ii) the amount appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year is equal to or greater than the amount appropriated for salaries and expenses of such Administration for fiscal year 2008 multiplied by the adjustment factor applicable to the fiscal year involved under section 736(c); and, except that in making deter-

minations under this subparagraph for the fiscal year involved there shall be excluded the amounts of fees collected under this part, section 736, section 738, and section 740.

In applying clauses (i) and (ii) there shall not be taken into account salaries or expenses that are paid from fees, including those collected under subsection (a), section 736, 738, 740, 741B, and 741D.".

(c) CONTENTS OF REGISTRATION.—Paragraph (2) of section 415(a) (21 U.S.C. 350d(a)) is amended by striking "containing information" and all that follows and inserting the following: "containing information that identifies the following:

"(A) The name, address, and emergency contact information of each facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States that the registrant operates.

"(B) The primary purpose and business activity of each such facility, including the dates of operation if the facility is seasonal.

"(C) The general food category (as listed under section 170.3(n) of title 21, Code of Fed-

eral Regulations, or as the Secretary may otherwise designate for purposes of evaluating potential threats to food protection) of any food manufactured, processed, packed, or held at each such facility.

"(D) All trade names under which each such facility conducts business related to food.

"(E) The name, address, and 24-hour emergency contact information of the United States distribution agent for each such facility, which agent shall maintain information on the wholesale and retail distribution of food.

Such registration shall also include an assurance that the registrant will notify the Secretary of any change in the products, function, or legal status of each such facility (including cessation of business activities) not later than 30 days after the date of such change.".

(d) SUSPENSION AUTHORITY.—Such section is further amended by adding at the end the following:

"(6) SUSPENSION OF REGISTRATION.—

"(A) IN GENERAL.—The Secretary may suspend the registration of any facility registered under this section, including the facility of an importer—

"(i) for violation of this Act that could result in serious adverse health consequences or death to humans or animals; or

"(ii) if the facility, or employee of the facility, delays, limits, or denies an inspection by the Secretary under this Act.

"(B) NOTICE AND OPPORTUNITY FOR HEARING.—Before suspending the registration of a facility under this paragraph, the Secretary shall provide notice to a registrant of an intent to suspend the registration and provide the registrant with an opportunity for an informal hearing. The Secretary may issue a written order of suspension following the hearing, if the Secretary finds that a violation described in subparagraph (A) has occurred.

"(C) REINSTATEMENT.—A registration that is suspended under this section may be reinstated pursuant to criteria published by the Secretary in the Federal Register and on a public website of the Food and Drug Administration.

"(D) APPEAL.—Any registrant whose registration is suspended under this section may

appeal that action in any appropriate district court of the United States.".

(e) EFFECTIVE DATE.—

(1) MODIFICATION OF REGISTRATION FORM.—Not later than 30 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall modify the registration form under section 415 of the Federal Food, Drug, and Cosmetic Act to comply with the amendments made by subsection (c).

(2) APPLICATION.—The amendments made by this section, other than by subsection (c), shall take effect on the date that is 30 days after the date on which such modified registration form takes effect, but not later than 60 days after the date of the enactment of this Act.

SEC. 102. FOOD SAFETY PLAN; PROCESS CONTROLS; AND PERFORMANCE STANDARDS.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

"SEC. 418. FOOD SAFETY PLAN; PROCESS CONTROLS; AND PERFORMANCE STANDARDS.

"(a) IMPLEMENTATION OF FOOD SAFETY PLAN.—

"(1) IN GENERAL.—Before a facility (as defined in section 415(b)) introduces or delivers for in-

troduction into interstate commerce any shipment of food, the owner, operator, or agent in charge of the facility shall develop and implement a written food safety plan (in this section referred to as a 'food safety plan') that is based on an analysis of—

"(A) the specific practices for—

"(i) obtaining and ensuring the safety of raw materials and ingredients for food produced, manufactured, processed, packed, or held at a facility;

"(ii) producing, manufacturing, processing, packing, and holding food at the facility; and

"(iii) transporting food to and from the facility; and

"(B) any hazard that has been present in or on, or is reasonably likely to be present in or on, any food that is manufactured, processed, packed, or held at the facility.

"(2) CONTENTS.—The food safety plan shall include each of the following elements:

"(A) A description of the preventive controls being implemented that are reasonably appropriate to control or limit identified hazards and to comply with applicable hazard-specific

performance standards and other food safety regulatory requirements.

"(B) Validation that such preventive controls are effective to reduce, control, or eliminate such hazard.

"(C) A description of monitoring of such preventive controls being implemented, including sampling and testing relating to the control of hazards where appropriate to verify that the controls are effective.

"(D) A description of the recordkeeping being conducted, including evidence of corrective actions, sampling and testing records, monitoring and verification records, and validation records.

"(E) A description of established procedures for the recall of such articles of food, whether voluntarily or when required under section 423.

"(b) FOOD SAFETY PLAN REVISIONS.—

"(1) IN GENERAL.—The food safety plan shall be revised—

"(A) when major changes have been made by the owner facility; and

"(B) as deemed appropriate by the Secretary.

"(2) INCLUSION OF SPECIFIC HAZARD CONTROLS.—The Secretary may require that a food safety plan for a facility include specific hazard controls, if such controls are needed to ensure the protection of the public health including to prevent intentional adulteration of food.

"(c) INSPECTION OF FOOD SAFETY PLAN IN COURSE OF FACILITY INSPECTION.—In the course of a facility inspection under section 704A, the Secretary shall conduct a review of the food safety plan to ensure the plan—

"(1) is based on a thorough hazard analysis and is adequate to protect the public health;

"(2) meets relevant regulatory and food safety standards; and

"(3) limits the presence and growth of contaminants in food prepared in a facility to meet performance standards of subsection (d).

"(d) PERFORMANCE STANDARDS.—

"(1) IN GENERAL.—To protect the public health, the Secretary may establish by regulation and enforce performance standards that define, with respect to specific foods and contaminants in food,

the level of food safety performance that a facility shall meet.

"(2) CONSULTATION.—In establishing performance standards under this subsection, the Secretary shall consult with the Centers for Disease Control and Prevention and infectious disease experts outside the federal government, and hold public meetings for the purpose of receiving public input and comment.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to food shipments introduced or delivered for introduction into interstate commerce on and after the date that is 2 years after the date of the enactment of this Act.

SEC. 103. SAFETY STANDARDS FOR FRESH PRODUCE.

Chapter IV (21 U.S.C. 341 et seq.), as amended by section 102(a), is further amended by adding at the end the following:

"SEC. 419. SAFETY STANDARDS FOR FRESH PRODUCE.

"(a) IN GENERAL.—Section 418 (relating to food safety plan; process controls; and performance standards) shall apply with respect to the production of a type of fresh produce for consumption in the United States 1 year after the date on which the Secretary by regulation de-

scribes how a producer of such type of fresh produce may comply with such section.

"(b) LOCAL GROWING CONDITIONS.—The Secretary shall assist a State or foreign country in identifying how, considering local growing conditions, producers in such State or foreign country may comply with section 418, as applied under subsection (a).

"(c) VARIANCES.—If the Secretary issues a regulation under subsection (a) with respect to the production of a type of fresh produce, the Secretary shall provide for a variance from such a regulation for producers in a State or foreign country if the State or foreign country determines, and the Secretary concurs, that the variance—

"(1) is necessary in light of local growing conditions; and

"(2) will be at least as effective in controlling hazards as if the variance had not been provided.

"(d) FRESH PRODUCE DEFINED.—In this section, the term 'fresh produce' means any fruit or vegetable that is intended to be sold to the consumer—

"(1) in its unpeeled, natural form; or

"(2) with minimal processing (such as peeling, chopping, or trimming).".

SEC. 104. PERIODIC INSPECTIONS OF FOOD FACILITIES.

(a) IN GENERAL.—Chapter VII is amended by adding after section 704 the following:

"SEC. 704A. PERIODIC INSPECTIONS OF FOOD FACILITIES.

"(a) NATURE OF INSPECTIONS.—

"(1) IN GENERAL.—The Secretary shall provide for an inspection system for the conduct of unannounced inspections of facilities (as defined in section 415(b)) to determine whether such facilities are operating in compliance with this Act and with good manufacturing practices, including the requirements of section 419. Inspections shall include review of records and sampling of food products.

"(2) TIMING OF INSPECTIONS.—

"(A) IN GENERAL.—Subject to subparagraph (B), inspections of facilities shall be conducted every 4 years.

"(B) NONCERTIFIED FACILITIES.—Inspections of facilities that are not certified under section 418 shall be conducted every 2 years.

"(3) SANCTION FOR INTERFERENCE WITH INSPECTIONS.—If a facility or employee of a facility delays, limits, or denies an inspection of the facility under this section, the Secretary shall make a determination that may result in the facility losing its registration under section 415.

"(b) CONDUCT OF INSPECTIONS.—

"(1) SCOPE.—An inspection under subsection (a) of any facility shall extend to all things therein that bear on whether food products are in compliance with this Act. Access to records may include the copying of such records.

"(2) AUTHORITY.—In conducting such inspections, officers or employees duly designated by the Secretary, upon presenting appropriate credentials to the owner, operator, or agent in charge, are authorized—

"(A) to enter at reasonable times any facility in or to enter any vehicle being used to transport or hold such food products;

"(B) to inspect in a reasonable manner such facility or vehicle and all pertinent equipment, finished and unfinished materials, containers, labeling, processes, controls, and premises;

"(C) to collect and retain samples of food products or ingredients or of any other items found during an inspection that may contribute to a finding of whether such food products are unsafe for human consumption or adulterated or misbranded under this Act;

"(D) to review food safety plan established under section 418; and

"(E) may take photographs and such photographs shall be treated as documents subject to section 301(j).

"(3) WRITTEN REPORT.—Within 24 hours after completion of inspection, the Secretary or certifying agent making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed which indicate that either processing controls are inadequate to prevent or minimize food safety hazards or that any food from such facility is unsafe for human consumption, or adulterated or misbranded under this Act.

"(c) PRODUCT DETENTION AND CONDEMNATION.—

"(1) ORDERS.—If, during an inspection conducted under this section, the Secretary or certifying agent has reason to believe that a food product is unsafe for human or animal consumption, or adulterated or misbranded under this Act, the Secretary may order the food product segregated, impounded, and if objection is not made within 48 hours, condemned. If objection is made, such food products that are in perishable form may be processed to the

extent necessary to prevent spoilage, and a hearing shall be commenced expeditiously.

"(2) RELABELING.—If the Secretary determines that, through re-labeling or other action, such food products can be brought into compliance with this Act , the food may be released following a determination by the Secretary that such re-labeling or other action as specified by the Secretary has been performed.

"(3) DESTRUCTION OF CONDEMNED FOOD.—Any food product condemned without objection, or after an informal hearing, shall be destroyed under supervision of the Secretary.".

(b) CONFORMING AMENDMENTS.—

(1) Section 415(a) (21 U.S.C. 350d(a)), as amended by section 101(b), is amended by adding at the end the following:

"(7) INSPECTION.—Every facility that is registered under this section shall be subject to inspection pursuant to section 704A.".

(2) OTHER INSPECTION RIGHTS AND DUTIES.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following new subsection:

"(h) The rights and duties under this section of duly designated officers and employees and of other persons

shall apply to the exercise of authority under section 704A.".

SEC. 105. REINSPECTION FEE APPLICABLE TO FACILITIES.

(a) IN GENERAL.—Part 3 of chapter VII (21 U.S.C. 371 et seq.), as added by section 101(b)(2), is further amended by adding at the end the following:

"SEC. 741A. REINSPECTION FEE APPLICABLE TO FACILITIES.

"(a) IN GENERAL.—The Secretary shall assess and collect fees from each facility (as defined in section 415(b)) that—

"(1) during such fiscal year, commits a violation of any requirement of this Act relating to food, including any such requirement relating to good manufacturing practices; and

"(2) because of such violation, undergoes additional inspection by the Food and Drug Administration.

"(b) AMOUNT OF FEES.—The Secretary shall set the amount of the fees under this section to fully defray the costs of conducting the additional inspections referred to in subsection (a)(2).

"(c) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to this section available sole-

ly to pay for the costs of additional inspections referred to in subsection (a)(2).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to additional inspections occurring after the date of the enactment of this Act.

SEC. 106. FOOD FACILITY CERTIFICATION PROGRAM.

(a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102(a) and 103, is amended by adding at the end the following:

"SEC. 420. FOOD FACILITY CERTIFICATION PROGRAM.

"(a) IN GENERAL.—

"(1) CERTIFICATION.—The Secretary shall establish a program for the certification of a facility as being in compliance with the applicable requirements of this Act. Such program shall provide for—

"(A) direct certification by the Secretary; or

"(B) certification by a certifying agent that has been accredited under subsection (b).

"(2) VOLUNTARY CERTIFICATION.—Any facility may apply to be certified to the Secretary under this section.

"(3) FACILITY DEFINED.—For purposes of this section, the term 'facility' has the meaning given

such term in section 415(b), and includes both foreign and domestic facilities.

"(4) CERTIFIED FACILITY DEFINED.—For purposes of this chapter, the term 'certified facility' means a facility that has been certified under the program established under this subsection.

"(b) LISTING AND NOTICES.—

"(1) PUBLIC LISTING OF CERTIFIED FACILITIES.—The Secretary shall make available to the public through the Internet Web Site of the Food and Drug Administration a list of each facility that is certified under this section and the date on which such certification will no longer be in effect.

"(2) DURATION OF CERTIFICATION.—The certification for a facility under this section shall be in effect for 2 years from the date the Secretary or certifying agent approves the application for such certification of the facility.

"(3) REQUIRED INSPECTION.—No facility shall be certified without having been inspected by the Secretary or a certifying agent.

"(4) NOTICES OF VIOLATIONS.—

"(A) IN GENERAL.—If a certifying agent in the process of inspecting a facility for certification determines that the facility's food safety

plan is in violation of this Act and that the facility has failed to take corrective action within 30 days, the agent shall notify the Secretary of such violation and such failure.

"(B) IMMEDIATE NOTICE.—A certifying agent shall notify the Secretary immediately during inspection of a facility if the food at the facility appears to be unsafe for human or animal consumption or adulterated or misbranded

"(5) SUSPENSION OF CERTIFICATION.—The Secretary may suspend the certification of a facility under this section if, after opportunity for an informal hearing, the Secretary finds that—

"(A) the food safety plan of the facility fails to comply with requirements of section 418; or

"(B) the facility is found on inspection not to be in compliance with other applicable requirements of this Act.

"(c) ACCREDITATION OF FOREIGN GOVERNMENTS AND CERTIFYING AGENTS.—

"(1) IN GENERAL.—Beginning not later than 2 years after the date of enactment of this section, the Secretary shall establish and implement an accreditation system under which a foreign government, a

State or regional food authority, a foreign or domestic cooperative that aggregates the products of growers or processors, or any other third party that the Secretary determines appropriate, may request permission to certify that facilities meet the applicable requirements of this Act.

"(2) REQUEST BY FOREIGN GOVERNMENT.—Prior to accrediting a foreign government as a certifying agent under this paragraph (1)(A), the Secretary shall perform such reviews and audits of food safety programs, systems, and standards of the government (including all statutes, regulations, and inspection authority) as the Secretary deems necessary to determine that they are adequate to ensure that facilities certified by such government meet the requirements of this Act with respect to food manufactured, processed, packed, or held for import to the United States.

"(3) REQUEST BY OTHER THIRD PARTY.—Prior to accrediting a third party under paragraph (1)(B), the Secretary shall perform such reviews and audits of the training and qualifications of inspectors used by the agent and conduct such reviews of internal systems and such other investigation of the party as the Secretary deems necessary to determine that

each facility certified by the party has systems and standards in use to ensure that such facility meets the requirements of this Act.

"(d) IMPORTATION.—As condition of accrediting such government or certifying agent, the government or certifying agent shall agree to issue a written and electronic certification to accompany each food shipment made for import from a facility certified by such government or certifying agent, subject to requirements set forth by the Secretary.

"(e) MONITORING.—Following any accreditation of a certifying agent under subsection (b), the Secretary may at any time—

"(1) conduct an on-site audit of any facility certified by the agent, with or without the certifying agent present; or

"(2) require the agent to submit to the Secretary, for any facility certified by the agent, an on-site inspection report and such other reports or documents the agent requires as part of the audit process, including for a facility located outside the United States documentation that the facility is in compliance with registration requirements and prior notice requirements for food imported to the United States.

"(f) DEFINITIONS.—For purposes of this section:

"(1) CERTIFYING AGENT.—The term 'certifying agent' means a foreign government or other third party that conducts certification of facilities.

"(2) INSPECTOR.—The term 'inspector' means a person who has completed training as required by the Secretary in the conduct of food safety inspections.

"(g) LIMITATION.—

"(1) TO SPECIFIED FOOD PRODUCTS.—The Secretary may limit the accreditation of a foreign government or a third party under this section to the certification of facilities for the import to the United States only of specified food products (or specified categories of food products), as determined by the Secretary.

"(2) TO AVOID CONFLICTS OF INTEREST WITH CERTIFYING AGENTS.—The Secretary shall promulgate regulations to ensure that there are adequate protections against conflicts of interest between a certifying agent and the facility to be certified by such agent.

"(h) WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation from a certifying agent under subsection (b)—

"(1) if food from facilities certified by such agent is linked to an outbreak of human or animal illness;

"(2) following an investigation and finding by the Secretary that the agent no longer meet the requirements of subsection (b) for accreditation; or

"(3) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to ensure continued compliance with the requirements set forth in this section.

"(i) RENEWAL OF ACCREDITATION.—The Secretary shall audit accredited certifying agents whenever needed, but no less than once every three years, to ensure the continued compliance with the requirements set forth in this section. Renewal of accreditation shall occur following each satisfactory audit.".

(b) FEE.—Part 3 of chapter VII, as added by section 101(b) and amended by section 105(a), is amended by adding at the end the following:

"SEC. 741B. CERTIFYING AGENT FEE.

"(a) IN GENERAL.—The Secretary shall assess and collect a fee for the accreditation of a foreign government or third party as a certifying agent under section 420 for the purpose of defraying the costs of the implementation

of the accreditation programs required to carry out such section.

"(b) AMOUNT OF FEE.—The amount of a fee under this section shall be as determined by the Secretary.".

SEC. 107. TESTING OF FOOD SHIPMENTS; ACCREDITED LABORATORIES.

(a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(oo) The introduction or delivery for introduction into interstate commerce by facility that is not certified under section 420 of any shipment of food before arranging for sampling and testing of such shipment and submitting the results of such sampling and testing to the Secretary in accordance with section 421.".

(b) TESTING OF FOOD SHIPMENTS; ACCREDITED LABORATORIES.—Chapter IV (21 U.S.C. 341 et seq.), amended by sections 102(a), 103, and 106(a), is further amended by adding at the end the following:

"SEC. 421. TESTING OF FOOD SHIPMENTS; ACCREDITED LABORATORIES.

"(a) TESTING IN NON-CERTIFIED FACILITIES.—Before introducing or delivering for introduction into interstate commerce any shipment of food, a facility (as defined in section 415(b)) that is engaged in manufacturing, processing, packaging, or holding such food and that is not

certified under section 420 with respect to such food shall arrange for a laboratory accredited under subsection (c)—

"(1) to conduct sampling and testing of such shipment to ensure compliance with applicable food safety standards; and

"(2) to simultaneously submit electronically the results of such sampling and testing to the Secretary and to the owner of such facility.

"(b) TESTING IN CERTIFIED FACILITIES.—A facility certified under section 420 that is engaged with manufacturing, processing, packaging, or holding food shall arrange for a laboratory accredited under subsection (c)—

"(1) to conduct, on a periodic basis specified by the Secretary, sampling and testing of shipments of food being introduced or delivered for introduction into interstate commerce to ensure compliance with applicable food safety standards; and

"(2) to submit electronically the results of such sampling and testing to the Secretary and to the owner of such facility.

"(c) ACCREDITATION OF LABORATORIES.—

"(1) IN GENERAL.—The Secretary shall accredit laboratories for the purpose of conducting sampling and testing under subsections (a) and (b).

"(2) STANDARDS.—Not later than 1 year after the date of the enactment of this section, the Secretary shall establish and publish in the Federal Register standards to accredit or deny accreditation to laboratories under this subsection. A laboratory shall not be accredited unless it has paid the accreditation fee required under section 741C.

"(3) AUDITS.—To ensure that laboratories accredited under this subsection continue to meet the standards of accreditation, the Secretary shall—

"(A) make onsite visits on an annual basis to each accredited laboratory to audit the performance of such laboratory; and

"(B) take such additional measures as the Secretary determines to be appropriate.".

(c) ACCREDITATION FEE.—Part 3 of chapter VII, as added by section 101(b) and amended by sections 105(a) and 106(b), is amended by adding at the end the following:

"SEC. 741C. LABORATORY ACCREDITATION FEE.

"The Secretary shall assess and collect an annual fee, specified by the Secretary, for accreditation under section 421(c) for the purpose of defraying the costs of the accreditation activities under such section.".

(d) EFFECTIVE DATE.—Sections 301(oo) and 421(a) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall apply to shipments of food introduced or delivered for introduction into interstate commerce on or after such date, not later than 3 years after the date of the enactment of this Act, as the Secretary of Health and Human Services shall specify.

SEC. 108. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

Chapter VIII (21 U.S.C. 381 et seq.) is amended by adding at the end the following:

"SEC. 805. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

"(a) IN GENERAL.—Beginning not later than 2 years after the date of the enactment of this section, the Secretary shall establish by regulation and carry out a program under which the Secretary expedites the movement of food through the importation process under this Act if each facility involved in the production, manufacture, processing, packaging, and holding of the food—

"(1) is certified under section 420; and

"(2) has agreed to abide by, and has been determined by the Secretary to be in compliance with, the food safety and security guidelines developed under subsection (b) with respect to such food.

"(b) GUIDELINES.—

"(1) DEVELOPMENT.—For purposes of the program established under subsection (a), the Secretary shall develop safety and security guidelines applicable to the importation of food.

"(2) FACTORS.—Such guidelines shall take into account the following factors:

"(A) The personnel of the person importing the food.

"(B) The physical and procedural safety and security of such person's food supply chain.

"(C) The sufficiency of access controls for food and ingredients purchased by such person.

"(D) The need for tracking and maintaining records on food and ingredients purchased by such person or moved through the supply chain.

"(E) Documentation processing through such person's supply chain.

"(F) Access by the Secretary to such person's business records for review.

"(G) Vendor and supplier information.

"(H) Such other factors as the Secretary determines necessary.".

Subtitle B—Intervention

SEC. 111. IMPORTS AND COMMERCIAL FOOD IMPORTATION THROUGH SPECIFIC PORTS OF ENTRY.

Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102(a), 103, 106(a), and 107(b), is further amended by adding at the end the following:

"SEC. 422. IMPORTS AND COMMERCIAL FOOD IMPORTATION THROUGH SPECIFIC PORTS OF ENTRY.

"Beginning on a date (not later than 5 years after the date of enactment of this section) specified by the Secretary, food shall only enter the United States, other than only for personal use, through a port of entry that is located in a metropolitan area with a federal laboratory, unless each facility (as defined in section 415(b)) that has manufactured, processed, packed, and held the food is certified under section 420.".

SEC. 112. RESEARCH ON TESTING TECHNIQUES FOR USE IN INSPECTIONS OF IMPORTED FOOD SAFETY; PRIORITY REGARDING DETECTION OF INTENTIONAL ADULTERATION.

Section 801 (21 U.S.C. 381) is amended by adding at the end the following: "

"(p) RESEARCH ON TESTING TECHNIQUES FOR USE IN INSPECTIONS OF IMPORTED FOOD SAFETY.—

"(1) IN GENERAL.—The Secretary shall (directly or through grants or contracts) provide for research on the development of tests and sampling methodologies, for use in inspections of food under this section—

"(A) whose purpose is to determine whether food is adulterated by reason of being contaminated with microorganisms, chemical toxins, or pesticide chemicals or related residues; and

"(B) whose results are available not later than approximately 60 minutes after the administration of the tests.

"(2) PRIORITY.—

"(A) IN GENERAL.—In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States, with the greatest priority given to the development of such tests that the Secretary determines would be useful in detecting the intentional adulteration of food.

"(B) SPECIFIC PRIORITIES.— In providing for such research, the Secretary shall give pri-

ority under this paragraph to conducting research on the development of tests and sampling methodology for detecting the presence in or on food of—

"(i) pathogens, including Escherichia coli (STEC) 0157, salmonella, cyclospora, cryptosporidium, hepatitis A, Clostridium botulinum, or listeria;

"(ii) pesticide chemicals and related residues;

"(iii) chemical toxins; and

"(iv) such other pathogens or substances as the Secretary determines to be appropriate, including any pathogen or substance that the Secretary determines is a candidate for use to intentionally adulterate food.

"(C) GOAL.—The Secretary shall establish the goal of developing, by the expiration of the 3-year period beginning on the date of the enactment of this subsection, tests and methodologies under paragraph (1) for each of the pathogens and substances receiving priority under this paragraph.

"(3) PERIODIC REPORTS.—

"(A) IN GENERAL.—The Secretary shall submit to the Congress periodic reports describing the progress that has been made toward the goal referred to in paragraph (1)(C) and describing plans for future research toward the goal.

"(B) CONTENTS.— Each of the reports shall provide an estimate by the Secretary of the amount of funds needed to meet such goal, and shall provide a determination by the Secretary of whether there is a need for further research under this subsection.

"(C) DEADLINES.— The first report under this paragraph shall be submitted not later than 2 years after the date of the enactment of this subsection. Subsequent reports shall be submitted annually until such goal is met.

"(4) CONSULTATION.—The Secretary shall carry out the program of research under paragraph (1) in consultation with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Administrator of the Environmental Protection Agency. The Secretary shall with respect to such research coordinate the activities of the Department of Health and

Human Services. The Secretary shall in addition consult with the Secretary of Agriculture (acting through the Food Safety and Inspection Service of the Department of Agriculture) in carrying out the program.".

SEC. 113. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331), as amended by section 107(a), is amended by adding at the end the following:

"(pp)(1) The failure to notify the Secretary in violation of section 423(a).

"(2) The failure to comply with—

"(A) an order issued under section 423(b) following any hearing requested under section 423(c); or

"(B) an amended order issued under section 423(d)(1).".

(b) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.—Chapter IV (21 U.S.C. 341 et seq.), as amended by sections 102(a), 103, 106(a), 107(b), and 111, is further amended by adding at the end the following:

"SEC. 423. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED ARTICLES OF FOOD.

"(a) NOTIFICATION TO SECRETARY OF VIOLATION.—

"(1) IN GENERAL.—A person (other than a household consumer or other individual who is the intended consumer of an article of food) that has reason to believe that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury shall, as soon as practicable, notify the Secretary of the identity and location of the article.

"(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation.

"(b) RECALL AND CONSUMER NOTIFICATION.—

"(1) VOLUNTARY ACTIONS.—On receiving notification under subsection (a) or by other means of a suspected adulteration or misbranding of food, if the Secretary finds that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first

sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury (as determined by the Secretary), the Secretary shall provide all appropriate persons (including the manufacturer, importer, distributor, or retailer of the article) with an opportunity (as determined by the Secretary)—

"(A) to cease distribution of the article;

"(B) to notify all persons—

"(i) that produce, manufacture, pack, process, prepare, treat, package, distribute, or hold the article, to cease immediately those activities with respect to the article; or

"(ii) to which the article has been distributed, transported, or sold, to cease immediately distribution of the article;

"(C) to recall the article;

"(D) in consultation with the Secretary, to provide notice of the finding of the Secretary to all consumers to which the article was, or may have been, distributed and to appropriate State and local health officials; and

"(E) to notify State and local public health officials.

"(2) MANDATORY ACTIONS.—If the appropriate person referred to in paragraph (1) does not carry out the actions described in that paragraph with respect to an article within the time period and in the manner prescribed by the Secretary, the Secretary—

"(A) shall issue an order requiring the person—

"(i) to immediately cease distribution of the article; and

"(ii) to immediately make the notification described in paragraph (1)(B); and

"(B) may take control or possession of the article.

"(3) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1) to consumers to which the article was, or may have been, distributed and to appropriate State and local health officials.

"(c) HEARINGS ON ORDERS.—

"(1) IN GENERAL.—The Secretary shall provide a person subject to an order under subsection (b)(2) with an opportunity for a hearing on—

"(A) the actions required by the order; and

"(B) any reasons why the article of food that is the subject of the order should not be recalled.

"(2) TIMING OF HEARINGS.—If a hearing is requested under paragraph (1) with respect to an order, the Secretary shall hold the hearing as soon as practicable, but not later than 2 business days, after the date of issuance of the order.

"(d) POST-HEARING RECALL ORDERS.—

"(1) AMENDMENT OF ORDERS.—If, after providing an opportunity for a hearing (and a hearing if requested) under subsection (c), the Secretary determines that an article of food when introduced into or while in interstate commerce, or while held for sale (regardless of whether the first sale) after shipment in interstate commerce, is adulterated or misbranded in a manner that, if consumed, may result in illness or injury, the Secretary may, as the Secretary determines to be necessary—

"(A) amend the order under subsection (b)(2)—

"(i) to require recall of the article or other appropriate action; and

"(ii) to specify a timetable during which the recall shall occur;

"(B) require periodic reports to the Secretary describing the progress of any such recall; and

"(C) provide notice of such a recall to consumers to which the article was, or may have been, distributed.

"(2) VACATION OF ORDERS.—If, after providing an opportunity for a hearing (and a hearing if requested) under subsection (c), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

"(e) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.".

(c) EFFECTIVE DATE.—Sections 301(pp)(1) and 423(a) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall apply with respect to articles of food as of such date, not later than 1 year after the date of the enactment of this Act, as the Secretary of Health and Human Services shall specify.

Subtitle C—Response

SEC. 121. CIVIL PENALTIES RELATING TO FOOD.

(a) IN GENERAL.—Chapter III (21 U.S.C. 331 et seq.) is amended by adding after section 303 the following:

"SEC. 303A. CIVIL PENALTIES RELATING TO FOODS.

"(a) IN GENERAL.—

"(1) ASSESSMENT.—The Secretary may assess against a person that commits an act prohibited by section 301 with respect to an article of food a civil penalty for each such act of not more than—

"(A) $100,000, in the case of an individual; and

"(B) $500,000, in the case of any other person.

"(2) SEPARATE OFFENSES.—Each prohibited act described in paragraph (1) and each day during which the act continues shall be considered to be a separate offense.

"(3) NOTICE AND OPPORTUNITY FOR HEARING.—The Secretary shall not assess a civil penalty under this section against a person unless the person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code.

"(4) DETERMINATION OF CIVIL PENALTY AMOUNT.—The amount of a civil penalty under this section—

"(A) shall be assessed by the Secretary by written order, taking into account—

"(i) the gravity of the violation;

"(ii) the degree of culpability of the person;

"(iii) the size and type of the business of the person; and

"(iv) any history of prior offenses by the person; and

"(B) shall be reviewed only in accordance with subsection (b).

"(b) JUDICIAL REVIEW.—

"(1) IN GENERAL.—An order assessing a civil penalty against a person under subsection (a) shall be final unless the person—

"(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in—

"(i) the United States court of appeals for the circuit in which the person resides or has its principal place of business; or

"(ii) the United States Court of Appeals for the District of Columbia Circuit; and

"(B) simultaneously sends a copy of the petition by certified mail to the Secretary.

"(2) FILING OF COPY OF RECORD.—The Secretary shall promptly file in the court a certified copy of the record on which the order was issued.

"(3) STANDARD OF REVIEW.—The findings of the Secretary relating to the order shall be set aside only if the findings are found to be unsupported by substantial evidence on the record as a whole.

"(c) COLLECTION ACTIONS FOR FAILURE TO PAY ASSESSMENT.—

"(1) REFERRAL TO ATTORNEY GENERAL.—If a person fails to pay a civil penalty assessed under subsection (a) after the order assessing the civil penalty has become a final order, or after the court of appeals has entered final judgment in favor of the Secretary, the Secretary may refer the matter to the Attorney General.

"(2) ACTION BY ATTORNEY GENERAL.—The Attorney General shall bring a civil action to recover the amount of the civil penalty in United States district court.

"(3) SCOPE OF REVIEW.—In a civil action under paragraph (2), the validity and appropriateness of the order of the Secretary assessing the civil penalty shall not be subject to review.

"(d) PENALTIES DEPOSITED IN TREASURY.—All amounts collected as civil penalties under this section shall be deposited in the Treasury of the United States and shall be available to cover costs of the Administration in carrying out food safety activities under this Act.

"(e) PENALTIES IN LIEU OF OTHER ACTIONS.—Nothing in this Act requires the Secretary to report for prosecution, or for the commencement of any libel or injunction proceeding, any violation of this Act in any case in which the Secretary believes that the public interest will be adequately served by the assessment of a civil penalty under this section.

"(f) REMEDIES NOT EXCLUSIVE.—The remedies authorized by this section shall be in addition to any other remedies that may be available.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to prohibited acts committed on or after the date of the enactment of this Act .

SEC. 122. ENFORCEMENT AND RECALL.

Section 801 (21 U.S.C. 381), as amended by section 112, is further amended by adding at the end the following:

"(q)(1) The Secretary may deny importation of food, other than only for personal use, from any foreign country, or which is manufactured, processed, packed, or held by

a facility (as defined in section 415), if the government of such country, or such facility, respectively, does not timely consent to an investigation by the Administration when food from that country or facility is linked to a food-borne illness outbreak or is otherwise found to be adulterated or mislabeled. Any food imported for consumption in the United States may be detained and condemned pursuant to section 704A(c) or recalled pursuant to section 423.".

Subtitle D—Miscellaneous

SEC. 131. LABELING REQUIREMENT FOR MEAT, POULTRY PRODUCTS, AND SEAFOOD THAT CONTAIN CARBON MONOXIDE.

(a) LABELING REQUIREMENT.—

(1) IN GENERAL.—Paragraph (t) of section 201 (21 U.S.C. 321) is amended by adding at the end the following:

"(4) In the case of food that is meat within the meaning of the Federal Meat Inspection Act, a poultry product within the meaning of the Poultry Products Inspection Act, or seafood (including all fresh or saltwater fish, molluscan shellfish, crustaceans, and other forms of aquatic animal life) intended for human consumption as food within the meaning of section 201(f) (referred to collectively in this paragraph as 'seafood'), the term 'color

additive' shall include carbon monoxide under conditions of use that may impart, maintain, preserve, stabilize, fix, or otherwise affect the color of fresh meat, poultry products, or seafood, unless the label of such food bears, prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary person, the following statement to prevent consumer deception and serious risks to the public health: 'CONSUMER NOTICE: Carbon monoxide has been used to preserve the color of this product. Do not rely on color or the "use or freeze by" date alone to judge the freshness of the product.' ".

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to food labeled on or after the date that is 30 days after the date of the enactment of this Act.

(b) DISCRETIONARY AUTHORITY.—If, not earlier than 5 years after the effective date described in subsection (a)(2), the Secretary of Health and Human Services finds, based on competent and reliable scientific evidence, that the statement prescribed in section 201(t)(4) of the Federal Food, Drug, and Cosmetic Act is no longer required to prevent consumer deception and other harms, then the Secretary is authorized to issue regulations establishing alternative labeling requirements that are shown

to be adequate and effective in preventing consumer deception and other harms related to the conditions of use of carbon monoxide, including with respect to preventing any consumer deception or other harm that may result from the actual conditions of carbon monoxide use and its potential to impart a persistent color to meat, poultry products, or seafood described in such section through a reaction with natural pigment.

SEC. 132. FOOD SUBSTANCES GENERALLY RECOGNIZED AS SAFE.

Section 409 (21 U.S.C. 348) is amended by adding at the end the following:

"Substances Generally Recognized as Safe

"(k)(1) Not later than 60 days after the date of receipt by the Secretary after the date of the enactment of this subsection of a request for a substance to be determined by the Secretary to be a GRAS food substance, the Secretary shall publish such notice in the Federal Register.

"(2) Not later than 90 days after the date of publication of a notice concerning a GRAS food substance, the Secretary shall determine whether the substance is considered generally recognized as safe.

"(3) In this subsection, the term 'GRAS food substance' means a substance excluded from the definition of

the term 'food additive' in section 201(s) because such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substances used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

"(4) A determination whether a substance is generally recognized as safe by the Secretary shall be published in the Federal Register.".

SEC. 133. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF SOURCE OF INGREDIENTS.

(a) FOOD.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

"(z) In the case of a processed food if—

"(1) the labeling of the food fails to identify the country in which the final processing of the food occurs; and

"(2) the website for the manufacturer of the food fails to identify the country (or countries) of origin for each ingredient in the food.

"(aa) In the case of non-processed food if—

"(1) the labeling of the food fails to identify the country of origin of the food; and

"(2) the website for the original packer of the food fails to identify the country of origin for the food.".

(b) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations to carry out the paragraphs (z) and (aa) of section 403(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) EFFECTIVE DATE.—The requirements of paragraphs (z) and (aa) of section 403 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), takes effect on the date that is 2 years after the date of the enactment of this Act.

SEC. 134. NEW FOOD AND ANIMAL FEED EXPORT CERTIFICATION FEE TO IMPROVE THE ABILITY OF UNITED STATES FIRMS TO EXPORT THEIR PRODUCTS.

Part 3 of chapter VII (21 U.S.C. 371 et seq.), , as added by section 101(b) and amended by sections 105(a), 106(b), and 107(c), is further amended by adding at the end the following:

"SEC. 741D. NEW FOOD AND ANIMAL FEED EXPORT CERTIFICATION FEE TO IMPROVE THE ABILITY OF UNITED STATES FIRMS TO EXPORT THEIR PRODUCTS.

"(a) IN GENERAL.—If the Secretary provides for the issuance of export certificates for foods and animal feeds in cases where exportation is restricted without such a certificate, the Secretary may impose a fee for the issuance of such a certificate.

"(b) AMOUNT.—The amount of the fee under this section shall be an amount that is reasonably related to the cost of issuing such certificates.

"(c) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to this section available solely to pay for the costs of issuance of such certificates.".

TITLE II—DRUG AND DEVICE SAFETY

SEC. 201. REGISTRATION FEE APPLICABLE TO PRODUCERS OF DRUGS AND DEVICES.

(a) PROHIBITED ACT.—Subsection (p) of section 301 (21 U.S.C. 331), as amended by section 101(a), is amended by striking "501(k);" and inserting "501(k), the failure to pay an annual registration fee in violation of 736C,".

(b) REGISTRATION FEE.—Part 2 of subchapter C of chapter VII is amended by adding at the end the following:

"SEC. 736C. REGISTRATION FEE.

"(a) IN GENERAL.—The Secretary shall assess and collect an annual fee for registration under subsection (b), (c), (d), or (i) of section 510 for the purpose of defraying the costs of inspecting establishments registered under such subsection to ensure that such establishments are in compliance with the requirements of this Act relating to drugs and devices.

"(b) AMOUNT OF FEE.—The amount of a fee under this section shall be—

"(1) such amount as the Secretary determines for establishments with respect to drugs; and

"(2) such amount as the Secretary determines for establishments with respect to devices.".

(c) EFFECTIVE DATE.—The Secretary of Health and Human Services shall first impose the fee established under section 736C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), for fiscal years beginning with fiscal year 2009.

SEC. 202. INSPECTION OF PRODUCERS OF DRUGS, ACTIVE PHARMACEUTICAL INGREDIENTS, DEVICES, AND DEVICE PARTS.

(a) PROHIBITED ACT.—Subsection (p) of section 301 (21 U.S.C. 331), as amended by sections 101(a) and 201(a), is amended by inserting before "or the failure to provide a notice required by section 510(j)(2)" the fol-

lowing: "the introduction or delivery for introduction into interstate commerce of any drug, any active pharmaceutical ingredient, any class II or III device, or device part to such a device, as determined by the Secretary, before an initial inspection is complete in violation of section 510(h)(2),".

(b) INSPECTION.—Subsection (h) of section 510 (21 U.S.C. 351) is amended—

(1) by striking "(h)" and inserting "(h)(1)";

(2) by striking "Every establishment in any State registered with the Secretary pursuant to this section" and inserting "Every establishment registered with the Secretary pursuant to subsection (b), (c), (d), or (i)"; and

(3) by adding at the end the following:

"(2) Upon receipt of an initial registration under subsection (b), (c), (d), or (i) for an establishment, the Secretary shall ensure that such establishment is promptly inspected pursuant to section 704. Until such initial inspection is complete, any drug (including any active pharmaceutical ingredient) or class II or III device or any device part of such a device (as determined by the Secretary that is manufactured, prepared, propagated, compounded, or processed by such establishment shall not be introduced or delivered for introduction into interstate commerce.

There shall be a new initial inspection of a drug or device establishment when the establishment begins to manufacture, prepare, propagate, compound, or process a drug, active pharmaceutical ingredient, class II or III device, or a part of such a device (as determined by the Secretary) before its introduction or delivery into interstate commerce unless the product constitutes only a minor modification to a product previously manufactured, prepared, propagated, compounded, or processed at the establishment..

"(3) A drug or device establishment, or employee of such an establishment, that delays, limits, or denies an inspection under this Act is subject to suspension of registration under section 510. If the Secretary determines that such an establishment delays, limits, or denies such an inspection, the establishment shall not place into interstate commerce any drug or device it manufactures, prepares, propagates, compounds, or processes.".

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to drugs introduced or delivered for introduction into interstate commerce on or after the date that is 2 years after the date of the enactment of this Act

(2) ESTABLISHMENTS ALREADY REGISTERED, BUT NOT INSPECTED.—In the case of any establish-

ment that is registered under subsection (b), (c), (d), or (i) of section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) as of the effective date specified in paragraph (1) but has not been inspected pursuant to section 704 of such Act (21 U.S.C. 374) as of such date, such amendments shall not apply until 2 years after such effective date.

SEC. 203. DOCUMENTATION FOR ADMISSIBILITY OF DRUG IMPORTS.

Section 801 (21 U.S.C. 381), as amended by sections 112 and 122, is amended by adding at the end the following:

"(r) Beginning 3 years after the date of enactment of this subsection, a drug shall only enter the United States, other than only for personal use, through a port of entry that is located in a metropolitan area with a federal testing laboratory, unless the party offering that drug for import provides the Secretary, at the time of offering the drug for import, documentation demonstrating compliance with applicable requirements pertaining to identity, strength, quality, purity, approval, listing, labeling, and registration. The Secretary may require that such documentation include verification of compliance by an accredited third party or by the Secretary during an inspection within the past two years, and such other information as

the Secretary determines is necessary for protection of the public health.".

SEC. 204. ORIGIN OF INGREDIENTS.

(a) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by inserting after "; or" at the end the following: "or (D) if it is a drug and it bears, contains, or consists of an active or inactive ingredient and the manufacturer of that ingredient and of each drug that contains that ingredient does not have, and provide to the Secretary upon request, adequate documentation to establish where the ingredient was made, including all previous producers and manufacturers, that the ingredient is not adulterated or misbranded, that the ingredient will perform in accordance with specifications, is not contaminated, and does not have any undisclosed additives, and that the ingredient was manufactured, distributed, shipped, warehoused, processed, brokered, imported, and conveyed under conditions that ensure the identity, strength, quality, and purity of the drug; or".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on a date, specified by the Secretary of Health and Human Services, not later than 3 years after the date of the enactment of this Act.

SEC. 205. TESTING FOR DRUG PURITY AND IDENTITY.

(a) IN GENERAL.—Section 501(a)(2) (21 U.S.C. 351(a)(2)), as amended section 204(a), is amended by inserting after "; or" at the end the following: "or (E) if it is a drug, unless each manufacturer of the finished dosage form, active ingredients, and inactive ingredients contained in or consisting of that drug verifies its product's purity and identity using scientifically sound and appropriate methods of sufficient analytical precision and specificity to detect and quantify the product separate from contaminants, impurities, and adulterants; or (F) if it is a drug, unless each manufacturer of an active pharmaceutical ingredient contained in or consisting of that drug periodically evaluates its ingredient's impurity profile to verify that it remains substantially similar to or better than the profile of the lot (or lots) used in the clinical studies and/or toxicological evaluation. If no clinical studies or toxicological evaluation was conducted, then the impurity profile shall determined according to standards to be established by the Secretary; or".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on a date, specified by the Secretary of Health and Human Services, not later than 3 years after the date of the enactment of this Act.

SEC. 206. COUNTRY OF ORIGIN LABELING.

(a) DRUGS AND DEVICES.—Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

"(y) If it is a drug or device and—

"(1) its labeling fails to identify the country (or countries) which is the source of the active pharmaceutical ingredient in whole or in part and of its place of manufacture in the case of a drug, or the country of manufacture in the case of a device; or

"(2) in the case of a drug the website of the manufacturer of the drug does not list the country of origin for any drug ingredient of such drug.".

(b) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall promulgate final regulations to carry out section 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(c) EFFECTIVE DATE.—The requirement of section 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), takes effect 2 years after the date of the enactment of this Act.

SEC. 207. RECALL AUTHORITY FOR DRUGS.

Subchapter E of chapter V is amended by adding at the end the following:

"SEC. 568. RECALL AUTHORITY FOR DRUGS.

"The Secretary shall have the same authority with respect to drugs as the Secretary has with respect to devices under section 518(e). In applying the previous sentence, any reference in such section to a device shall be deemed a reference to a drug.".

SEC. 208. DESTRUCTION OF ADULTERATED, MISBRANDED OR COUNTERFEIT DRUGS OFFERED FOR IMPORT.

(a) IN GENERAL.—The fifth sentence of section 801(a) (21 U.S.C. 381(a)) is amended by inserting before the period at the end the following: ", except that any product that is refused admission may, at the discretion of the Secretary, be destroyed and not exported if (1) it appears to pose a risk of injury or death, or (2) has a value of less than $2,000, as determined by the Secretary".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect the date of the enactment of this Act, regardless of when the product may have been refused admission.

SEC. 209. ADMINISTRATIVE DETENTION OF DRUGS THAT APPEAR TO VIOLATE THE LAW.

(a) IN GENERAL.—Section 304(g) (21 U.S.C. 334(g)) is amended—

(1) by inserting "drug or" before "device" each place it appears; and

(2) in paragraph (1), by inserting after "adulterated or misbranded" the following: "or, in the case of a drug, which in the determination of the officer or employee making the inspection appears to be in violation of section 505,".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on a date, specified by the Secretary of Health and Human Services, not later than 1 year after the date of the enactment of this Act.

(c) TRANSITION.—Until such time as the Food and Drug Administration issues regulations to carry out the amendments made by subsection (a), the regulations applicable under section 304(g) of the Federal Food, Drug, and Cosmetic Act shall apply to drugs, as included by the amendment made by such amendments.

SEC. 210. CIVIL MONEY PENALTIES FOR VIOLATIVE DRUGS AND DEVICES AND IMPROPER IMPORT ENTRY FILINGS.

(a) IN GENERAL.—Section 303 (21 U.S.C. 333) is amended by adding at the end the following:

"(h)(1) Any person who violates a requirement of this Act that relates to drugs and devices for human use shall be liable to the United States for a civil penalty not to

exceed $100,000 per violation. Each day during which a violation continues shall be considered a separate violation.

"(2) Any person, including a manufacturer, distributor, importer, broker, or filer, who knowingly reports or enters false data on documents related to the introduction of drugs and devices in interstate commerce shall be liable to the United States for a civil penalty not to exceed $150,000. Each act of reporting or entering false data shall be considered a separate violation.

"(3) The provisions of paragraphs (2), (5), (6), and (7) of subsection (g) shall apply to a civil money penalty under paragraph (1) or (2) of this subsection in the same manner as they apply to a civil money penalty under subsection (g)(1).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to violations occurring on or after the date of the enactment of this Act.

TITLE III—COSMETIC SAFETY

SEC. 301. REGISTRATION OF COSMETIC FACILITIES.

(a) IN GENERAL.—Chapter VI is amended by adding at the end the following new section:

"SEC. 604. REGISTRATION OF FACILITIES.

"(a) IN GENERAL.—The Secretary shall by regulation require that any facility engaged in manufacturing,

processing, packing, or holding of cosmetics in the United States or for import to the United States be registered with the Secretary.

"(b) APPLICATION OF FOOD REGISTRATION RULES AND REGISTRATION FEE.—Except as provided in this section, the provisions of section 415 and section 741 shall apply to registration of cosmetic facilities under subsection (a) in the same manner as they apply to registration of facilities (as defined in section 415(b)) under such respective section, except that, with respect to registration fees imposed under this subsection, any reference in section 741 to 'food' is deemed a reference to 'cosmetics'. Each facility shall list in the registration the cosmetic products it manufactures, processes, packs, or holds and, in the case of a manufacturing facility, a list of the ingredients for each product so listed that it manufactures.

"(c) ADVERSE EVENT REGISTRY.—The Secretary shall by regulation require a facility that manufactures cosmetics to report to the Secretary all anticipated and unanticipated serious adverse events relating to the use of cosmetics it has manufactured.

"(d) GOOD MANUFACTURING PRACTICES.—The Secretary shall by regulation require that the methods used in, and the facilities and controls used for the manufacture, process, packing, or holding of a cosmetic conform

to good manufacturing practices as prescribed in such regulations.".

(b) EFFECTIVE DATES.—

(1) REGISTRATION AND FEES.—Cosmetic facilities shall be required to register (and pay registration fees) under subsections (a) and (b) of section 604 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), beginning 6 months after the date of the enactment of this Act.

(2) ADVERSE EVENT REGISTRY AND GOOD MANUFACTURING PRACTICES.—The Secretary of Health and Human Services shall establish the adverse event registry and the good manufacturing practices under the amendment made by subsection (a) not later than 18 months after the date of the enactment of this Act.

TITLE IV—MISCELLANEOUS

SEC. 401. REGISTRATION AND FEE FOR COMMERCIAL IMPORTERS OF FOOD, DRUGS, DEVICES, AND COSMETICS.

(a) PROHIBITIONS.—Section 301 (21 U.S.C. 331), as amended by sections 107(a) and 113(a), is further amended by adding at the end the following:

"(qq) The importation of food, drugs, devices, or cosmetics other than only for personal use by an importer

that is not registered with respect to such food, drugs, devices, or cosmetics under section 415, 510, or 604, respectively, unless the importer is registered under section 801(s).".

(b) REGISTRATION.—Section 801, as amended by sections 112, 122, and 203, is amended by adding at the end the following:

"(s) The Secretary shall by regulation require that an importer of food, drugs, devices, or cosmetics, other than only for personal use, that is not registered with respect to such food, drugs, devices, or cosmetics under section 415, 510, or 604, respectively, shall be registered with the Secretary in a form and manner specified by the Secretary. The Secretary shall assign a unique identification number to each importer so registered.".

(c) FEE.—Subchapter C of chapter VII is amended by adding at the end the following:

"PART 6—IMPORTERS OF FOOD, DRUGS, DEVICES, AND COSMETICS

"SEC. 742. IMPORTERS OF FOOD, DRUGS, DEVICES, AND COSMETICS.

"(a) IN GENERAL.—The Secretary shall assess and collect an annual fee for the registration of an importer of food, drugs, devices, or cosmetics under section 801(s).

"(b) AMOUNT OF FEE.—The amount of the fee under this section shall be $10,000.".

(d) EFFECTIVE DATE.—

(1) REGISTRATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish procedures for the registration of importers under section 801(s) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) REGISTRATION.—The amendments made by this section shall first apply not later than 1 year after the date of the enactment of this Act.

SEC. 402. UNIQUE IDENTIFICATION NUMBER FOR FOOD, DRUG, AND DEVICE FACILITIES AND ESTABLISHMENTS.

(a) FOOD AND COSMETICS.—Section 415(a)(3) (21 U.S.C. 350d(a)(3)) is amended by adding at the end the following: "Such a registration number shall be a unique identification number for each such facility that may be used for purposes other than registration under this subsection.".

(b) DRUGS AND DEVICES.—Section 510(e) (21 U.S.C. 360(e)) is amended by adding after the first sentence the following: "Such a registration number shall be a unique identification number for each such establish-

ment that may be used for purposes other than registration under this subsection.".

(c) APPLICATION TO COSMETICS.—The amendment made by subsection (a) applies to cosmetics through the operation of section 604 of the Federal Food, Drug, and Cosmetic Act, as added by section 301(a).

(d) APPLICATION TO IMPORTERS.—See section 402(b) of this Act for the requirement for a unique identification number for importers that are registered.

(e) EFFECTIVE DATE.—The Secretary of Health and Human Services shall implement the amendments made by this section not later than 1 year after the date of the enactment of this Act.

SEC. 403. DEDICATED FOREIGN INSPECTORATE.

Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

"(h) The Secretary shall establish and maintain a corps of inspectors dedicated to inspections of foreign food, drug, device, and cosmetics facilities and establishments. This corps shall be staffed and funded by the Secretary at a level sufficient to allow it to conduct inspections of foreign food, drug, device and cosmetic facilities and establishments at a frequency at least equivalent to the inspection rate of domestic food, drug, device, and cosmetic facilities and establishments.".

SEC. 404. CONTINUED OPERATION OF FIELD LABORATORIES.

(a) IN GENERAL.—Subject to subsections (b) and (d), the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall not—

(1) terminate any of the 13 field laboratories that were operated by the Office of Regulatory Affairs of the Food and Drug Administration as of January 1, 2007;

(2) consolidate any such laboratory with any other laboratory;

(3) terminate any of the 20 district offices or any of the inspection or compliance functions of any of the 20 district offices of the Food and Drug Administration functioning as of January 1, 2007; or

(4) consolidate—

(A) any such district office with an office in any other district; or

(B) transfer any of the compliance or inspection functions of any such district office to any other district.

(b) REPORT BY SECRETARY.—

(1) SUBMISSION.—The Secretary shall submit a reorganization plan involving the termination or consolidation of the laboratories, the district offices, or the functions of such district offices specified in sub-

section (a) to the Comptroller General of the United States, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

(2) CONSULTATION.—In preparing the reorganization plan described in paragraph (1), the Secretary shall consult with personnel and unions to be affected by the plan.

(c) REPORT BY GAO.—The Comptroller General shall study the cost effectiveness of the reorganization plan described in subsection (b) and its impact on the safety of food, drug, and other products regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) and report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(d) REORGANIZATION.—

(1) CONGRESSIONAL REVIEW.—The reorganization plan described in subsection (b) is deemed to be a major rule (as defined in section 804(2) of title 5, United States Code) for purposes of chapter 8 of such title.

(2) EFFECTIVE DATE.—Notwithstanding section 801(a)(3) of title 5, United States Code, the reorganization plan described in subsection (b) shall take effect (unless disapproved under section 802 of such title) on the date that is specified in such plan, but not earlier than 180 days after the date on which the Comptroller General submits the report required by subsection (c).

SEC. 405. FALSE OR MISLEADING REPORTING TO FDA.

(a) IN GENERAL.—Section 301(q)(2) (21 U.S.C. 331(q)(2)) is amended by inserting after "device" the following: "food, drug, or biological product".

(b) EFFECTIVE DATE.— The amendment made by subsection (a) shall apply to submissions made on or after the date of the enactment of this Act.

SEC. 406. APPLICATION TO BIOLOGICAL PRODUCTS.

Under section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)), the amendments made to the Federal Food, Drug, and Cosmetic Act by this Act shall also apply to biological products.

SEC. 407. LIMITATION TO COMMERCIAL IMPORTATION.

Nothing in this Act, or the amendments made by this Act, shall be construed as applying to importation other than commercial (and not personal) importation.

FOOD MARKETING INSTITUTE

BOARD APPROVED POLICY

Recall Authority

Adopted November 16, 2007

- The Food Marketing Institute (FMI) supports granting the Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) the authority to mandate a recall when a company refuses or delays to voluntarily recall a product that FDA and/or USDA have determined poses an imminent and substantial risk of serious adverse health consequences or death to humans or animals.
- This authority should be used to enhance systems currently in place and foster clear and accurate communication.

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Food Safety:
The Supermarket Perspective

FOOD MARKETING INSTITUTE

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The most important goal of America's food retailers and wholesalers is to ensure that the products they sell are safe. As the purchasing agent for the consumer and the final link in the supply chain, the supermarket industry continually seeks ways to make the nation's food supply safer. As a result, the American consumer enjoys unmatched choice and convenience, as well as safe, abundant food year-round.

Retailers and wholesalers have a long history of anticipating and responding to food safety and defense challenges. They strengthen food safety on many fronts by working independently and collectively through the Food Marketing Institute (FMI).[1] For example, retailers and wholesalers work with suppliers globally, observe rigorous standards in supermarkets and warehouses, ensure that store managers and their associates follow the requirements of the *FDA Food Code* and through extensive public outreach campaigns help teach consumers to follow the most important food safety practices.

FMI's Board of Directors reconfirmed the industry's commitment to improving food safety by reinstating its Food Safety Task Force in June 2007. The Task Force identified the following priorities:

1. Strengthen consumer confidence in the safety of the food supply.
2. Develop programs to help reduce foodborne illness.
3. Educate consumers how to select nutritious and wholesome food.
4. Develop public policies to improve the safety of America's food supply.

In addition, the Task Force then identified five key operational areas on which to focus its attention:

- Improve the food recall system.
- Align food safety programs and priorities among retailers, wholesalers and suppliers.
- Identify and implement best practices.
- Improve produce safety with measures that include product traceability.
- Enhance customer education programs.

[1]Food Marketing Institute (FMI) conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $680 billion — three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from more than 50 countries.

1. Strengthen Consumer Confidence in the Safety of the Food Supply

Research shows that consumer confidence in food safety swings widely depending on events in the marketplace. Media coverage of recent outbreaks, recalls and food safety scares have contributed to a decrease in consumer confidence and revealed new challenges to ensuring the food supply is safe in an ever-changing marketplace. In 2007, consumer confidence in the safety of food they purchase in supermarkets reached its lowest point since 1989. FMI's survey of consumers, presented in the annual *U.S. Grocery Shopper Trends* report (*Trends*), found that consumer confidence dropped from 82 percent in 2006 to 66 percent in 2007. This same survey revealed that consumer confidence in restaurant food was even lower in 2007 at 42 percent.

In 2008, with the federal government and private sector working together to improve food safety, consumer confidence rebounded: 81 percent of those responding to the 2008 *Trends* survey said they are "completely" or "somewhat confident" in the safety of the food bought in supermarkets. Yet this confidence is fragile. Only 11 percent are "completely confident" and 70 percent are only "somewhat confident."

To secure high levels of confidence, the industry and government must address changes in the marketplace. These include handling new sources of food, advances in production and distribution methods, and the growing volume and diversity of imports. These changes call for a vigorous approach to protect our food from unintentional or deliberate contamination. The quality and safety of the U.S. food supply must be protected from farm to fork — throughout food production, processing, storage and distribution. This multi-sector effort requires the active participation and cooperation among producers, processors, manufacturers, retailers, government and the scientific community. FMI and its members are dedicated to improving food safety by working throughout the supply chain to ensure that consumers continue to receive the safe, high-quality and affordable food they have every right to continue to expect.

2. Develop Programs to Help Reduce Foodborne Illness

FMI members partner with their suppliers to ensure the food that consumers purchase is safe. One way to do this is through rigorous standards for the production and manufacturing of safe food, verified through independent, third-party certification systems. Using proven risk-assessment methods such as the Hazard Analysis and Critical Control Point (HACCP) system, suppliers can implement and monitor their practices to ensure food production methods are safe. Conformance to these best practices can then be verified using a dependable auditing program that relies on accredited certification measures.

The Safe Quality Food Supplier Certification Program

To help the supplier community to reach this new, higher level of assurance, FMI offers the Safe Quality Food (SQF) Program. This is a leading, global food safety and quality certification program and management system, designed to meet the needs of retailers and suppliers worldwide. The SQF Program provides independent certification that a supplier's food safety and quality management system complies with international and domestic food safety regulations. This enables suppliers to assure their customers that food has been produced, processed, prepared and handled according to the highest possible standards.

Launched in 1994, the SQF Program is administered by the SQF Institute (SQFI), a division of the Food Marketing Institute (FMI). More than 10,000 certificates have been issued to companies operating in the Asia-Pacific region, Europe, Middle East and North and South America.

SQF certification is supported by an increasing number of U.S. and international retailers and foodservice providers that express a preference for SQF-certified suppliers. In addition, the SQF Program is part of a landmark agreement among seven global retailers on mutual acceptance of global food safety systems. This program offers the only system endorsed by the Global Food Safe Initiative (GFSI)[2] that provides certification for primary food production and for manufacturing, storage and distribution and agent/broker management.

The SuperSafeMark® Employee Training and Certification Program

Within the domestic retail setting, training store managers and workers in food safety is an important tool for protecting the public health. FMI offers extensive training programs on safe food-handling methods based on the model *FDA Food Code*. In 2003, FMI launched SuperSafeMark®, the most comprehensive food safety and sanitation instruction and certification program ever offered to food retail employees. This program includes methods for combating foodborne illness with time and temperature controls, measures to prevent cross contamination, personal hygiene and cleaning and sanitizing best practices. Currently, SuperSafeMark® trains and certifies 15,000 store-level managers and their associates each year, along with thousands of employees who handle food in retail stores.

[2]Representing the world's leading food retailers and suppliers, GFSI recognizes food safety certification programs that require compliance with rigorous and commonly accepted international standards and that have independent accredited auditors to verify compliance.

An Initiative to Improve Food Recall Communications

FMI members are also working closely with their suppliers to improve communications in food recalls. While the industry responds quickly and efficiently in the event of a recall, FMI members believe that the system can be improved. In a year-long project, retailers, wholesalers and suppliers developed and are testing an electronic recall portal, the FMI Recall Collaboration Zone. This portal is powered by GS1, formerly the Uniform Code Council, which oversees the Universal Product Code (U.P.C.) and numerous technological standards and programs for industries worldwide. This portal provides an automated alert system that allows suppliers to send information to retailers and wholesalers rapidly and accurately, 24/7, so they can remove recalled product from the distribution chain and retail shelves as quickly as possible.

3. Educate Consumers How to Select Nutritious and Wholesome Food

FMI has long provided consumers with practical, science-based guidance on safe food-handling at home. As a founding member of the Partnership for Food Safety Education, FMI continues to support the development of meaningful food safety education programs for consumers. The Partnership brings together consumer advocacy groups, the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), Centers for Disease Control and Prevention (CDC), national industry associations and health and scientific groups. The Partnership created the award-winning Fight BAC!® campaign to teach food safety to children in school. Its BAC Down! program urges consumers to use thermometers to ensure their refrigerators remain at safe temperature levels — no higher that 40°F. Most recently, the Partnership launched the Be Safe Food campaign in cooperation with USDA to provide retailers with a wide range of resources to educate their customers about safe food practices.

Approximately, 6,000 FMI member supermarkets serving some 81 million consumers, have volunteered to implement Be Food Safe through their in-store and external consumer communications programs. 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.

The Partnership for Food Safety Education — governed by a memorandum of understanding among the federal agencies, industry associations and consumer groups — has been extremely effective in educating Americans how to handle food safely.

4. Develop Public Policies to Improve the Safety of America's Food Supply

The food industry has a long and active history in protecting the food that consumers purchase, but the government must also provide strong leadership. To date, food safety regulation has been hindered by a patchwork of statutory authorities. FMI and its members believe that the following public policy actions are needed to strengthen our food safety oversight systems.

A. Designate a Lead Food Safety Agency

Food safety regulation in the United States is governed by an uneven mosaic of laws and regulations enforced by multiple federal, state and local agencies, which results in inefficient redundancies in some areas and gaps in others. This system must be redesigned to address the current and future challenges of our rapidly evolving food supply system. FMI believes it is time to designate a lead food safety agency with responsibility to coordinate the safety of our entire food system. The resources needed for such an agency already reside within multiple existing agencies. The challenge is primarily one of restructuring and reallocation. Eliminating the duplication that now exists could result in substantial budget savings, improve oversight performance and create a safer food supply.

B. Establish a More Uniform and Efficient Recall System

Recalls have long been carried out by the industry on a voluntary basis in a timely and efficient manner. Many consumers are surprised, however, to learn that neither USDA nor FDA has the legal power to mandate a recall of adulterated foods. We believe that these federal agencies should have the authority to compel a recall when a company refuses or delays to recall a product that FDA or USDA has determined poses an imminent and substantial risk of serious adverse health consequences or death to humans or animals. On November 16, 2007, the FMI Board of Directors approved a policy statement that supports providing these agencies with the authority to require a recall under these circumstances (copy attached).

C. Develop Traceback Systems for Each Commodity Group

The government should require systems that will improve the capability of commodity groups to trace back foods to their source. Such systems would enable USDA, FDA and the industry to prevent or contain foodborne illness outbreaks more quickly. Each commodity group should be required to create an automated traceback system that is cost-effective and complements current business operations.

D. Expand the Role of Third Parties

Given the breadth and reach of today's food supply chain, neither USDA nor FDA will ever have the resources needed to inspect all products domestically and globally to ensure that they are safe and to verify that supplier systems comply with all food safety regulations. Enhancing the government's role in assessing food safety systems in the future will require the prudent use of private sector auditing and certification programs. Both FDA and USDA should be given the authority to establish criteria for the recognition of accredited third-party food safety certification programs. The industry has already established independent, effective and credible private sector food safety certification systems such as FMI's SQF Program. FDA and USDA should be authorized to use private sector resources as part of their overall risk management and inspection system.

E. Permit Certification for Select Imports

FDA and USDA should also be allowed to use private sector certification programs such as SQF to assess the safety of imported foods. The government should be able to use private sector certification as a way to prioritize those products and facilities that pose the highest risk and focus resources where they are most needed. FDA lacks sufficient budget and personnel resources to perform its current functions, much less to set up a massive new overseas inspection and verification service. If food cannot be imported from a country or facility until FDA has approved it, the U.S. food industry's ability to import food products from abroad would be seriously crippled.

Conclusion

The retailers and wholesalers of FMI will continue to look for new ways to strengthen food safety to better protect our customers. Americans have the safest and most affordable, abundant and diverse food supply in the world, but more can be done to make it even safer. Just as the sources of the U.S. food supply are ever-changing, so must the focus of our safety standards and programs change accordingly. FMI members are committed to working with Congress, the White House, government agencies, all other industry sectors, and the scientific and consumer community to implement improvements in the system that are workable and based on sound food safety science. For FMI and its members, food safety will always be a paramount priority.

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