THE FOOD AND DRUG IMPORT SAFETY ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

ON

H.R. 3610

SEPTEMBER 26, 2007

Serial No. 110–68

Printed for the use of the Committee on Energy and Commerce

energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

44–576 PDF WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON ENERGY AND COMMERCE

JOHN D. DINGELL, Michigan, *Chairman*

HENRY A. WAXMAN, California
EDWARD J. MARKEY, Massachusetts
RICK BOUCHER, Virginia
EDOLPHUS TOWNS, New York
FRANK PALLONE, JR., New Jersey
BART GORDON, Tennessee
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
BART STUPAK, Michigan
ELIOT L. ENGEL, New York
ALBERT R. WYNN, Maryland
GENE GREEN, Texas
DIANA DEGETTE, Colorado
Vice Chairman
LOIS CAPPS, California
MIKE DOYLE, Pennsylvania
JANE HARMAN, California
TOM ALLEN, Maine
JAN SCHAKOWSKY, Illinois
HILDA L. SOLIS, California
CHARLES A. GONZALEZ, Texas
JAY INSLEE, Washington
TAMMY BALDWIN, Wisconsin
MIKE ROSS, Arkansas
DARLENE HOOLEY, Oregon
ANTHONY D. WEINER, New York
JIM MATHESON, Utah
G.K. BUTTERFIELD, North Carolina
CHARLIE MELANCON, Louisiana
JOHN BARROW, Georgia
BARON P. HILL, Indiana

JOE BARTON, Texas
Ranking Member
RALPH M. HALL, Texas
J. DENNIS HASTERT, Illinois
FRED UPTON, Michigan
CLIFF STEARNS, Florida
NATHAN DEAL, Georgia
ED WHITFIELD, Kentucky
BARBARA CUBIN, Wyoming
JOHN SHIMKUS, Illinois
HEATHER WILSON, New Mexico
JOHN B. SHADEGG, Arizona
CHARLES W. "CHIP" PICKERING, Mississippi
VITO FOSSELLA, New York
STEVE BUYER, Indiana
GEORGE RADANOVICH, California
JOSEPH R. PITTS, Pennsylvania
MARY BONO, California
GREG WALDEN, Oregon
LEE TERRY, Nebraska
MIKE FERGUSON, New Jersey
MIKE ROGERS, Michigan
SUE WILKINS MYRICK, North Carolina
JOHN SULLIVAN, Oklahoma
TIM MURPHY, Pennsylvania
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee

PROFESSIONAL STAFF

DENNIS B. FITZGIBBONS, *Chief of Staff*
GREGG A. ROTHSCHILD, *Chief Counsel*
SHARON E. DAVIS, *Chief Clerk*
DAVID L. CAVICKE, *Minority Staff Director*

SUBCOMMITTEE ON HEALTH

FRANK PALLONE, JR., New Jersey, *Chairman*

HENRY A. WAXMAN, California
EDOLPHUS TOWNS, New York
BART GORDON, Tennessee
ANNA G. ESHOO, California
GENE GREEN, Texas
Vice Chairman
DIANA DEGETTE, Colorado
LOIS CAPPS, California
TOM ALLEN, Maine
TAMMY BALDWIN, Wisconsin
ELIOT L. ENGEL, New York
JAN SCHAKOWSKY, Illinois
HILDA L. SOLIS, California
MIKE ROSS, Arkansas
DARLENE HOOLEY, Oregon
ANTHONY D. WEINER, New York
JIM MATHESON, Utah
JOHN D. DINGELL, Michigan *(ex officio)*

NATHAN DEAL, Georgia,
Ranking Member
RALPH M. HALL, Texas
BARBARA CUBIN, Wyoming
HEATHER WILSON, New Mexico
JOHN B. SHADEGG, Arizona
STEVE BUYER, Indiana
JOSEPH R. PITTS, Pennsylvania
MIKE FERGUSON, New Jersey
MIKE ROGERS, Michigan
SUE WILKINS MYRICK, North Carolina
JOHN SULLIVAN, Oklahoma
TIM MURPHY, Pennsylvania
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee
JOE BARTON, Texas *(ex officio)*

CONTENTS

H.R. 3610, THE FOOD AND DRUG IMPORT SAFETY ACT

WEDNESDAY, SEPTEMBER 26, 2007

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

The subcommittee met, pursuant to call, at 10:08 a.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. (chairman) presiding.

Members present: Representatives Waxman, Eshoo, Green, DeGette, Allen, Schakowsky, Hooley, Matheson, Dingell, Deal, Wilson, Buyer, Pitts, Ferguson, Sullivan, Murphy, Burgess, and Blackburn.

Staff present: Brin Frazier, Lauren Bloomberg, Melissa Sidman, John Ford, Jack Mariko, Dave Nelson, Robert Clark, Chad Grant, Nandan Kenkeremath, Andrew Woelfling, and Chris Knauer.

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

Mr. PALLONE. I call the hearing to order. Good morning to everybody. Today we are having a hearing on H.R. 3610, the Food and Drug Import Safety Act introduced by our chairman, Mr. Dingell, and I will recognize myself initially for an opening statement.

Mr. Dingell's legislation seeks to strengthen our Nation's import safety system, and I am also a proud co-sponsor of the legislation. We all know that while the United States has one of the world's safest food and drug supplies and some of the most stringent standards for consumer protection, recent outbreaks of contaminated products and cases of food borne illness demonstrate that we have to do better. Contaminated pet food, toothpaste, and seafood products from China have highlighted the failings of our import safety system and sparked fear and distrust among consumers.

Democrats in Congress have heard consumers' concerns, and we have already begun to address the issue. Last week Congress passed the Food and Drug Administration Revitalization Act, which we call PDUFA, I guess, or includes PDUFA, and that bill provides the FDA with the resources and the authority necessary to improve our Nation's drug safety system. Also included in this measure, however, are improvements to our Nation's food safety program including new public notification requirements of outbreaks of illness due to contaminated food. In addition, the PDUFA legislation will establish an adulterated food registry so that inci-

dents can be reported and the FDA can quickly alert the public. It also calls for transparency during recalls of human or pet food, and will require the FDA to post information on recalled products in an easy to use searchable format.

Now while this was a modest step which was included, as I said, in the PDUFA bill, a lot more can and needs to be done with regard to food safety. The recent contamination incidents raised questions about our current food and drug safety laws, many of them enacted in the 1900s. Have they kept pace with new techniques in food production and processing, are these laws still sufficient to keep us safe. Rather than reacting to outbreaks of contaminated products, we need to change our system to better prevent such incidents from happening in the first place.

Recently, a White House working group—and I actually spoke to the FDA Commissioner about this yesterday—released a report on Government import safety protocols. This report acknowledges the limitations of our current import safety system and calls for a shift basically to review not only our imports at the point of entry in the United States, but also to regulate production abroad. The report tells us what we already know that the current system isn't working. The administration recognizes its failings, a lack of coordination amongst agencies, loopholes in the system that allow contaminated products to slip in, but merely reporting on the problem is too little and too late.

Now Chairman Dingell has taken the initiative in his legislation that is before us today and proposed a solution for increasing import safety including requiring agencies to conduct research to develop better testing techniques and insuring accurate labeling on products to prevent consumer deception, and his bill would give the FDA the authority to recall adulterated products if necessary. Chairman Dingell's bill would also insure that products from other countries are only permitted to enter the United States if they meet our strict safety standards, and it puts in place regulations for ports of entry, certification, and inspection that will enable us to enforce this standard. These new process controls would be paid for by a new imported food inspection fee.

The Dingell bill also addresses imported drugs by allowing the FDA to assess and collect user fees on drugs imported into the United States. These fees will help pay for inspectors, laboratory tests to detect adulterated drugs, and overseas inspections of drug shipments. But we know that contamination isn't limited to imported products alone. In the last few months, *E. coli* bacteria was discovered on lettuce and spinach from California. We had to recall peanut butter due to salmonella contamination, and botulism was found in canned green beans. All of these recent examples actually involve domestic products.

There are incidents of serious concern. The Centers for Disease Control estimates that 76 million people became ill this year and 5,000 actually died from illnesses caused by the presence of microbial pathogens in their food. The spinach contamination alone caused 200 reported illnesses and three deaths last year. Now I have also introduced a bill that I have actually had for a number of years that would strengthen process controls on domestic products by establishing strict inspection and oversight procedures to

prevent contamination at food processing facilities. It would require the FDA to set standards for sanitation and limits for the level of contaminations in food, and my bill would also require food processing facilities to register annually, and it would increase the number of inspections at facilities both in our country and in the country of origin.

And I am looking forward to working with Mr. Dingell and my colleagues. I know others have introduced legislation to address these concerns as well. If I could just say in conclusion that I think that improving our Nation's import and domestic food and drug safety programs is of great importance. I wanted to thank, he is not here, but Mr. Stupak, as you know, has had a couple of hearings in the O&I Subcommittee on this issue. The bottom line is that American consumers should be able to trust that the products they purchased have been properly regulated and inspected and thereby making them safe. And that is why we are here today, and I thank all of you, and the witnesses who are here to help us in that regard. And at this point, I would recognize Mr. Deal, our ranking member, for an opening statement.

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

Mr. DEAL. Thank you. During the month of August, I held town hall meetings all across my district and repeatedly heard from constituents who were concerned about the safety of their nation's food supply. They asked about country of origin labeling, imports from China, and wanted to know what was being done to make sure that the food that they feed their families is indeed safe. Coming from a town that calls itself the poultry capital of the world, I am also very familiar with the reciprocal impact that restrictions we place on producers in other countries can have on our own domestic producers.

In my experience poultry imports are one of the first products another country bans if they are upset with new United States trade regulations. I am glad that we are holding this hearing today so that we can look at these issues and try to strike the right regulatory balance with legislation to help address the concerns expressed by my constituents. However, it is also important to recognize the complexities of these issues and be careful that our legislation does not hamper the reforms being made within the industry to provide consumer safe food products. I know the administration will also be making some recommendations shortly on import safety, and I believe it would be useful for us to evaluate those recommendations as we craft legislation on this subject.

Also, during our work on the Food and Drug Administration Amendments Act of 2007 the issue of counterfeit drugs was highlighted, and I am glad we are continuing to work on this subject. While I am proud of the drug safety work that we did in that bill, I want to thank Mr. Buyer of our committee who raised a very valid point that if counterfeit medicines were entering the drug supply then in fact it does undermine our drug safety efforts. He has taken on himself to become perhaps the best informed on a personal basis of this issue, and I commend him for that.

I want to thank our witnesses on the panels here today for their attendance. I look forward to your testimony on this very complex issue, and we look forward also to your recommendations as to how to solve the problems we face. Thank you, Mr. Chairman, and I yield back my time.

Mr. PALLONE. Thank you, Mr. Deal. And I would recognize now our vice chairman from Texas, Mr. Green.

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

Mr. GREEN. Thank you, Mr. Chairman, for holding this hearing on the Food and Drug Import Safety Act. There is no question that glaring gaps exist in our food safety infrastructure. The GAO concurs, and has dubbed our Nation's food safety program as high risk. The news media has highlighted the most high profile problem stemming from imports from China. We have also held two hearings in the Oversight and Investigations Subcommittee on food safety, with the most recent hearing serving to investigate problems with the safety of food imports.

This bill is a natural response to the problems that have been uncovered in the news media, and in our own subcommittee investigations. I support many of the provisions in the bill, and applaud the chairman of the full committee for his commitment to improving the safety of our Nation's food supply. I will whole heartedly support provisions granting the FDA recall authority over dangerous food. We learned through our O&I process that the voluntary recall process does not quickly and effectively protect Americans from tainted food, especially given the FDA often issues recalls after the food's shelf life has already expired.

My goal is for the FDA to become a more nimble agency ready to respond to food safety threats in a time to make the difference and keep Americans from getting sick, and I hope these additional authorities will help them achieve that goal. While the bill has many provisions I support, I would be remiss if I didn't express my significant concerns about the language that would restrict the number of ports of entry for food imports. I am proud to represent the Port of Houston, which is the largest port in the country in terms of foreign tonnage. Granted, a good portion of that tonnage is related to our energy sector, but the port had made it a point to increase the number of food shipments it handles, more than 2.3 million tons of food coming through the port of Houston the first 7 months of this year alone.

In fact, the port of Houston is one of only four ports in the country certified by the New York Board of Trade as a coffee exchange, and we are the only coffee port west of the Mississippi. Despite these commercial successes, the port would essentially be shut out of the food import business under this bill since no FDA lab is located in the Houston area. In fact, there is no FDA lab in the State of Texas. To make matters worse, no FDA lab located in the State despite the fact that our State shares the longest border with Mexico, one of our most prominent trading partners.

There is so much produce and foodstuffs that comes across from Mexico through Texas land ports. I would think Laredo, TX may be the largest inland port in the country, if not the world, and yet

there is no FDA lab in Laredo either. And I looked at the investigation from the O&I Subcommittee, and I am proud to serve on it, and I noticed the inspections that did turn up a number of problems from China but the next biggest country was Mexico. And so I think we need to do better on figuring out how we can address that. The situation brings up an interesting chicken or the egg scenario. Given the levels of trade in Texas on our southern border with Mexico, why isn't there an FDA lab located somewhere in Texas? It seems to be a glaring omission that adds more weight to our argument that the FDA simply doesn't have enough resources to adequately protect the Nation's food supply.

On the flip side, there are only 13 FDA labs in the country, several of which are not located in heavy import areas. My neighbors in Arkansas would have to forgive me, but I have never considered Jefferson, Arkansas, a hub of import activity. I understand the chairman's desire to prevent port shopping. I share his concerns. But I question whether the presence of an FDA lab is really an appropriate reference to determine the ports of entry for food products in the country, and I fear this restriction of these imports to those extremely limited number of metropolitan areas could not strike the right balance in securing the safety of our food and supporting the flow of commerce, commerce that keeps my port supplying much needed jobs to my constituents who are the longshoremen who work on those docks.

I look forward to hearing from our witnesses on this issue, and hope to work with the chairman of the full committee as we move forward in the process, and I share his goals of improving food safety, but I hope we can do it in a way that doesn't bring commercial activity in our country to a grinding halt. Mr. Chairman, I yield back my time.

Mr. PALLONE. Thank you. Next is the gentleman from Texas also, Mr. Burgess.

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

Mr. BURGESS. Thank you, Mr. Chairman. I thank you for having this hearing today. Just like Ranking Member Deal, I had my town hall meetings last month, and heard repeatedly about this issue, and the number of recalls of imported goods clearly caught people's attention across the country. And I am extremely concerned about the safety and security of household products, food supply, and our Nation's pharmaceutical supply. While I remain confident that America has the safest food supply in the world, what I am more concerned about is the safety of imported goods and particularly those imported from the People's Republic of China.

My friend and colleague, Mr. Greg Walden, and myself sent numerous communications to the committee over the past few months asking for an investigation regarding the many food and consumer products safety recalls from China. I continue to urge the leadership of this committee to fully examine this matter. I am also looking forward to the Oversight and Investigations staff report from their recent trip to China, and I believe this report will further inform the legislation that we have under consideration today. Amer-

ica does have the safest, least expensive, most abundant food supply of any country in the world.

In the past, whenever I went into a supermarket to buy food for myself or my family, you pick it up and you worry about, No. 1, does it taste good, No. 2, well, if it was in the 1980s, I worried about fat grams, in the 1990s, I worried about carbs. But now I worry about is this stuff going to make me sick? We just never had to stop and wonder about is the food safe to eat, is it going to make someone in my family ill, and the security of our food supply in my mind has never been in question, but I believe that while it is safe and secure the recent outbreaks of both *E. coli* and salmonella have caught the country's attention. Certainly they have caught my attention.

The industry itself can really scarcely afford further erosions in consumer confidence of its products. I thank Chairman Dingell for his attention to this matter. Having reviewed the legislation, I think the intentions are good but, we all know when God is in the plan, the devil is in the details. I believe that we need to look toward how other Federal agencies have dealt with this issue, and whether it would be appropriate for the Food and Drug Administration to have similar authorities. I am very interested in a proposal developed by Dr. Bill Hubbard, former FDA associate commissioner. He has been here in this committee, and we have heard him testify in the past at numerous hearings. His approach would grant the FDA the authority to embargo if specific food from a specific country, much like the similar authority the USDA has in regard to meat and meat products. My staff and I have reached out to the FDA on a number of occasions, and now I am gratified that we are going to be getting together to review some aspects of that proposal.

I am hopeful that moving forward we can discuss the matter fully with the agency. Now we just have come through the S-CHIP battle, Mr. Chairman, and I hope that is a lesson for us in this committee. This subcommittee is important. This subcommittee has some of the most intelligent Members of the people's house on both sides of the dais, and it is an affront to this subcommittee to push major legislation through the U.S. House of Representatives without the input of this subcommittee, and I trust we will not see a repeat of that in the future. I will yield back the balance of my time.

Mr. PALLONE. Thank you. I recognize the gentlewoman from Colorado, Ms. DeGette.

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

Ms. DEGETTE. Thank you very much, Mr. Chairman, and thank you for holding the hearing today. I got involved in food safety legislation some years ago when a meat processing plant in my home State of Colorado sent out contaminated meat all around the West. And what I learned is probably the most important thing we can do as Members of Congress is work hard to protect the health and safety of our constituents. When our constituents to go the grocery store and buy a package of hamburger or when they buy spinach

to give to their children because they think it is a healthy choice, they rely on our Government and our food safety agencies, all 13 of them, to make sure that their food is wholesome and safe for them to eat.

That system has pretty much fallen apart from top to bottom, I think in large part because of imports from overseas in the last few years, and people are shocked by the continuing number of food safety issues we have. That is why I want to thank Chairman Dingell for developing comprehensive draft legislation that will deal with the issue of both resources and accountability. It seems to me there is a number of issues we need to discuss in the food safety issue. The first and key issue is resources. Our food safety agencies do not have the resources to do the job that we have been asking them to do and which increasingly they need to do. Second, the administration needs to think about how they are going to insure food safety. And, frankly, closing down FDA labs like the lab in my own back yard at the Federal Center in Denver is really not the way to go.

I have a whole different set of concerns about the FDA labs that Mr. Green has, and one of them is that we are going to lose scientists who have years and years of experience. The response from industry has been somewhat more responsive, and I am happy to hear later today from the Grocery Manufacturers Association about their proposals. There are a couple of issues I have been working on ever since I got involved in these issues some years ago. The first one is giving mandatory recall authority to the FDA. People are shocked when they find out that the Consumer Product Safety Commission can recall toys although it is cumbersome but that we can't recall tainted baby food that we feed to those same babies. We need to have mandatory recall authority for a variety of reasons.

Second, and there is a bill, H.R. 3484, that I have introduced that grants mandatory recall authority to the FDA and to the USDA. The second issue that I would really—I am glad the chairman has arrived because I would really urge him to look at this in the legislation. That legislation I have been working on, H.R. 3485, the Trace Act, which would set up a product tracing system that would track food from the farm to the grocery store which would enable to recall in the event of contamination. That also would help us go a long way in keeping our food supply that we give to consumers safe.

Mr. Chairman, the bill before us is a great start. I am happy that we are having a hearing on it, and I look forward to working with you and the chairman of the full committee to making sure that we pass comprehensive food safety legislation in this session of Congress. Thank you.

Mr. PALLONE. Thank you. The gentleman from New Jersey, Mr. Ferguson.

OPENING STATEMENT OF HON. MIKE FERGUSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. FERGUSON. Thank you, Mr. Chairman, and I want to thank you and Mr. Deal and members of the subcommittee and our witnesses for being here today to discuss this very important issue of

the safety and the security of our country's food and drug supply. I am pleased that we are again addressing this critical issue in this most important subcommittee. It is paramount to the citizens of this country that they are able to have faith in our Government's ability to monitor and insure the safety of our food and our drugs. Recently, that has not been the case with several instances of toxic food and counterfeit drugs entering our supply chain.

I hope that our witnesses today will be able to provide us with some insights to why there are perhaps some gaps in the security of our imported food and drugs. My biggest concern, and I believe perhaps the biggest concern of many of us, is how counterfeit drugs are entering our market place. How and why is this happening. My friend from the other side of the aisle who just spoke, Ms. DeGette, summarized the situation very well in a hearing earlier this year at a meeting of this subcommittee. She was speaking about the topic of a recent New York Times investigation that found that toxic cough syrup was being manufactured in China and shipped around the world.

Even under the current construction of the law the dangers of counterfeit drugs are very, very real. I believe we need to grant the FDA the power and the authority to seize and destroy and investigate the origin of these counterfeit drugs. Alarming counterfeiting is happening not only with imported drugs but with our food supply, as we have heard several instances of that mentioned this morning, before they come here to the United States. Recently, the Agriculture Committee and the FDA provided testimony concerning imported aquaculture products from China containing unapproved antibiotics and contaminants. This is pretty disturbing as to why these products containing unapproved ingredients that can be harmful or even deadly to the consumer are making their way to American supermarket shelves.

This shipment from China was found to contain nitrofurans, which has been shown to be a carcinogenic in animal studies. It is really unacceptable that food containing this harmful contaminant should be entering America's food supply, I hope that we will be able to address these and other important safety issues in the coming weeks. I look forward to the testimony of our witnesses. I particularly appreciate Chairman Dingell and his bill and the work that he has done on his legislation. I appreciate the seriousness with which he has taken up this issue, so much so that he has worked on legislation and introduced legislation to do so.

I also hope as we move forward that the work of this subcommittee and this legislative product will include the very, very good work of our colleague, Mr. Buyer. As Mr. Deal mentioned earlier, he has really taken it upon himself to do extraordinary work and research and working on legislation that would address this counterfeit drug issue, and I am very hopeful and optimistic that in a bipartisan way that our committee, this subcommittee, and our full committee can come together to incorporate many of the good parts of the work product that Mr. Buyer is putting together as well. Thank you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you. I next recognize the chairman of the full committee and the sponsor of the legislation, Mr. Dingell.

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

Mr. DINGELL. Mr. Chairman, first of all, thank you for holding this hearing today. I appreciate your leadership, and I commend you for your vigorous efforts in this matter. Our Nation's consumers are experiencing a significant crisis, and confidence in the imported food products and other products they import. For months Americans have been inundated with reports about tainted products shipped from abroad, melamine tainted pet food, antibiotic tainted seafood, lead tainted toys, tainted counterfeit drugs, and counterfeit drugs that do nothing that we know of beneficial, and so on.

As these reports have surfaced, the Subcommittee on Oversight and Investigations led by our able colleague, Mr. Stupak as chairman, intensified its investigation into how the Food and Drug Administration works to protect the public health against tainted food and drug and appliance imports. The preliminary results of these ongoing investigations revealed an under funded importation safety system equivalent in the terms of holes to a block of Swiss cheese. It is clear that Food and Drug cannot and is not doing its job for want of money, for want of staff, for amount of resources.

We hear periodically about how they are going to be a leader organization, and how they are going to do more with less. I have been listening to that since I came on this committee long ago, and I must say that today it is as much phooey as it was then. Last week, Mr. Chairman, you and Chairman Stupak joined me in introducing H.R. 3610, the Food and Drug Import Safety Act. And I would urge my colleagues here in the committee and others of our colleagues in the Congress to join us in co-sponsorship with it. This legislation takes a vigorous proactive step towards correcting the problem of tainted food and drug imports. It closely resembles the discussion draft, which I released earlier in August.

I would point out in response to comments I have heard from my colleagues on both sides it is my full intention that this matter will be pursued both vigorously and in a bipartisan fashion. And I invite my colleagues on both sides, Republicans and Democrats, to join in that undertaking, and I assure them that we are anxious to hear what they have to say about this because this committee will work best when we cooperate on matters of this importance. The legislation that we are discussing aims to increase Food and Drug Administration inspections both at the border and abroad by instituting a small user fee. That is something we have found is necessary because without this kind of financing there will be no adequate performance by Food and Drug, no adequate resources, no adequate staff or funding.

The fee would also fund laboratory analysis to insure that imports are safe to enter our stream of commerce, and I would observe that the efforts of Food and Drug to close its laboratories have been met with uniform condemnation particularly from this committee. Next, it grants the authority to ferret out bad actors that seek to game the current regulatory system and pass off bad products as safe for consumption, a problem which we read about almost daily in the press. As our committee staff stated in their

July 2007 report, FDA's current regulatory approach, which relies on voluntary guidelines for most foods, is inadequate to assure the safety of our modern food supply.

I would observe that the credo down there and the mechanism under which this appears to be done is to trust us, and we have found to our regret that we simply cannot trust that kind of activity to an agency so poorly funded and so poorly staffed. Finally, the bill seeks to attempt a balance by rewarding those who employ best practices allowing them to participate in a voluntary program that gives expedited movement of food imports through the food inspection system.

Mr. Chairman, I look forward to the comments of my colleagues today, and the testimony of our witnesses today as the committee seeks to protect the public health from tainted food and drug imports. I would urge that we be vigorous. I want this to be a bipartisan effort. We will build upon the things which we did in the earlier legislation on this matter, and the commitments I made to my colleagues—that we would hear all Members when we commence the process—remain as good today as they were when we made them earlier. So I urge my colleagues to work together. This is a serious effort to protect the public health, the public safety, and the public welfare from serious wrongdoing, which is now hurting us. I thank you for your recognition.

Mr. PALLONE. Thank you, Chairman Dingell. Next is Mr. Murphy of Pennsylvania.

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

Mr. MURPHY. Thank you, Mr. Chairman, for holding this important meeting and hearing on an issue that is so vitally important to America's livelihood, and actually our lives and our families. Several things that we are going to cover today are important with regard to the FDA's role in protecting our Nations' medicine cabinets. There is a role for the FDA, I also believe in regulating our food supply, and such things as counterfeit imported drugs, which of course mean that you may have people who are taking drugs with toxins in them or ineffective drugs which actually are contributing to their own health problems. We want to make sure the FDA focuses as much of its attention nowadays on drug safety as new drug approval.

As appalling as it is to think that manufacturers would be involved in this outside of the criminal labs, we have to be aware that we are going to have a more vigilant role in dealing with this. And that is probably because of the Nation's increased awareness of what has been happening with China. China, who we have a great deal of trade with and we would like to be a good trading partner, but when we have raised questions about steel dumping or manipulation of their currency if their response is that they are going to sell off their treasury bonds to be punitive it hardly seems to be the words coming from a partner.

Furthermore, they give us the toys with lead paint, bibs and vinyl lunch boxes with lead, diapers with fungus, contaminated pet food, reused chopsticks, tires that cause fatal accidents, juice with

unsafe color additives, baby bottles with an ingredient that can alter a child's hormones, pacifiers with carcinogen, carcinogenic chemicals, teething rings with toxic chemicals, and also let us not forget they have spied on us, they have cyber techs in the Pentagon, they have stolen our national secrets, they have provided bullets and bombs and their components are used to kill our soldiers in Iraq, and to supply the Taliban. This is not the action of a friendly nation to us.

The FDA is on the front lines of protecting American citizens' health, but really in the broader scheme of things this can be an important partnership between the FDA and the American people in making sure the American people are aware of any problems with any products, that such products are recalled quickly, that action is taken to inspect at our borders and put increased pressure on China and any other nation that tries to violate the laws and the protections that we consider so important for people's welfare and health.

Mr. Chairman, as we continue on with this and other hearings, we will hear more and more horror stories of things that have happened, and American companies need to be vigilant. But let us not forget it is not the companies themselves that are involved with this. Companies cannot possibly babysit everything that happens with a nation where they consider it a common practice to go ahead and have lower health standards, lower wages, pollute the air more, and expect our citizens to pick up the tab on this or perhaps turn a blind eye. We will not do that as a nation. We will not do that as a Congress. And I am pleased this committee is going to take firm action on making sure that we draw out every possible exposure of this and get the FDA as a strong partner to protect the health and welfare of American citizens. I yield back.

Mr. PALLONE. Thank you. I recognize the gentlewoman from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman. I am going to waive my opening statement time and save it for questions. Thank you for having this really critically important hearing.

[The prepared statement of Ms. Eshoo follows:]

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

Mr. Chairman, I thank you for convening today's hearing on H.R. 3160, the Food and Drug Import Safety Act, legislation that would give the Food and Drug Administration enhanced authority and resources to inspect imported foods and drugs, as well as additional authority to protect public health.

Even before reports this year about tainted foods and consumer products coming into our country, there have been substantial concerns about the safety of our food supply.

The CDC's estimates of foodborne illness have been startling: 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year.

The domestic inspection and monitoring system for food is not nearly as rigorous as it should be. The authority of the major food safety agencies to enforce standards and recall suspect food has been virtually non-existent. That's why I'm pleased that H.R. 3160 grants recall authority to the FDA.

The major concern now is the ability of food safety agencies to keep pace with the rapid increase of food imports.

The FDA, which is under the jurisdiction of the Energy and Commerce Committee, is responsible for ensuring the safety of approximately 80 percent of all food products—virtually every food item that is not meat or poultry. In the last decade the volume of food imports under FDA's purview has tripled. At the same time, the

percentage of shipments inspected by FDA has dropped from 1.7 percent to 1 percent.

Unlike the USDA's Food Safety and Inspection Service, which bars the importation of meat and poultry unless the country from which the product is shipped has been certified as having standards equivalent to U.S. standards, the FDA does not require equivalency certifications. Instead, FDA relies on inspections of imported goods to protect consumers.

My understanding is that the FDA has stated that it does not have the resources to implement equivalency certifications. H.R. 3160 attempts to address this problem by imposing user-fees to expand inspections and by requiring equivalency standards.

Much more needs to be done to improve food safety, and the legislation we're examining today will help plug some of the holes in the food safety system. I look forward to the testimony we'll hear from today from the FDA and other witnesses.

Mr. PALLONE. Thank you. Ms. Schakowsky.

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

Ms. SCHAKOWSKY. I thank you, Chairman Pallone, for holding today's hearing on the Food and Drug Safety Act. I thank Chairman Dingell for this important legislation which makes crucial strides in strengthening FDA's ability to monitor the safety of our Nation's food and drug imports. During the past year, consumer confidence in our Nation's food safety framework has been shaken time and time again particularly by tainted imports. Cases of poisoned toothpaste, antibiotic laden seafood and toxic pet food demonstrate how we rely on the food safety practices of foreign countries and producers, and illustrates the importance of the legislation before us today.

More than $75 billion worth of food and agricultural products are imported into the United States annually, which is nearly double the value of just over a decade ago before NAFTA and WTO took effect in the mid-1990s. In 2005 nearly 15 percent of all U.S. food consumption was imported. Despite the increase in imports FDA estimates that in 2007 it will conduct border inspections on only a paltry 0.6 percent of the food it regulates down from 8 percent just a decade ago. USDA, while not a model of perfection, has at least managed to inspect 11 percent of the beef, poultry, and other products it regulates in 2007. Chairman Dingell's bill incorporates several crucial and common sense solutions to the present food safety crisis. The bill would provide FDA with the additional resources and authority it needs to certify and inspect food safety procedures of foreign countries and facilities as well as the products entering our ports.

It institutes country of origin labeling, something that 92 percent of Americans support within 6 months of the bill's enactment into law. I am particularly pleased that it gives the FDA the authority to issue mandatory product recalls and halt imported products until a foreign entity has resolved the problem. These measures will help prevent future food safety outbreaks and help restore the shaken consumer confidence. While I strongly support the intent of this bill and the vast majority of the solutions it proposes there are some provisions that I believe need more discussion. Sections 3 and 4 require the Health and Human Services Secretary to assess and collect user fees to fund inspections, lab testing, and research on testing techniques for food and drug imports.

I fully support the emphasis on proactive safety inspections and testing. However, if we are forced to rely on user fees, I am concerned that we make it clear that those companies that pay those fees do not have undue influence on agency policies and practices. The subcommittee has worked to address this problem, and the FDA's drug approval process, and I hope, in fact, I am sure, that we can prevent similar problems here.

I am also concerned with provisions in section 5 that would restrict the number of eligible ports from the current number of more than 300 to just 13, excluding some of our Nation's busiest ports such as Chicago, which I represent part of, and Houston and Boston. While the Secretary has the authority to waive this requirement, I believe we need to create a food safety system that enables busy ports like Chicago to continue receiving food imports. I am interested in hearing more about the consequences of the drastic reduction on areas with no direct port access as well as how we can insure transparent and accountable decision-making process with regard to this waiver authority.

There is much work to be done to restore consumer confidence in our Nation's food supply, the kind of food safety framework that will make the high profile cases of this year a thing of the past. And I look forward to hearing from all of the witnesses. With that, I yield back. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. I recognize the gentlewoman from New Mexico, Mrs. Wilson.

OPENING STATEMENT OF HON. HEATHER WILSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW MEXICO

Mrs. WILSON. Thank you, Mr. Chairman. The events over the last year really highlighted for Americans and raised awareness of just how vulnerable our food supply is, and it is not just food. It is food, medicine, consumer products, even our water and the things that we drink are vulnerable to contamination. Not only accidental contamination or what might have been unintentional or the result of bad sanitary practices in companies that are poorly regulated overseas but the potential for intentional contamination of our food supply. It is a serious issue, and we have a duty in this Congress to make sure that imported food and goods are safe from contamination whether accidental or intentional, and make sure that any problem with the food supply is detected so that we prevent public health problems before they occur.

My colleagues on this committee have recounted the problems that we have had with China, but it is not a single country issue. Globalization creates a vulnerability here in the United States and starting at our border is not where we need to be. I believe very strongly that we need an integrated system for food safety and security with layers of protection. I look forward to the testimony here today, and looking at the legislation in front of us to make sure that we are providing that integrated system for food safety and security rather than setting up a system where there are single points of potential failure after which public health problems can occur. We have a food safety laboratory in the State of New Mexico at New Mexico State University, and I am a strong sup-

porter of what they do, not only in food technology and evaluation but also in a counterterrorism technologies laboratory where they develop tools in order to make sure that our food supply is safe.

I look forward to hearing the testimony of the witnesses today, and look forward to working with my colleagues on the committee to make sure we strengthen our ability to prevent the intentional or unintentional contamination of America's food supply. Thank you, Mr. Chairman.

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. Chairman. I first of all want to thank you and Chairman Dingell for your leadership on food safety issues. I know this is an issue that the chairman cares about very deeply, and I am glad we are taking up this legislation. I too want to make sure that we can assure the American public that our foods and other products are safe. Recent incidents involving adulterated products from China have again brought to the forefront the critical importance of food safety. Although the vast majority of food entering the United States is safe, now is the time to act to strengthen our system to limit harmful food products from entering the country.

Monitoring the safety of imported foods is a tremendous challenge for FDA. Over 825,000 different importers brought shipments into the United States last year. Those importers bring products to approximately 326 ports. The value of U.S. imports has nearly doubled since fiscal year 2000. The FDA's resources are stretched too thin to meet the growing demand of its inspectors. Fortunately, I think almost universal agreement exists on that point, that the FDA needs more resources to its job properly. I also believe it is vital to insure that our food is not only safe but that we work to permit the free flow of goods into the United States. The safe and secure food importation program is an important step to help expedite the importation of food from those parties willing to abide by rigorous food safety guidelines established by the FDA.

This program provides the appropriate incentives to importers by rewarding those who take extra steps to ensure safety. I also look forward to hearing from our witnesses today regarding the provisions restricting port of entry to only 13 ports. I believe that steps can be taken to help ensure we are able to better inspect imported foods, but I believe we can do so in a less burdensome manner. I have a significant food processing industry in the district I represent. I am concerned about the impact restrictions on port of entry may have on consumers and the food processing industry by making them wait longer to get fresh products.

I also fear that having only 13 ports of entry will raise production costs and put food processors in the fifth district at a competitive disadvantage to those cities with an FDA lab, without materially improving safety. I believe we can find other alternatives that ensure safety and still meet the needs of our consumers and producers. As the author of the country of origin food labeling, COOL provisions for produce passed in the 2002 farm bill, I believe COOL

can be an important resource for consumers. It is also critical to ensure such requirements can be practically administered.

COOL with processed foods present challenges that are not present with fresh produce or meat. I hope our witnesses will share their thoughts on the impact of COOL as it relates to processed foods in particular, and practical approaches to implementing such requirements. I look forward to working with Chairman Pallone and Chairman Dingell as we move forward with this very important legislative process on H.R. 3610. Thank you, Mr. Chairman, and I yield back the remainder of my time.

Mr. PALLONE. Thank you. Mr. Buyer from Indiana.

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

Mr. BUYER. Thank you very much. And to Chairman Dingell, I want to thank you for giving me the opportunity to work with you and your staff. As I traveled the country and went to our mail facilities and to our private carriers, I learned that your staff, and, Mr. Pallone, your staff had also been there. In 3 minutes I can't even cover the vast—my summer, what I did on my summer vacation. But what I would like to do is say I believe that our ideal is to insure the highest standards of health care for Americans. We do that with regard to health care. The demands for high standards are placed upon our health providers, our pharmaceuticals, our medical devices, our medical technologies, our medical research.

But with regard to drugs and medical devices, how do we protect our system? We look to the FDA as the gold standard but then when you think about this, we just passed PDUFA, and PDUFA, and all the dollars, the hard work that we put into the reauthorization I believe is useless if we cannot protect the system and close it off from the harmful products and bad actors who are these counterfeit criminal syndicates that are preying upon Americans. We must safeguard citizens from unknown dangers using the information we have on the threats to America's health. We know that there are multi-million dollar worldwide criminal enterprises doing business growing at unfathomable rates to manufacture counterfeit drugs. 20,000 to 30,000 packages enter each of our 12 international mail facilities every day, and that is not counting the private facilities.

Less than 1 percent of these packages are screened by FDA. That means 99 percent of them are sent to individuals across the Nation without ever being inspected, much of which, in excess of 70 percent perhaps, are unapproved drugs. Now when you look about how many times we have touched this law, we touched it back in 1938. Chairman Dingell and his initiatives in 1988 touched this issue. So if you will indulge us, Mr. Chairman, I hopefully will have a discussion draft, it has been at the leg counsel here for the last 2 weeks, by mid next week. What we propose to do is give FDA the authority to destroy counterfeit drugs coming into our postal system and the private carrier system, give FDA the authority to seek the disgorgement of counterfeiters profits.

We want to increase minimal Federal standards to States to use in licensing prescription drug wholesalers. We want to implement

a Federal pedigree standard so we can effectively trace prescription drug products throughout their chain of custody. This further secures our domestic supply chain from bad actors. We want to establish the electronic pedigree standards to modernize our system and prevent fraud of paper pedigrees. We want to work toward a goal of serialization of all products, prescription drugs, so we can further protect them from the counterfeiters.

We will also enlist State's help in tracking counterfeiters down by providing them with some financial incentives to help the Federal Government. We also will insure that any repackaged drug products are held to the same high standard as the original drug products, insure also that drug wholesalers engaged in criminal counterfeiting activities are debarred and prohibited from future work with the FDA. We want to create a study to investigate the international domestic threats to the Nation's drug supply. So, Mr. Chairman, I want to continue to work with you. We will get this discussion draft hopefully back from leg counsel, get it to your staff, and we all will get this and work together. And I appreciate, Chairman Pallone, working with you and Chairman Dingell, along with Mr. Deal. I appreciate your leadership along with Mr. Barton and his staff. Thank you.

Mr. PALLONE. Thank you. The gentleman from Utah.

OPENING STATEMENT OF HON. JIM MATHESON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF UTAH

Mr. MATHESON. Thank you, Mr. Chairman. Clearly, this is an issue of great concern. We want to ensure the integrity of our food supply. And I think it is a complicated issue, and to resolve it, I think that a good bipartisan effort is the best way to go about it. I think this committee can really step up to the plate in that regard. I think we need to take a look at this in the context of the global market place, and we need to look at the whole chain, supply chain, if you will. I would suggest that you could connect this issue with the toy safety discussion that is also going on in another subcommittee. In that case, we are looking more at the manufacturing end. In this case, I am hearing a lot about the domestic end of the equation where we inspect food when it gets to our country. I would suggest we need more of a blended approach, and we ought to be looking at the supply chain in general about where we can make the most rational and efficient efforts to ensure the integrity of the food supply.

And this discussion seems to be a lot about imported food but we also of course should not forget our domestic production as well and make sure that food produced domestically can be assumed to be safe when it reaches a family dinner table. There are two issues I just wanted to raise briefly in this opening statement of concern to me that I think we need to keep in mind as we look at this broad issue of food safety. The first has to do with the impact on our relationships with our trading partners. I am concerned that this effort at addressing food safety concerns could invite a more protectionist agenda than I think would be appropriate or good for this country, and I think as we look at this issue we ought to make sure that does not happen. I think we should recognize that there—and we should ask questions about how the existing WTO

agreement that talks about the application of sanitary and by sanitary measures how that does work and if there are issues that we ought to think about to make it work better then I think we should recognize we are in that global market place, and we should try to maintain the integrity of that global market place.

The second issue I want to raise that we ought to be looking at has to do with comments that FDA provided during the Agriculture Appropriations Subcommittee hearing on food safety. FDA issued some concerns about imported aquaculture products, seafood products, and the issue of antibiotic resistance, based on antibiotics being used with the seafood product. I think that is a very important issue when it comes to the issue of the development of antibiotic resistant diseases. I plan on introducing legislation this week with my colleague, Representative Ferguson, which seeks to address this issue about how this country can better position itself for trying to develop new antibiotics that can take on these organisms that are currently resistant to current antibiotics, and I think that is an emerging public health concern and it turns out even in this food safety discussion that public health concern is now merged as well, so those are just two quick issues that I think we also ought to keep in mind as we look at this broad food safety issue. With that, I will yield back, Mr. Chairman.

Mr. GREEN [presiding]. Mrs. Blackburn.

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

Mrs. BLACKBURN. Thank you, Mr. Chairman. I would like to thank the chairman for calling the hearing to discuss all of our issues with FDA oversight and the food and drug imports into the country. This is indeed a critical public safety issue as well as a national security concern, and when we hear the reports as we have heard in recent days about the episodes around the country, we do become keenly aware of the potential for terrorists to exploit these weaknesses. The combined efforts of the food industry and the regulatory agencies are often credited with making the U.S. food supply the safest in the world. And we know that we have at least 15 different agencies administering over 30 different rules related to food safety.

And in spite of this widespread approach, we have a tremendous track record of success and those involved in that process are to be commended. We know that the FDA is responsible for insuring that all domestic and imported food products except most meats and poultry are safe, nutritious, wholesome, and accurately labeled. Although all imported food products must meet the same safety standards as domestically produced foods, international trade rules permit a foreign country to apply its own differing regulatory authorities and institutional systems in meeting such standards under an internationally recognized concept known as equivalence.

As Americans consume increasing amounts of imported food and drink and as U.S. producers are demanding more overseas ingredients, we see an increase in this volume. Globalization is playing a part. It has tripled our imports in the past decade. I was impressed by the staff that the FDA received more than 10 million imported

food entries in 2006 and compared that with less than 2.8 million entries in 1996. That is an indication of the volume that is before the agency. Just over 1 percent of these shipments were physically examined in fiscal year 2006 compared with 1.7 percent in fiscal year 1996. According to the USDA, the United States is expected to import a record 70 billion in agricultural products this year.

The legislation before us today causes some concerns to me with the user fees, the trade implications, new labeling, the negative impact on small business with these user fees and those being passed on to the consumer, and of course the bureaucracy that is there. I am also concerned about the restriction of ports of entry and what that would do to food plants that are not in close proximity to a metropolitan area. But, Mr. Chairman, I look forward to the discussion, and I thank the committee for the efforts spent on the issue. I yield back.

Mr. GREEN. Mr. Waxman.

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

Mr. WAXMAN. Thank you very much, Mr. Chairman. There doesn't seem to be a day that doesn't go by when we pick up the morning newspaper and we hear about the dangers of some imported product that turns out to be unsafe. We have been hearing a lot about toys. We have been hearing about lead. And we have been hearing particularly alarming information about food that comes into our country from foreign lands that are not safe. So we need to do something about this issue, and I want to point out that I think this Food and Drug Import Safety Act of 2007 makes some critical steps forward getting FDA what it needs to protect the American public.

And I want to applaud Chairman Dingell for the good work he has done on this legislation. The bill, as we look at this bill at this hearing today, makes important improvements to food and drug import safety, but its most dramatic and in some ways most critical changes would affect food imports because the bill deals not just with food imports but other imports within the jurisdiction of the FDA. If we look at FDA, FDA's experience with food importation, we want them to focus on securing the entire supply chain, not just stopping unsafe foods at the border. The bill would give the FDA clear authority to require a recall of unsafe foods. The bill provides for strong civil monetary penalties to hold bad actors accountable, and it has a strong food regulatory system. All of this represents an important step forward.

I was pleased to listen to the very thoughtful statement of our colleague, Congressman Matheson of Utah, where he pointed out we need to look at the whole chain of the food supply from the original source. And so this legislation doesn't just deal with the problem at the border, it requires that within 5 years FDA would have to certify that all food importers, either individual facilities or countries, have a system in place to insure the safety of the foods that they export to the United States.

I think this makes a lot of sense. If they don't have a system in place then FDA would be required to go and examine the facility

itself. It may be impossible for FDA to review and certify the overwhelming volume of facilities in countries seeking to enter the U.S. market. If that is so, we are all going to lose so I hope the FDA will provide some guidance on what exactly it needs to do this important job. I want to raise an issue of concern about the user fee. I think we rely too much on user fee, and I also want to point out as Mr. Matheson did, we have a domestic food supply question as well, and I know that Chairman Pallone has introduced a bill that I think is highly commendable on this subject.

But let us go into this issue with the expectations that we are going to get the job done, but let us don't fool ourselves. We don't provide the authorities, and if we don't provide the resources FDA will do the best it can but it will fall short of what needs to be done. And I hope we don't have another hearing in another year that the problems have not got resolved.

Mr. GREEN [presiding]. Mr. Pitts.

Mr. PITTS. I would like to thank the chairman for holding this vital hearing, this hearing on a very vital issue, food and drug safety for the American people. And I would like to thank the gentleman from Indiana, Mr. Buyer, for his leadership on this issue, and would like to yield the balance of my time to him.

Mr. BUYER. I thank the gentleman. I would like to say to Chairman Dingell, back in 1988 when you touched this issue, we didn't have the Internet, and the Internet is presenting great challenges to the protection of our system today, so when people believe they can get on the Internet and they pull up a Canadian Web site, and these Web sites can go up one day and down the next. For example, I don't want to give great compliments to FDA, American people could go to a Canadian Internet pharmacy, which was *www.rxnorth.com*, and they were led to believe the products were coming directly from London and that they were safe and it is all legal and it is approved. And what is happening today is that our Government by way of our policy are being the enablers of these very complex criminal enterprises. So why I say enablers is the FDA believes through their interpretation of the law that they do not have the authority to destroy these drugs when they see them.

Now if it's a schedule 1 or 2, they do a seizure and they can destroy, but they can send it to a lab and they can destroy it. Many of them were never sent to a lab. And I felt that the absolute frustration by many of the pharmacists at our international mail facilities working for the FDA that they will place their stamps, FDA stamps, and things on these drugs, and they have a return to sender policy. Now you think about that. You got a flim-flam operation here, a snake oil salesman selling bad goods to people, and they are taking their money, and the Government is giving the product back to the flim-flam man to go somewhere else to scam people. That is what is happening here.

And the FDA, they want the ability to destroy these drugs, and we need to give it to them. And what I am referring to here is with regard to these criminal enterprises the FDA last summer, they did an FDA bust in cooperation with British officials at Heathrow Airport. Now these drugs were manufactured in China. They were shipped transient through Hong Kong to the United Arab Emirates. They went to Heathrow. From Heathrow they then go to the

Bahamas to a fulfillment center where that Canadian pharmacy, *rxnorth.com*, would then contact the Bahamas, and say, okay, I have an order that has been placed from somewhere in the United States. They contact the Bahamas. The Bahamas then fills that order, send it to Heathrow. From Heathrow then it comes into the United States.

Now the challenge is to actually take down these syndicates because they are moving transit through so many different countries. And to give you an example, this is a drug, Fosamax. This is to improve bone density for those diagnosed with osteoporosis. Now when you look at these packages, you look at them here, which one is the counterfeit and which one is real? Now the only way that you can tell is you got to go to the manufacturer themselves. And you look here and the yellow is just a little bit lighter if you look really close. That one is real. When you turn to the inside on both of them, they both have the blister packs. All the way to instructions it looks real. It is not. It is fake.

When you look at the packages and you go to the bar coding, you can bar code the counterfeit and bar code the real, and they both bar code correctly. You go to the lot numbers. The lot numbers are both correct. You go to the expiration dates. They are both correct. The sophistication of these criminal syndicates is absolutely extraordinary, and we have to get on our heels and on our toes and give FDA the authority to destroy these and protect our country. And that is why I want to work with everyone and anyone who wants to help protect our system from these bad actors who prey on the most vulnerable in our society. I yield back.

Mr. GREEN. Thank you. And we have about 6 minutes until our vote. Representative Allen for opening statement.

OPENING STATEMENT OF HON. TOM ALLEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MAINE

Mr. ALLEN. Thank you very much, Mr. Chairman. Thank you for convening this hearing to address the important issue of food and drug import safety. Like many Americans, I have become increasingly concerned about the safety of our food supply. Food imports have more than doubled over the past decade, and the Food and Drug Administration currently lacks the resources and the authority to protect Americans from tainted products. For example, the FDA first issued an alert on unsafe seafood from China as early as 2001, but we all know from watching the news in June 2007 contaminant levels were still unacceptably high for many imports, including catfish and shrimp.

The Food and Drug Import Safety Act of 2007 takes several important steps toward increasing the safety of our food supply. I want to highlight a few of the provisions I think are particularly important. First, the legislation would require that all imported food intended for consumption be subject to the same safety standards already applied to domestically produced food. Most Americans would be appalled to realize that today this is not the case for many food products. Under the bill, the FDA must certify that foreign countries or facilities that import food into the United States are enforcing food safety standards as good or better than the standards in place here already. I applaud this proactive ap-

proach, which has the potential to identify and address problems in the food supply before the food ever reaches our borders.

Second, this legislation would institute mandatory country of original labeling for all foods, drugs, and medical devices regulated under the FDA. All consumers have a right to know where their food comes from. I am particularly pleased that for the first time the rule will apply to processed seafood. These foods might be at greater risk of contamination because of extended processing but until now have been exempt from the country of origin labeling requirement. Finally, the legislation would help level the playing field for American producers. For example, fishermen in my home State of Maine are renowned for safe, sustainable, and high quality seafood products, yet these hard-working Americans often encounter the economic hardship because the seafood market is flooded with cheap, lower quality imports that have not had to meet the same rigorous safety standards applied to home grown or caught products.

One possible problem I just wanted to highlight, the bill would reduce the number of ports open to food imports dramatically, and this is legislation that I think really needs some revision. I do thank the chairman again for holding this hearing on such an important topic and look forward to working with my colleagues to advance this important legislation. Mr. Chairman, I yield back.

Mr. GREEN. Thank you. Since we have votes on the floor the subcommittee will stand in recess. We finished the opening statements so we will get to your testimony as soon as we return hopefully in about 20 minutes.

[Recess]

Mr. GREEN. The subcommittee is going to come back in order, and again I appreciate everyone's patience this morning for our vote schedule. We may have another one in about an hour on the continuing resolution, so we will try and get through our statements. Again, I know your time is valuable like everyone else.

I would like to recognize our first panel. Dr. Lutter is Deputy Commissioner for Policy, Food and Drug Administration, and he is accompanied by Dr. Acheson, and also Dr. Solomon. So, again, proceed with your testimony, and thank you for being here.

STATEMENT OF RANDALL L. LUTTER, DEPUTY COMMISSIONER, POLICY, FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD; ACCOMPANIED BY: DAVID ACHESON, M.D., ASSISTANT COMMISSIONER, FOOD PROTECTION, U.S. FOOD AND DRUG ADMINISTRATION, AND STEVEN M. SOLOMON, D.V.M., DEPUTY DIRECTOR, OFFICE OF REGIONAL OPERATIONS, OFFICE OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMINISTRATION

Mr. LUTTER. Good morning. Thank you, Mr. Chairman, and members of the subcommittee. I am Dr. Randall Lutter, Deputy Commissioner for Policy at the Food and Drug Administration in the U.S. Department of Health and Human Services. I am very pleased to be here today with my colleagues, Dr. David Acheson, Assistant Commissioner for Food Protection, and Dr. Steven Solomon, Deputy Director of the Office of Regional Operations in FDA's Office of Regulatory Affairs.

Thank you for the opportunity to discuss the important issues relating to the safety of imported FDA regulated products. I would also like to take this occasion to thank the committee for all its recent hard work in passing the Food and Drug Administration Amendments Act of 2007. The programs that this legislation reauthorizes are vitally important to the agency and its continued ability to protect and promote the public health. We look forward to working to implement this legislation.

I assure you that FDA is committed to ensuring that America's supply of food, drugs and other products that we regulate continues to be as safe as possible. In recent years, the agency has done a great deal to detect unintentional and deliberate contamination in imported products. However, increasing globalization and trends towards production of these products abroad pose significant challenges. Recent incidents involving unsafe imported products underscore the need to renew our focus on integrated product safety strategies.

Food has recently been in the news. Dr. David Acheson, Assistant Commissioner for Food Protection, provides leadership on strategic and substantive food safety on food defense matters for both imported and domestic foods. He is developing a strategy to enhance our food safety and food defense systems that will address changes in the global food distribution system, identify the most critical needs, and serve as a framework to help us address the challenges we face.

Our goal is to ensure a comprehensive and robust food safety and food defense program that focuses first on prevention, second on risk-based interventions to ensure and verify our preventive controls are effective, third, rapid responses when contaminated food or feed is detected or when there is harm to humans or animals. The strategy will provide a risk-based farm to table approach that coordinates food safety and food defense efforts on both imported and domestic products and focuses on prevention, intervention, and response.

The President is engaged directly in the effort to make sure we are doing everything we can to protect Americans from unsafe imports. On July 18 he issued an Executive order creating a Cabinet level working group on import safety to promote the safety of imported products. It includes representatives from 12 Federal departments and agencies including FDA and the U.S. Department of Agriculture, and is reviewing the procedures, regulations, and practices for ensuring that imported foods, drugs, and other consumer products are safe.

Secretary of Health and Human Services Michael O. Leavitt chairs this working group, and FDA plays a key role in the group's activities. Secretary Leavitt and FDA Commissioner von Eschenbach have traveled extensively throughout the United States during the past few months visiting ports of entry and reviewing import operations in the field. The insights that they gained during their review of field operations helped shape the strategic framework that was released by the working group on September 10. That report "Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety," outlines an approach that, like the food

protection strategy, is based on the organizing principles of prevention, intervention, and response.

The Strategic Framework recognizes that we must find new ways to protect American consumers and continually improve the safety of imports. It identifies the need to shift from the current model that relies on snapshots at the border to interdict unsafe products. The new prevention focused approach would identify and target those steps in the import life cycle where the risks of unsafe products are greatest and verifying the safety of products at those important phases. Such a risk-based prevention focus model will help ensure that much more information about safety and risk is available to border inspectors and that safety is built into products before they reach our borders.

Supporting the working group model are six building blocks, one is to advance a common vision, two, increase accountability and enforcement, three, focus on risks over the life cycle of an imported product, four, build interoperable systems among Federal agencies, five, foster a culture of collaboration, and, six, promote technological innovation and new science. The interagency working group on import safety has an aggressive schedule for public comment and follow up. Next Monday, the working group will hold a public meeting to identify actions the public and private sectors can take to promote the safety of imported products.

By mid-November the working group will present an action plan to the President. The plan will reflect the public comments and recommend specific actions that the Federal Government and stakeholders can take to enhance import safety at all levels. The action plan will be based on the Strategic Framework that is already public and will lay out a road map for short and long-term recommendations.

In addition to these efforts, FDA has recently initiated a series of meetings with officials in China to negotiate draft memorandums of agreement aimed at creating a framework to help assure the safety, quality, and effectiveness of products exported from China to the United States. The agreements also aim to increase cooperation and information sharing between the regulatory bodies of the two nations with the goal of strengthening China's regulatory process.

Furthermore, FDA is also looking into ways that it can increase information sharing with other governments that will assist FDA in better allocating its inspection resources. Recently, FDA has completed a pilot project with Swissmedic to facilitate such information sharing.

I would like to comment briefly on H.R. 3610, the Food and Drug Import Safety Act of 2007, which was introduced by Chairman Dingell on September 20. It contains a variety of provisions that relate to the safety of imported food and drugs in addition to other matters.

The administration has not yet taken a position; however, we would be pleased to provide technical assistance to committee and subcommittee staff. We share Chairman Dingell's interest in enhancing the safety of imported product, and look forward to continuing to work with him and his staff and others on the sub-

committee and on the committee. We also look forward to working with you on the action plan that we discussed above.

Ensuring the safety of imported products is a significant task, and I want to assure you that FDA is diligently working to efficiently and effectively use the resources and authorities we have been provided by Congress to help protect American consumers.

Thank you for the opportunity to discuss FDA's activities to enhance the safety of imported products. We would be happy to answer any questions.

[The prepared statement of Mr. Lutter follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

RANDALL LUTTER, PH.D.

DEPUTY COMMISSIONER FOR POLICY

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON HEALTH

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2007

For Release Only Upon Delivery

INTRODUCTION

Good morning, Chairman Pallone and Members of the Subcommittee. I am Dr. Randall Lutter, Deputy Commissioner for Policy at the U.S. Food and Drug Administration (FDA or the Agency) in the Department of Health and Human Services (HHS). I am accompanied today by my colleagues from FDA, Dr. David Acheson, Assistant Commissioner for Food Protection, and Dr. Steven Solomon, Deputy Director of the Office of Regional Operations in FDA's Office of Regulatory Affairs. Thank you for the opportunity to discuss the important issues relating to the safety of imported FDA-regulated products and to discuss H.R. 3610, the "Food and Drug Import Safety Act of 2007," introduced by Chairman Dingell.

FDA is the Federal agency that regulates everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at the U.S. Department of Agriculture (USDA). FDA's responsibility extends to live food animals and animal feed. FDA also is responsible for ensuring that human drugs, human biological products, medical devices, and radiological products as well as animal drugs are safe and effective and that cosmetics are safe.

I assure you that FDA is committed to ensuring that America's supply of the food, drugs and other products we regulate continues to be among the safest in the world. In recent years, the Agency has done a great deal to detect unintentional and deliberate contamination in imported products. However, we face significant challenges. The recent incidents involving unsafe

imported products underscore the need to renew our focus on multidisciplinary and integrated product safety strategies.

One of the significant challenges we face is the rapid increase in the volume of imported products. Each year, approximately $2 trillion worth of imported products enter the U.S. Experts project that import volume will triple by 2015. The volume of FDA-regulated imports has doubled in the last five years, and 60 percent of these imported shipments are food or food-related. Currently, there are over nine million entries of imported food and food-related products annually and most are large volume commercial shipments. It is estimated that approximately 15 percent of the U.S. food supply is imported, but for some products such as fresh fruits, imports account for 50 to 60 percent of the supply.

The President has engaged directly in the effort to make sure we are doing everything we can to protect Americans from unsafe imports. On July 18, he issued an Executive Order creating a Cabinet-level Working Group on Import Safety to promote the safety of imported products. HHS Secretary Michael O. Leavitt chairs the Working Group. I will discuss the Working Group's activities and recent report below.

REGULATION OF IMPORTED FDA-REGULATED PRODUCTS

FDA's primary authority over imported food, cosmetics, drugs, biological products, and medical devices, derives from section 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Imported radiation emitting products are regulated under section 534 of the

FD&C Act. These authorities provide a broad statutory framework to ensure that the products are safe. Imported products are subject to examination. FDA can refuse admission into the U.S. if they appear, based on examination or other information, to be adulterated, misbranded, or otherwise violative.

Imported Food

As you know, in 2002, Congress gave FDA significant new authorities to enhance protection of the food supply in the Public Health Security and Bioterrorism Preparedness and Response Act (Bioterrorism Act). I wish to thank the Members of this Subcommittee and the full Committee for your leadership in enacting this landmark legislation.

One of the major provisions of the Bioterrorism Act that enhances our ability to protect American consumers from contaminated imported food is the requirement to submit to FDA prior notice of food, including animal feed, that is imported or offered for import into the U.S. This advance information enables FDA, working closely with Customs and Border Protection (CBP), to more effectively target imported food that may pose a significant risk so it can be inspected before it moves into the U.S. FDA is currently reviewing approximately 33,400 prior notice submissions per business day.

The prior notice requirement not only allows the electronic system to review and screen the shipments for potential serious threats to health (intentional or otherwise) before food arrives in the U.S., but it also allows FDA staff to review prior notices of those products flagged by the system as presenting the most significant risk and determine whether the shipment should

be held for further investigation. If the result of our prior notice review suggests the food presents a significant threat, we will not release the food into commerce until we have information indicating it does not pose such a threat.

FDA worked closely with CBP in developing the targeting system. In particular, FDA worked with analysts at CBP's National Targeting Center to utilize their Automated Targeting System as an additional tool to enhance the Agency's ability to focus attention on those imported foods that may pose a serious threat to public health.

Another significant provision of the Bioterrorism Act gave FDA the authority to commission other Federal officers and employees to conduct examinations and investigations. Pursuant to this authority, FDA and CBP signed a Memorandum of Understanding in December 2003 to commission CBP officers to conduct examinations on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff in the enforcement of FDA's prior notice requirements. This collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade. In accordance with the commissioning authority, FDA has commissioned over 9,900 CBP officers.

To manage the ever-increasing volume of imported food shipments, FDA utilizes risk-management strategies in the review of foods that are being imported or offered for import into the U.S.. In addition to the screening and targeting based on the prior notice submissions, we use information submitted through CBP's electronic systems for import entries, along with other information, to determine if the shipment meets identified criteria for

physical examination or sampling and analysis or warrants other review by FDA personnel. FDA is working to enhance its targeting ability by utilizing data from a much wider range of sources to better inform our entry decisions and by improving our information technology (IT) systems to use this information more efficiently and effectively.

FDA also performs routine surveillance inspections of imported foods to check for compliance with U.S. requirements. If, based on a physical examination or other information, FDA determines that a food shipment is or appears to be violative, the Agency has the authority to refuse its admission into U.S. commerce. It is important to note that while FDA is not able to physically inspect a large percentage of food entries, we electronically screen all import entries through the Operational and Administrative System for Import Support (OASIS). OASIS is an automated system for processing FDA-regulated products offered for import and helping FDA make admissibility determinations. It includes criteria designed to identify those products posing the greatest safety risk.

FDA has additional tools and authorities which enable the Agency to take appropriate action regarding imported products. For instance, FDA can issue import alerts, which signal FDA inspectors to pay special attention to a particular product, producer, shipper or importer. Recently, for example, the Agency established import alerts for certain products from China, including all vegetable proteins and certain types of aquacultured fish. Based on the information in these import alerts, FDA field staff may initiate refusal of admission into the U.S. without physically examining the product. If FDA initiates refusal, the importer has an

opportunity to demonstrate that the products in question are free of the relevant contaminants or otherwise not violative.

FDA also performs laboratory analysis on a sampling of products offered for import into the U.S. and performs periodic filer evaluations to ensure that the import data being provided to FDA is accurate. In addition, certain violations relating to imported food may lead to civil or criminal charges.

Imported Drugs, Biologics, and Certain Devices

The FD&C Act strictly limits the drugs and biologics, as well as certain devices, that may be imported into the U.S.. Congress enacted these provisions to create a relatively "closed" distribution system for such products, which helps ensure that the domestic supply is safe and effective.

To comply with the FD&C Act, any entity that intends to import drugs or biologics requiring pre-market approval into the U.S. must ensure, among other things, that the products comply with the FDA approval in all respects. The importer must ensure that each drug or biologic meets all U.S. labeling requirements, and that prescription drugs are not re-imported after export in violation of the Prescription Drug Marketing Act. FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, and container/closure system. Medical devices requiring pre-market approval are subject to similar requirements.

NEW INITIATIVES

Food Protection Strategy

The FDA Commissioner, Dr. Andrew von Eschenbach, recently appointed Dr. David Acheson to the newly created position of Assistant Commissioner for Food Protection, to provide advice and counsel on strategic and substantive food safety and food defense matters at FDA. He is developing a new strategy to enhance FDA's food safety and food defense systems that will address changes in the global food safety and food defense system, identify our most critical needs, and serve as a framework to help us address the challenges we face. The goal is to ensure a comprehensive and robust food safety and food defense program that is tailored to meet the risks posed by the types of foods FDA regulates and that focuses on prevention, risk-based interventions to ensure preventive controls are effective, and rapid responses when contaminated food or feed is detected, or when there is harm to humans or animals. The strategy will provide a risk-based farm-to-table approach that coordinates food safety and food defense efforts and focuses on prevention, intervention, and response.

Interagency Working Group on Import Safety

As noted earlier, the President has established an Interagency Working Group on Import Safety. The working group, which includes representatives from twelve Federal departments and agencies, including FDA, USDA, and the Department of Commerce, is reviewing the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe. Secretary of Health and Human Services Michael O. Leavitt chairs this working group, and FDA plays a key role in the group's activities.

Secretary Leavitt and Commissioner von Eschenbach have traveled extensively throughout the U.S. to examine our nation's import process. On stops in nearly two dozen cities over the last two months, Secretary Leavitt and Commissioner von Eschenbach visited ports and post offices; railroads and airports; supermarkets and retail stores; seafood warehouses and meat processing facilities. They examined the inspection process of fruits and vegetables, meat, fish, toys, and medicines. Along the way, they were accompanied by the USDA Secretary, the Department of Homeland Security Secretary, and the Environmental Protection Agency Administrator. From border towns like Nogales, Arizona, the gateway for nearly 70 percent of imported fruits and vegetables during the winter months to O'Hare International Airport in Chicago where inspectors handle 100,000 pieces of mail every single day, they have seen first hand the sheer vastness of our import system.

The insights that they gained during their review of field operations helped shape the strategic framework that was released by the Working Group on September 10th. That report, "Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety," outlines an approach that, like the Food Protection Strategy, is based on the organizing principles of prevention (prevent harm in the first place), intervention (intervene when risks are identified), and response (respond rapidly after harm has occurred).

The Strategic Framework recognizes that we must find new ways to protect American consumers and continually improve the safety of imports. It identifies the need to shift from the current model that relies on "snapshots" at the border to interdict unsafe products to a

cost-effective, prevention-focused "video" model that identifies and targets those steps in the import life cycle where the risks of unsafe products are greatest and verifies the safety of products at those important phases. Such a risk-based, prevention-focused model will help ensure that safety is built into products before they reach our borders.

Supporting the Working Group model are six building blocks: 1) advance a common vision, 2) increase accountability and enforcement, 3) focus on risks over the life cycle of an imported product, 4) build interoperable systems, 5) foster a culture of collaboration, and 6) promote technological innovation and new science.

The Working Group has an aggressive schedule for public comment and follow-up. On October 1, the Working Group will conduct a public meeting to identify actions the public and private sectors can take to promote the safety of imported products. By mid-November, the Working Group will present an Action Plan to the President. The plan will reflect the public comments and recommend specific actions that the Federal government and stakeholders can take to enhance import safety at all levels. The Action Plan will be based on the Strategic Framework and will lay out a road map with short- and long-term recommendations.

Although the Action Plan will bring forth more detailed actions, Federal agencies have already begun to implement high-priority Working Group recommendations. The interoperability of import data systems is the fourth of the six building blocks and is an essential component of import safety. By November 12, Federal agencies (including FDA)

that rely on IT systems in their review of imported cargo must develop implementation plans to achieve interoperability with the International Trade Data System managed by CBP. This action is consistent with the Security and Accountability for Every (SAFE) Port Act of 2006. This action will ensure a single-window system for reporting on imports electronically.

H.R. 3610, "THE FOOD AND DRUG IMPORT SAFETY ACT OF 2007"

The bill introduced by Chairman Dingell on September 20 contains a variety of provisions that relate to the safety of imported food and drugs in addition to other matters. The Administration has not yet taken a position on this legislation; however, we would be pleased to provide technical assistance to Committee and Subcommittee staff. We share Chairman Dingell's interest in enhancing the safety of imported products and look forward to continuing to work with him and his staff and others on the Committee and Subcommittee. We also look forward to working with you on the Action Plan discussed above.

CONCLUSION

Ensuring the safety of imported products is a significant task, but I want to assure you that FDA is diligently working to efficiently and effectively use the resources and authorities we have been provided by Congress to help protect American consumers. Thank you for the opportunity to discuss FDA's activities to enhance the safety of imported products. I would be happy to answer any questions.

Mr. GREEN. Thank you, Doctor, and I know you heard in my opening statement about my concerns with the bill's requirement that food imports are only allowed to arrive through ports of entry that have an FDA lab located in the metropolitan areas. Given the list of the current FDA labs it seems fair to say that there is no FDA lab presence in not only the No. 1 port that I represent but also in, in fact, the 10 largest seaports. There is no FDA lab presence in Houston, Charleston, Hampton Roads, Savannah or Miami, and also coming from Texas we have the largest land port in the Port of Laredo. There seems to be a disconnect that suggests that the locations for FDA labs determine the basis for the need for their presence in heavy import areas. Can you explain the decision making for determining the location of the FDA labs? Was there an intent to put them near a port of entry?

Mr. LUTTER. I am unaware of the history of how the labs actually ended up where they are currently. As you may know, we have developed a plan to consolidate labs. That is temporarily suspended, and we will examine that when the time comes in the future. Maybe I can ask Dr. Solomon from the Office of Regulatory Affairs if he knows about the history of how labs got located where they are.

Dr. SOLOMON. I don't think there is any relationship necessary to ports of entry. I think there were locations throughout the United States to make sure that the domestic industry was primarily covered, and that was the genesis of initial thinking on the establishment of labs. Of course, that has been over many years.

Mr. GREEN. Do you think it would be reasonable that in that provision in the bill that if the labs were more geographically available that that requirement that it only be in a port that has an FDA lab, you could have inspectors there without necessarily having the lab. I know you could send samples to anywhere literally very quickly. I assume that is what happens now with FDA even though the lab may not be there.

Dr. SOLOMON. That is correct. With today's ability to ship products, samples are collected at many different ports of entry and they are sent to laboratories. There is a lot of benefit of having large volume laboratories because that creates good throughput and quality assurances in those laboratories. That is currently what we do.

Mr. GREEN. And you could even have mobile laboratories, I assume, if you had a heavy port. For example, if you didn't have a lab in Laredo, TX, and if you stand there and watch those trucks come across from Mexico that are bringing all sorts of food products then you could easily have a mobile lab there.

Dr. SOLOMON. We actually do have two mobile labs. One is a microbiology mobile lab, one is a chemistry lab, and we do take those and rotate those around to different ports of entry.

Mr. GREEN. OK. FDA actually has inspectors at 90 ports of entry and you do inspections there but you really only have the 13 labs, and so it would be almost unworkable to have it only at a location where there is a lab.

Dr. SOLOMON. The numbers you said are correct.

Mr. GREEN. Dr. Lutter, and other FDA panel, the other question I had was the bill allows the Secretary to waive the restriction of

food imports and ports of entry located near an FDA lab. To do so, however, the Secretary must certify that the import would not increase the probability of adverse health effects. I can only imagine there would be an influx of waiver requests to the FDA based on the provision and the fact that the current FDA lab structure does not cover those ports with heavy traffic. From the FDA's perspective, are there any concerns about the workability of the provisions? Does the FDA currently have the resources to meet the potential high demand for these waivers much less the inspections?

Mr. LUTTER. We haven't yet had an opportunity to examine that particular provision so I think at this point what we can say is workability of new requirements and legislation is always a concern to us, and we will have to get back to you on the specifics regarding that one point. I would like to reiterate what Dr. Solomon pointed out a moment ago with respect to labs. What we are really concerned with is the capacity overall of facilities within FDA to do laboratory analysis, and the location is something that is relatively secondary from our perspective. What we would really like is the opportunity to do throughput of laboratory analysis everywhere, and that is the overarching concern that we have rather than the particular location of the facilities.

Mr. GREEN. Well, if we are going to expand your responsibility, we would hope you would both have the staff and the resources to be able to do that.

Mr. LUTTER. Absolutely.

Mr. GREEN. Thank you. Our ranking member, Congressman Deal.

Mr. DEAL. Thank you. Dr. Lutter, your written testimony does not appear to actually cover the legislation which is the subject of this hearing. When will the administration be in a position to send us a written review of the actual legislation?

Mr. LUTTER. We are working on it now. We look forward to offering technical assistance absolutely as soon as possible. It is probably a matter of some weeks. As I mentioned earlier in the oral, we are also developing a food protection strategy, and the President will receive a report in mid November on import safety, and I think all of that will provide information that may be of some value to the committee and to the subcommittee.

Mr. DEAL. Could you tell us what agencies might be involved in legislation such as this, and I understand there is an interagency task force on imports, and would everyone in that interagency work group potentially be involved in this kind of legislation?

Mr. LUTTER. Well, the interagency working group on import safety involves actually a very large number of agencies. Maybe I could speak—I will let David talk to the actual list. It does include USDA and USTR, and also the Department of Commerce and maybe you can add more to that list.

Dr. ACHESON. Yes, there are at least a dozen departments and agencies that are a part of that that cover a whole gamut of imports so it is related to the trade issues, the customs and border protection issues, as well as the product safety issues.

Mr. LUTTER. And so, for example, it also includes a consumer product safety commission which has regulatory authority over toys which have been mentioned earlier in this session.

Mr. DEAL. The bill before us I think has user fees that seem to apply by line item, and can you explain to us what a line item is and how would that impact facilities such as restaurants that import various items of food, maybe an ethnic restaurant, for example?

Dr. SOLOMON. A line item is an entry, a shipment that comes in of one commodity that is all covered under one customs tariff code, so if there are products of different commodities that come in the shipment, they would all come as a different line entry as they are submitted to the FDA.

Mr. DEAL. Would that mean then that an ethnic restaurant who uses a lot of different line item products would be paying fees on each of those line item products?

Dr. SOLOMON. Each different product that would be entered would come under a different line entry.

Mr. DEAL. Does that have the potential of being adversely punitive to small restaurants as opposed to maybe larger restaurants who are buying in greater bulks?

Dr. SOLOMON. Well, certainly as currently structured each line item that has a separate charge would have different fees associated with it.

Mr. DEAL. Dr. Lutter, in your talk, you talk about risk-based prevention focus model that would seem very different from a simple border inspection. Would you describe the model in greater detail for us?

Mr. LUTTER. Yes. Thank you. The vision that many people have about inspections at the border is essentially an FDA inspector who is being asked to physically examine a product to ensure whether or not it meets certain standards for safety; and of course, this is fundamentally an approach that is potentially very inefficient and lacks promise of full safety and effectiveness in ensuring that the products actually meet appropriate standards. Ideally a risk-based model that we had envisioned would take into account a full set of information over the life cycle of the product from when it was first produced overseas including information about its storage, how it was produced, what other regulatory agencies may have thought about that product, including the ones in other countries such as China or ones in third-party countries such as the United Kingdom or Canada; and in that sense, the risk-based approach that we envision would look at a wide variety of physical characteristics of a product, who produced it, whether it is vulnerable to certain types of contamination, what we know about it over the life cycle, and what we know about what other parties may have thought about what risk may have been associated with that in determining how we should view it at the border.

Mr. DEAL. Is there indication that other countries who are trading partners would cooperate in that kind of model?

Mr. LUTTER. I mentioned that we have completed a pilot project with Swissmedic which is a medical products agency in Switzerland where we've done joint inspections with them to develop confidence and trust about the results of their inspections in their facilities and how they might compare with the result of our inspections. Yes, we're making progress in that regard.

Mr. DEAL. Thank you.

Mr. GREEN. Congresswoman Eshoo?

Ms. ESHOO. Thank you, Mr. Chairman, and thank you to each of the witnesses that are here today. I want to address my questions to Dr. Lutter.

In your testimony you note that each imported food and drug shipment is "screened" meaning that importer has provided prior notice of the shipment and the notice has been reviewed to determine the shipment's potential risk. Now, you reported that FDA reviews more than 33,000 of these notices each day, but the estimates are that only about 1 percent of the shipments are physically examined; and I think there's a big gap here between screened and physically examined. It is also estimated that fewer than 500 FDA inspectors are covering 300 to 400 points of entry. So with only 1 percent of food shipment being inspected, how is it that the FDA can demonstrate that the current "screening" and inspection regime is adequate? I mean, do you really believe that this is adequate?

Mr. LUTTER. We think there is a lot of room for improvement. We are working on a food protection strategy that will outline steps for that. With respect to the current process, we acknowledge that the physical inspection is conducted for a very small percent of the food products coming in.

Ms. ESHOO. Has the FDA in the last year or 2 years come to the Congress to say that we see that there are problems and we need resources, a plan, here is the plan and these are the resources that we need to address this? I mean, from a consumer standpoint, it seems to be kind of one scandal after another.

Mr. LUTTER. We are developing very actively and very vigorously a food protection strategy. We expect to be able to issue that before mid-November.

Ms. ESHOO. When was it begun? Before, during, or after these major reportings?

Mr. LUTTER. Dr. Acheson has had the lead developing it, and maybe I should let him answer that question.

Ms. ESHOO. I have more questions. I didn't do my opening statement so that I could ask as many questions as possible. Maybe we can get to Dr. Acheson to finish this.

Do you believe that there should be more physical examinations of imports?

Mr. LUTTER. I think there should be more physical examinations of imports, but more importantly than that, I think that the vision of how to ensure safety of imported products is not simply a question of increasing physical examinations at the border.

Ms. ESHOO. Then what else would you do?

Mr. LUTTER. It is important to build safety in over the lifecycle, it is important to ensure that there are processes and procedures abroad by pushing our borders out to ensure that the production and the processing of foods overseas is conducted in a manner to ensure that the products are safe and comply with FDA standards.

Ms. ESHOO. Do you think that equivalency standards provide a more cost-effective way to accomplish this to increase food safety?

Mr. LUTTER. I am not sure exactly what you mean by equivalent to.

Ms. ESHOO. Well, we have equivalency in the legislation that has been introduced, and it is at the heart I think one of the drivers of today's hearing. Has the FDA reviewed the bill?

Mr. LUTTER. We have looked at the bill. We are not prepared today as I mentioned to offer any specific comments——

Ms. ESHOO. OK. Fair enough. I would like to get to the OASIS database. How old is it?

Mr. LUTTER. Dr. Solomon, do you want to take that?

Dr. SOLOMON. It is a database developed in the 1990s. It has been around for some period of time.

Ms. ESHOO. So maybe about 20 years, do you think? It is the collection point for shipment notices and other related information, and it is the tool that the FDA uses I am told to assess risk, is it not?

Dr. SOLOMON. It is the point for entry and admissibility that the data reviews. It is one of the places where we put risk factors into it. That is correct.

Ms. ESHOO. So it is an important tool for the FDA?

Dr. SOLOMON. Yes, it is.

Ms. ESHOO. Now, one of our other witnesses today, Mr. Hubbard, who is a former FDA Associate Commissioner notes in his testimony that the FDA's information systems are "old and out of date." In a July 2007 report on food imports from China, CRS that we pay a lot of attention to, we rely on CRS for very clear information and facts, they reported and found it difficult to get certain information from FDA in part because of technical problems with OASIS. CRS could actually not even determine the total number of food shipments, nor could it find a volume of products that were rejected at the border.

So these are my questions. Do you think today that the OASIS database is really a robust tool for examining the risk?

Dr. SOLOMON. We have been looking in replacing that system with a new system called MARKS. This system integrates various different databases as you are aware of.

Ms. ESHOO. When is that scheduled to be accomplished and how much of your budget has been allocated to this change?

Dr. SOLOMON. We can get back to you with that information. I don't have that.

Ms. ESHOO. All right. Now, it is because it has technical problems that you just described what you did?

Dr. SOLOMON. As we described, it is a system developed many years ago that has exceeded the capacity of entries, has exceeded——

Ms. ESHOO. When do you expect the system to be brought up to date?

Dr. SOLOMON. I don't have a date for that.

Ms. ESHOO. I think that the committee needs to know that because you are reliant on this system, and as you have said, the system is about 20 years old.

Dr. SOLOMON. We will be sure to supply those answers to you.

Ms. ESHOO. Good. Thank you very much. Either now or later in writing, can you tell the subcommittee the volume of shipments that have been refused entry into our country in the last 12 months?

Mr. LUTTER. We will have to provide that later to you.

Ms. ESHOO. And can you tell the subcommittee the overall number of food shipments that are coming into the country?

Dr. ACHESON. That is on the order of, for 2007, around about 9 million lines.

Ms. ESHOO. I think we need really accurate numbers on this, and I am asking the last set of questions because they are questions that CRS reported that were difficult to find. So I think it is important for the subcommittee to get it and information——

Mr. LUTTER. We would be happy to provide and answer that. Just one word of caution about this. Historically, these numbers have been growing very, very rapidly, more than 10 percent per annum. So one question is simply what period, so we will give you an estimate of that for the most recent period.

Ms. ESHOO. Well, let me just ask the chairman, the subcommittee chairman. What time frame? We want to be specific with the FDA so that we get information that is going to really help us fill out our case.

Mr. GREEN. Well, again, The chairman of the full committee and the sponsor of the bill is here, and I would hope we would have it as quickly as possible. I would hope we would have it as quickly as possible because this bill——

Ms. ESHOO. He is saying the period of time, though.

Mr. LUTTER. The last 12 months.

Ms. ESHOO. Well, we will let you know.

Mr. GREEN. Whatever is reasonable, 30, 60 days at the maximum, probably.

Mr. LUTTER. Thank you.

Ms. ESHOO. No, not the period of time in which they have to respond but the period of time relative to the shipments. How broad of a lens do we want, a snapshot do we want of this, an accurate accounting for shipments? The committee staff will get back to you on that, but we don't want to spend 6 months trying to get the right numbers. CRS doesn't have it. We need it.

Mr. GREEN. Yes.

Ms. ESHOO. Thank you very much.

Mr. GREEN. Thank you. Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman. I just want to ask a couple questions. In my opening statement I raised a number of issues about the medications, the drugs that come in from other countries such as China, and I wanted to see what things we can expect from the FDA on this with regard to medications and dealing with counterfeit drugs. I know there was some reference to that. For example, do we see any hope in stemming the tide for this, are there any increase, decreases, do you see that some of the other inspections will work on this, do we need to take other steps? Any of you.

Mr. LUTTER. The problem of unapproved foreign drugs coming into the United States and being available to U.S. consumers concerns us deeply. These products include not only counterfeits which are made by people who have concern for profit but not the health of the people who are consuming the drugs but also substandard products which contain active ingredient in levels that are too low or too high or occasionally not at all, as well as contaminants and

bad labeling. Currently we face a very large volume, even a flood of such unapproved products at international mail facilities and courier facilities. This is a problem that we have wrestled with. Currently our strategy and overall stance has been one of public communications. We communicate to the public the risks associated with these products and to dissuade them from using them by being sure that they understand the risks.

Mr. MURPHY. Are you saying here that in this there are some who are unscrupulous, involved with criminal activity; but are other ones a matter of companies that do not properly inspect the materials that are being manufactured over there when it comes to dealing with medications or are these counterfeits coming from them?

Mr. LUTTER. I think the products come from all different types of sources as we have reported in the past. We noted, for example, in intercepts of products coming in from four foreign countries, India, Costa Rica, Israel, and Vanuatu in the Pacific. Nearly half of the products coming in from those countries had documentation indicating that they were in response to orders placed by Americans on Web sites that purported to be Canadian in some form. And this is an inherently misleading practice. Who knows where the products actually originated from? Almost half, again, of those products had some documentation indicating that they came from a set of countries all over the world. I think that set listed 26 countries including Eastern Europe. This is an international market filled by people who are looking for a quick buck in trading finished pharmaceutical products that have unknown origins, unknown handling, and they are intrinsically unsafe—and consumers shouldn't be buying them. It is somewhat akin to an unregulated market that in many other respects Americans and the U.S. Government have rejected as unsafe at least a century ago.

Mr. MURPHY. What do you see is the main way that consumers are getting these drugs? Are they trying to order them from what they consider legitimate sources?

Mr. LUTTER. They sit at their home computers I believe and log onto the Web site that might be selling these and then place orders over the web, and in that sense this is relatively easy for consumers; and because of that, it is one that we lack the resources at the borders to stop, so our effort over all has been to try and persuade people through public health announcements and advisories that this is an unsafe practice that they should be very wary of.

Mr. MURPHY. All right. I just want to shift gears here and ask one quick question on food issues about some of the risks you see for food and what are our greatest concerns for health and how do you overall see that some of the issues that have come by lately with regard to food and manufacturing and contamination, et cetera, that you would be able to deal with those?

Mr. LUTTER. If I may, I would like to ask our food expert, Dr. Acheson, to answer that.

Dr. ACHESON. I would be happy to. I think the risks associated with food are going to be dependent whether we are talking about domestic food supply or imported food supply. Essentially what we consider to be high risk are those foods where we see repeated problems, where we have seen repeated outbreaks leading to seri-

ous adverse health consequences, hospitalizations. So obviously a recent example would be leafy greens where we have seen repeated problems over the last decade with leafy greens becoming contaminated. When you get to imported products, similar fresh produce from various parts of the world as we have seen recently with imports from China or there can be other foods, too.

Mr. MURPHY. Well, I know I am out of time here, but I just think it is so important for American consumers, who I think over the last year have developed grave concerns about the safety of imported foods and even some domestic ones, too. It is so essential that we take an aggressive role in trying to address this because it is one that we cannot afford basically what is more death, more sicknesses, and more problems with our healthcare system. I know that one of the greatest things that has contributed to life expectancy in people in this country has been such things as clean water and clean sewer systems, better sewer systems. Now, we are dealing with some other levels here that have to do with the medicines and food that we have taken for granted for so long that were healthy we recognize are tainted too; and we cannot take that for granted, so we look towards all of you being extremely aggressive in helping hunt down anybody who is bypassing any laws, domestic or international. Thank you.

Mr. GREEN. Thank you, Mr. Murphy. The committee will stand in recess. We have another series of votes, and it will be hopefully about 20 minutes and we will be back.

[Recess.]

Mr. PALLONE [presiding].We will reconvene, and I believe the last person who asked a question was Mr. Murphy; so I will move to the chairman, Mr. Dingell.

Mr. DINGELL. I again commend you for this excellent hearing. It is very important to the business of this committee and, I think, the business of the country.

First I ask unanimous consent that I be permitted to include a letter or other letters which we are going to be sending to the Food and Drug Administration with regard to the subject matter of this hearing today .

Mr. PALLONE. So ordered.

Mr. DINGELL. And I ask that the record be kept open for that purpose.

Mr. PALLONE. So ordered.

Mr. DINGELL. To Mr. Lutter, staff from FDA has informed our staff that between 2,000 and 3,000 pharmaceutical companies in foreign countries are registered with the U.S. and are likely to ship drug products to the United States that should be subject to surveillance inspections. Is that correct?

Mr. LUTTER. It is our understanding that is right, sir.

Mr. DINGELL. All right. Now, the next question is, I understand that FDA has personnel and funds to undertake only 25 inspections due to resource restraints. Is that true?

Mr. LUTTER. I would like to refer that to my colleague, Dr. Solomon.

Mr. DINGELL. We were informed by your staff. Is that correct or not?

Dr. SOLOMON. FDA conducts several hundred foreign inspections of drug manufacturers.

Mr. DINGELL. We will give you a specific question on this, but I want to know how many foreign inspections you make a year. We were told that the number is 25. Please submit that for the record, and I would like to have it for the last 10 years.

Now, the committee staff has accompanied inspectors to India. The investigators have come back and told us that durations of greater than 2 or 3 years make it difficult for there to be an accurate picture of what is taking place inside a typical overseas firm. Isn't 3 years a difficult situation to enable you to know what is taking place in a foreign firm? Yes or no. My time is limited. Please respond.

Mr. LUTTER. It is very difficult to answer yes or no, sir. I think longer periods are more problematic than shorter periods, yes.

Mr. DINGELL. Under the law you are supposed to investigate American firms every 2 years, isn't that correct?

Mr. LUTTER. Yes.

Mr. DINGELL. All right. But can you investigate these foreign firms every 2 years?

Mr. LUTTER. We are not able to do so now, sir.

Mr. DINGELL. Now, I come down that 2,000 or 3,000 firms being able to investigate 20 a year gives you 100 years to get the firms all investigated, is that correct, just using the arithmetic?

Mr. LUTTER. The arithmetic is correct, sir.

Mr. DINGELL. The arithmetic is correct? I would like to know how often you can get around to investigate these foreign firms which are exporting drug products into the United States. Now, isn't it true that we have firms importing drug products to the United States that have not been investigated in 8, 10, or more years or never? Is that true?

Mr. LUTTER. That is correct.

Mr. DINGELL. So we are attempting to investigate and inspect domestic firms every 2 years in a well-regulated environment but we are having terrible times providing the necessary investigation and inspections of firms which do not have either a good regulatory law or which do not have proper investigation of their products as they are entering into the United States, is that a true statement?

Mr. LUTTER. That is correct, sir.

Mr. DINGELL. All right. You have mentioned in your testimony that FDA currently reviews approximately 33,400 prior notice submissions per business date. How many FDA staff review these prior notice submissions? Can you tell us now or do you wish to submit that for the record?

Mr. LUTTER. Put it in the record, please.

Mr. DINGELL. All right. How many prior notice submissions are received on weekends? Would you submit that for the record? How many staff would review these submissions? You say that FDA performs routine surveillance inspections. Can you tell us the frequency of these routine surveillance inspections?

Mr. LUTTER. We will have to put that in the record, sir.

Mr. DINGELL. All right, if you please. Now, you stated in your testimony that the FDA has the authority to commission other Federal officers and employees to conduct examinations and investiga-

tions. You note that FDA has commissioned over 9,900 customs and border patrol officers. When CBP officers are commissioned, do they work solely on FDA examinations and investigations or do they work on other matters?

Mr. LUTTER. It is our understanding they work on other matters as well.

Mr. DINGELL. All right. How easy is it for CBP officers to be pulled off their FDA duties?

Mr. LUTTER. We would have to get back to you on that, sir.

Mr. DINGELL. All right. Now, I am interested, how many ports are approved for admission of foreign manufactured pharmaceuticals? Please submit that for the record.

Mr. LUTTER. We do not approve ports, sir, so any port of entry would be permissible.

Mr. DINGELL. What percentages of your imports of pharmaceuticals are examined by FDA inspectors? Do you have any idea?

Mr. LUTTER. We would have to get back to you on that, sir.

Mr. DINGELL. All right, if you will submit that for the record. How many food shipments or what percentage of your food shipments are investigated by FDA investigators?

Mr. LUTTER. Physically inspected?

Mr. DINGELL. Physically inspected, yes. Please submit that for the record. We will have a letter on this particular point. Now, inform me how many inspections you make of devices and appliances that are regulated under your jurisdiction, that are imported from abroad?

Mr. LUTTER. Inspections of the shipments coming in or of the——

Mr. DINGELL. Yes, coming in.

Mr. LUTTER. We will get that to you on the record.

Mr. DINGELL. All right. First of all, American manufacturers are required to comply with the law by observing best manufacturing practices. Do you apply the requirements for best manufacturing practices to be performed by foreign companies which export pharmaceuticals to the United States?

Mr. LUTTER. The requirements——

Mr. DINGELL. Yes or no.

Mr. LUTTER. The requirements for good manufacturing practices apply independent of location, so yes, facilities abroad that we inspect and that are approved for the——

Mr. DINGELL. So the answer is you really don't do that, is it? And you really don't have any inspectors to do that, do you?

Mr. LUTTER. That is correct.

Mr. DINGELL. For example, how many inspections have you done in China to make sure that good manufacturing practices are carried forward by Chinese manufacturers that export to the United States?

Mr. LUTTER. We do not now have inspectors permanently located in China.

Mr. DINGELL. How many inspectors do you have over there looking at this question?

Mr. LUTTER. We don't have any right now that are permanently located in China, sir.

Mr. DINGELL. Now, please inform me, how many will you have under your next budgetary request?

Mr. LUTTER. We will have to get back to you on that, sir.

Mr. DINGELL. You will submit that for the record?

Mr. LUTTER. Yes, sir.

Mr. DINGELL. Now, please inform me, what happens to prescription pharmaceuticals that you find that are unsafe at the point of entry and what happens to foods that you find to be unsafe at the point of entry? What happens to them? They are rejected, they go back out of the country, is that right? Yes or no.

Mr. LUTTER. Foods are refused, yes, sir, and the drugs are also refused.

Mr. DINGELL. They go back out of the country?

Mr. LUTTER. Yes.

Mr. DINGELL. Is that true in all cases or sometimes you let them go through?

Dr. SOLOMON. If the product can be made in compliance, then that can be considered.

Mr. DINGELL. If it can be made in compliance? I wanted to ask you some questions on it because my time is expiring. Now, I want you to please tell me what percentages of those commodities that are rejected at the point of entry can you assure us are not coming in at another point of entry?

Mr. LUTTER. we will have to submit that to the record, sir.

Mr. DINGELL. All right. I want you to give me that. Now, I want you to tell me, and I will ask you to submit this to the record, how you are going to substitute for the laboratories which you had proposed to close under the earlier rulings and orders of your agency and the Office of Management and Budget? I want you to submit that for the record if you would please. We will have you a letter on this.

Mr. Chairman, I ask unanimous consent that the record remain open so that we can get this because this will tend to show us that the Food and Drug which says it is being leaner and meaner is just being leaner and weaker and is not capable of carrying out its important duty of protecting the American public, and I intend to try and get you folks, whether you like it or not, the resources and the authorities to do the things that you have to do to protect the American people.

Mr. Chairman, I thank you for your courtesy.

Mr. PALLONE. Thank you, Mr. Chairman. Mrs. Wilson.

Mrs. WILSON. Thank you, Mr. Chairman. The chairman of the full committee asked a number of questions that were very interesting and some of the answers I know you will have to get for the record, but did you want to elaborate on any response that you were not allowed or not able to make in the last round of questions?

Mr. LUTTER. No, thank you.

Mrs. WILSON. Fair enough. I just wanted to give you that opportunity. You mentioned in your testimony risk-based methods, and particularly the Bioterrorism Act that includes provisions that push the FDA in this direction. Could you talk a little bit more about risk-based methods for ensuring security, how that works and how it is working, how this is being implemented?

Mr. LUTTER. Let me turn to my colleague, Dr. Acheson, to address that.

Dr. ACHESON. Sure, would be happy to. In relation to imports, is that what you are asking about?

Mrs. WILSON. Yes.

Dr. ACHESON. OK. Essentially that has got multiple components. The machinery that makes it work is the prior notice center, but the prior notice center is primed with information derived from vulnerability assessments that have been done internally within FDA, and essentially what those vulnerability assessments are doing is asking the question, which foods are most likely to be contaminated with an agent that could cause maximum harm. So it has essentially been ranked based on the type of food and the type of agent that you might have concern. That information is fed into the prior notice center, and it is then combined with other intelligence information and law enforcement information and customs and border protection information to screen entries. So every time a line of food arrives in the United States, prior notice has to be submitted. The time up front varies with whether it is an air or truck or ship. That is reviewed electronically, and if it is a food that is of higher concern or origin is of higher concern or something to do with the importer or the person receiving the goods kicks a message out through studying the classified law enforcement systems, that will flag that product for specific action which is usually in the form of an inspection and/or sampling.

Mrs. WILSON. Are you developing new tools in this prior notice center or new things to enhance the ability to screen based on risk?

Dr. ACHESON. Prior notice center as I have described is entirely focused on deliberate attacks on the food supply. It is a food defense, bioterrorism tool. We work internally within the agency to change those parameters as necessary based on identification of new risks. As we move toward integrating food safety and food defense into an overall food protection strategy, those concepts of how do you define risk based on a variety of parameters need to be built into that. We are not completely there yet, but the food protection strategy that we are developing currently will address those broader issues.

Mrs. WILSON. Let me ask if you would elaborate a little bit about the food safety strategy you have under development, both the timing of it and who is involved, what are the issues you are addressing, what are the major thrusts of this new strategy?

Dr. ACHESON. The strategy was started in the beginning of May when the Commissioner created the position that I fill. It is a strategy that is focused on food and feed, domestic and imported products, and it is focusing on the full product life cycle. In the context of domestic, that takes you right back to the process of where the food is coming from and likewise for imports. It will be a risk-focused, a risk-based strategy because what we need to do is to look at those risks to find where the resources need to go. The other very important part of this is a major shift toward prevention. The agency has heavily focused on interventions through inspections and reacting to situations. What we need to do is get ahead of that curve and focus on preventative strategies, and that is a huge part of what the plan is going to look like.

Mrs. WILSON. In this effort to develop a food safety strategy to shift toward prevention and look systemically at this whole prob-

lem, have you involved private industry in these efforts, particularly for their input whether it be grocers or restaurants or food processors in thinking about these strategies and what they bring to the table?

Dr. ACHESON. That is part of the strategy, to involve them. What we want to do is to basically—

Mrs. WILSON. But are they being involved in the development of the strategy or just in its implementation?

Dr. ACHESON. They will be involved in implementing it and helping us figure out how to implement it. The strategy essentially is laying out the broad directions of prevention, intervention, and response. One of the very first deliverables in the strategy is going to be to have dialogs with various stakeholders, consumers, industry, State partners, on how to implement it and how to adjust it so that it is going to fit. But we want to roll out with something for people to respond to.

Mrs. WILSON. In your working group, and this is my final question, Mr. Chairman, and I appreciate the latitude, to develop this food safety strategy, are you involving experts in other elements of government who have worked on other safety and security kinds of strategies or is this mostly FDA?

Dr. ACHESON. At this stage it is an internal FDA strategy, and it is more than food safety. It is food safety and defense, so it is a food protection strategy that integrates, too. We are starting internally, but we anticipate that we are going to work with other stakeholders as it rolls out.

Mrs. WILSON. I would encourage you to do so, particularly we have National Laboratories whose expertise is systemic approach is to security and defense whose experience in other realms may be helpful to you.

Dr. ACHESON. I appreciate that. There is no question, we will.

Mrs. WILSON. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. I am going to recognize myself for questions. I wanted to ask Dr. Acheson if I could. I am just reading from a publication that said that you testified yesterday I guess before the House Agriculture Appropriations Subcommittee that the agency needs more powers to police the Nation's food supply, and I guess there wasn't a time for the chairman of the subcommittee to ask what new authorities the agency might seek. So I would simply ask that. What kind of authorities, Mr. Acheson, would you seek? Are these in the Dingell bill by reference or would they be something beyond the Dingell bill, if you would?

Dr. ACHESON. There is currently a very active dialog going on within FDA and HHS to address exactly what new authorities we would seek as part of this plan. So at this point, it is not fully defined, but there are a number of areas that are under consideration.

Mr. PALLONE. You want to comment on some of them at all or just give us some idea?

Dr. ACHESON. At this stage, I am not able to really say much beyond what I just articulated.

Mr. PALLONE. All right. Well, I would ask you if you could get back to us in writing and give us some indication.

Dr. ACHESON. Absolutely, and I would hope in the future as the plan starts to take shape, that we could work jointly between what we are developing and what the subcommittee is developing so that we have a holistic view of this that is fully integrated, building the best of all these ideas.

Mr. PALLONE. Absolutely. Then I want to go back to Dr. Lutter. Everyone knows that part of the problem with the food safety system is the lack of resource that the FDA has available to perform its responsibility. It is a recurring theme. I have heard it for years. Can you talk about the financial resources that the FDA has to perform its safety responsibility and has that budget increased or how has that budget increased if any? I will ask you some more specific things, but just in general?

Mr. LUTTER. I would prefer to pass that question onto my colleague.

Mr. PALLONE. Sure.

Dr. ACHESON. Yes, in recent history while there have been increases in the budget on the food side, they have largely been used to keep pace with inflation and pay increases, and there have not been substantive increases in programmatic support.

Mr. PALLONE. And do you have a specific percentage each year over the past 5 years, or you just say just to keep up with inflation essentially?

Dr. ACHESON. I would have to get back to you with specific numbers. I don't have it with me.

Mr. PALLONE. All right. I would appreciate it if you would, but basically you said what keeps up with inflation and that is it. Well, do you think that an importation fee like what Mr. Dingell was proposing is a good way to fill in the gaps and the lack of resources?

Dr. ACHESON. User fees are a double-edged sword. I think that there can be potential advantages to them. Clearly as you have articulated as have many of your colleagues in order to make a new system work that is going to be radically different, you have go to adequately resource it. So those resources have to come from somewhere. User fees are a potential source of revenue to do that, but one has to be very circumspect about whether you can implement them in a meaningful way that is fair that is actually going to get you where you want to go. It is an option.

Mr. PALLONE. But clearly you do think that your resources are inadequate? You agree, we need more resources, right? I didn't ask that question because I thought it was obvious.

Dr. ACHESON. It is obvious.

Mr. PALLONE. OK. Then I wanted to go back to Dr. Lutter unless you want to pass it over to him again. Let me say this. Mr. Dingell's bill directs funds specifically to strengthen imports, the system to regulate and inspect imports. But some of the recent contaminations, and I mentioned in my opening statement, have involved domestic products, not imports. Considering the current funding levels and the fact that very little money is targeted for imports regulation, how do you perceive strengthening inspection of national products while simultaneously managing the new import regulations? In other words, if we were to spend more money on imports, how are we going to strengthen inspection of domestic

products given the fact that we don't have a lot more money available so far?

Mr. LUTTER. The food protection strategy that we are developing would be holistic and integrated in the sense it addresses both imported foods and domestic foods, as well as risk from deliberate contamination and accidental contamination and over the life cycle. So in that sense the approach would be intended to encompass both domestic foods, and we have acknowledged that there are risks that are worthy of concern and additional action particularly with respect to leafy greens which the recent outbreaks have been domestic. So yes, we share concerns about that.

Mr. PALLONE. OK. All right. Thank you. I recognize Mr. Buyer from Indiana.

Mr. BUYER. Sure. I have no problem if you have further questions. You are on a roll. OK. Dr. Solomon, as Deputy Director for the Office of Regulatory Affairs, is it fair to say that you would have a good understanding of FDA's work at the international mail facilities?

Dr. SOLOMON. It is not my area of expertise, but I am heavily involved in import operations and familiar with processes and procedures at many of our import facilities.

Mr. BUYER. At these mail facilities and the private ports of entry, Customs will identify a particular package. Both of you, as I understand, have target search systems, am I correct?

Dr. SOLOMON. That is correct.

Mr. BUYER. So it is easier when you have a manifest as it is going through the private systems, FedEx, UPS, et cetera. When they have a manifest, you can examine it by your target systems, and so you kind of know what you are looking for, right?

Dr. SOLOMON. We have more information going through those systems, correct.

Mr. BUYER. Right. So as the packages are coming down the conveyor belt, it has been identified. So now you have a targeting system, there is an overlap, Customs has a targeting system, and the handler also has their own targeting system. So into the FDA bin get kicked a lot of packages, isn't that correct?

Dr. SOLOMON. That is correct.

Mr. BUYER. Is it fair to say that around 5 percent of those packages are inspected?

Dr. SOLOMON. Yes, sir.

Mr. BUYER. And these packages that go into the FDA bin at FedEx and UPS, the FDA, you don't work at night while others work, i.e. other Federal agencies and obviously the shippers. You work during the day to put the input with the data to identify from the manifest what packages you want sent to your bin, is that correct?

Dr. SOLOMON. Yes, products can be placed on hold and then examined the next day.

Mr. BUYER. Right. So then you come in the next day to examine. So 95 percent of these shipments, though, just gets kicked right back into the system?

Dr. SOLOMON. A large percentage of the products are not examined.

Mr. BUYER. OK. Now, of the packages that the FDA examines so a pharmacist can actually look at them, not all of these packages are forwarded to a laboratory, is that correct?

Dr. SOLOMON. That is correct. Only a percentage of them need further laboratory exam.

Mr. BUYER. OK. So when Customs will look at a package and prima facie, on its face, they can identify this is counterfeit, I know it is counterfeit, they destroy it. If they are not particularly sure, they also kick it over to the FDA. So now FDA, your investigators or inspectors look at this and you have got the pharmacist on site; and he looks at this and goes, no, we are not going to let this come into the country. Do you put some type of a sticker on it, don't you?

Dr. SOLOMON. The product is marked and set aside and then it is going to be detained.

Mr. BUYER. How is the product marked?

Dr. SOLOMON. I am not familiar with the exact mark on that.

Mr. BUYER. At two of the ports of entry that I went to in Chicago and at JFK, the pharmacist on site said that they keep seeing their own marks on counterfeits coming back to the system. Would that be accurate?

Dr. SOLOMON. That is possible.

Mr. BUYER. So earlier from my statement that the Federal Government, we are becoming an enabler to a criminal enterprise because people get the Internet, they think that, from that Canadian Web site, that it is OK because it says it is OK. These are legal, lawful drugs. It is OK. And when the criminal enterprise, the counterfeiters then send that product into the United States, they take the person's money from the credit card, then we, the Federal Government, by virtue of your policy or an interpretation of the law then, return to sender. That is what we do, is that correct? We take that product and return it to sender?

Dr. SOLOMON. That is for the most common products. Some products that are clearly of concern are not sent back to the sender.

Mr. BUYER. Excluding your schedules 1 and 2, right? Those would be destroyed. If in fact the package does not have a formal entry, a commercial formal entry in the amount of 2,500 or more, you can give your notice, and if they don't, within 30 days, respond it can be destroyed?

Dr. SOLOMON. That is correct.

Mr. BUYER. So I understand there are exceptions to that, but in general, most of these small packages either get through the system or if your inspectors are able to identify them, then they are returned to sender, correct?

Dr. SOLOMON. That is the most common procedure.

Mr. BUYER. Most common procedure? Now, as a policy standpoint from the FDA, do you think that is good policy to give back to the criminal enterprises their products so they can continue to send them back and prey upon people, whether it is our own country, hemisphere, or other countries and hemispheres around the world?

Dr. SOLOMON. I will let Dr. Lutter from the policy perspective——

Mr. LUTTER. We are concerned about the continued circulation of counterfeit and substandard products that might be sent overseas to the sender and then might be reintroduced again into the United

States. These products, if they were unsafe the first time, they are surely unsafe the second time.

Mr. BUYER. So if this committee puts into the law giving the authority to the FDA to destroy, stop this return-to-sender-policy, you would support that?

Mr. LUTTER. It is something we would look at very seriously to the extent that it mitigates this public health concern of ours. I think there are a couple of questions pertaining to destruction methods and the destruction costs and also whether or not the adequacy of due process before destroying goods. To the extent that it protects public health, we would look at it very seriously.

Mr. BUYER. Well, with regard to costs on destruction, Mr. Chairman, I think the FDA should be able to tell us, if we are going to protect the American system and America's health and ensure high standards, cost shouldn't be the problem here; and if in fact, you think that is a barrier to this, please let us know what you estimate the cost to be able to destroy is and how to handle that because Customs is doing that right now. And in your testimony, Mr. Chairman, they say that they anticipate these imports to triple by 2015. If in fact that is true, we have got to get off our heels and on our toes. So I want to work with you. When I mentioned in the opening that as soon as this gets from Legislative Counsel, we will get it to the chairman and Chairman Dingell and to the ranking members. I will also ship this down to you, and we want your comment. I know you agree with some of these areas, whether it is serialization or the pedigree issues, let us work through these. As I said earlier, this is an issue that Congress doesn't touch very often. 1938, 1988, and now. So I appreciate the chairman's indulgence, and I look forward to working with everyone.

Mr. LUTTER. Thank you. Likewise.

Mr. PALLONE. Thank you. Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman. Dr. Solomon, I was curious to hear your answer in response to Mr. Green's concerns about FDA lapses at ports. We don't have very many ports in my district, but what we do have is an FDA lab; and I thought I heard you say that there is a great benefit in having many labs. Is that correct?

Dr. SOLOMON. No, I think what I was alluding to is the benefit of laboratories, as Dr. Lutter explained before is the lab capacity to get a lot of throughput through those labs to ensure the quality of those products and labs. Lab capacity is the most critical issue versus the——

Ms. DEGETTE. OK. So you didn't intend, if you did say there is a great benefit in having many labs, because you are aware, aren't you, that the FDA has a proposal out to reduce the number of labs from 13 to seven.

Dr. SOLOMON. We are aware of that and as discussed earlier, that is in abeyance.

Ms. DEGETTE. Dr. Lutter, I also heard you say that, and I know it is in abeyance, that what you are really looking at with these labs is the ability to do analysis and the location is really secondary, correct?

Mr. LUTTER. One of our concerns is to be able to do the most possible analysis of suspect products given the resources we have.

Ms. DEGETTE. And for example, in the Denver lab, you have people who have been doing some of these very specialized food analyses for 23, 25 years, is that correct?

Mr. LUTTER. I am told that is the case.

Ms. DEGETTE. And these are also people, and I will just tell you in case no one has, I have talked to them personally and I don't blame them. Anybody who lives in Denver, CO, and has for 25 or 30 years doesn't want to move to a centralized lab. So those people will all quit. So my question is I know that you have temporarily suspended the reorganization. Mr. Dingell's bill would do it permanently, and I am wondering if the administration would be ready to drop the plans to close these laboratories and just go along with our committee proposal at this time?

Mr. LUTTER. We are committed to ensuring that the products that we have——

Ms. DEGETTE. OK. I don't need that kind of answer because I have only got 5 minutes. Yes or no, are you willing to drop this proposal at this time?

Mr. LUTTER. No.

Ms. DEGETTE. You are not? OK. In that case, previously I asked the FDA witness at other hearings to provide with an analysis justifying the closure of the food safety labs. Is the FDA prepared to do that, either a cost benefit analysis or a quality control analysis or any other kind of analysis? Can we get that from you?

Mr. LUTTER. I think we are working on one and will have to get back to you on——

Ms. DEGETTE. When will I be able to receive that analysis?

Mr. LUTTER. I will have to look into it and get back to you.

Ms. DEGETTE. OK. When will you get back to me about when you can get back to me about the analysis?

Mr. LUTTER. Later this week.

Ms. DEGETTE. Thank you. I will look forward by October 1 to having that timeline from you. The reason I am a little frustrated, I have been having difficulty getting requests from the FDA and other agencies, so I appreciate your comity in this area. One of our witnesses today is going to testify that the FDA only inspects 1 percent of imported food. Is this accurate?

Mr. LUTTER. With respect to physical inspections, yes.

Ms. DEGETTE. OK. Do you think that is adequate?

Mr. LUTTER. I think the key message is not the physical inspections but the information available to us to identify which products are really risky.

Ms. DEGETTE. OK. So given the available information to you, do you think that 1 percent of actual, physical inspection is sufficient——

Mr. LUTTER. No.

Ms. DEGETTE. OK. So if we gave you more resources you would like to be able to actually, physically inspect more food?

Mr. LUTTER. We would endeavor to inspect more food, but that is only part of the solution.

Ms. DEGETTE. Absolutely.

Mr. LUTTER. The real part is to put together a system that ensures the products are safe when they arrive at our borders.

Ms. DEGETTE. I agree that physical inspection can't be the only thing, and I think that is right. Does the administration have any idea what percentage of actual, physical inspection would be beneficial or is that part of the whole plan that Dr. Acheson and others were talking about the quality control?

Mr. LUTTER. It is really the latter. What we are really looking at is a transformational strategy that will use much more information to ensure that the inspections at the border are well-targeted, are efficient in figuring out which products are safe, but also to ensure that the products themselves are safe when they arrive at the border.

Ms. DEGETTE. Absolutely.

Mr. LUTTER. And so it is not only the physical inspections that we should be focusing on.

Ms. DEGETTE. Right. I agree with that. And so my question, I was very pleased to hear your response to one of the other members when they said would it be fair to say you don't have adequate resources and you said yes. Does the administration have any idea how many additional resources it would take so that you could adequately perform these duties, and does the FDA support the user fees that are included in the bill?

Mr. LUTTER. With respect to the user fees in particular, the question that we would have in examining the proposal more closely is the extent to which they are adequate to perform the services they were expected to do as part of the bill, and we will have to get back to you on that. We look forward to offering technical assistance to the committee on that key question.

Ms. DEGETTE. And do you have any idea how many additional resources you are going to need to perform your job in the way you would like to?

Mr. LUTTER. I think that information also will have to come later as part of the food protection——

Ms. DEGETTE. OK. So for those two things, does the FDA have some idea when it will have the answers to those questions?

Mr. LUTTER. We expect to go public with this by mid-November.

Ms. DEGETTE. Mid-November? OK. Thank you very much, Dr. Lutter.

Mr. PALLONE. Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I know that Secretary Leavitt is working on a proposal, and I am pleased that he is because I understand he is taking personal charge of the matter; and we should be working closely with the administration because we all want the same goals. I think we can all agree that the concept behind the provisions of this bill make good sense. We want to have every confidence that the foods we import are from countries and from facilities that have systems in place to ensure those foods are safe, and who better to give us that confidence than FDA. So before imported foods would be permitted to enter the U.S., the bill would require FDA to certify that those foods come from a country that has in effect food safety standards at least as protective as ours. FDA would have also to certify that the country is monitoring for compliance with those standards in taking appropriate enforcement actions when that compliance is lacking. If FDA is unable to make that certification as to the entire country, the bill

would give FDA the option to certify each company on a facility-by-facility basis and I agree with this concept. But I want to be sure we are giving the FDA the appropriate authorities and resources so that this is a job they can handle. If you don't think the agency will be able to do this job, I would hope you would give us specific suggestions about how to make it work. That responsibility lies with the agency. So I think we need to get an understanding here on the size and scope of the job we're asking the agency to do.

Let us just look at China for an example. Obviously given the many recent incidents of unsafe imported Chinese foods, it seems unlikely that FDA would be prepared to certify the country as a whole anytime soon. Would you agree with that, Dr. Lutter?

Mr. LUTTER. Dr. Acheson recently returned from China, and I would like to have him——

Mr. WAXMAN. Are we ready to certify that China has in place a system as reliable as the one we have here in the United States?

Dr. ACHESON. Not yet.

Mr. WAXMAN. If FDA could not certify the country as a whole, FDA would be faced with the prospect of certifying each of the Chinese facilities seeking to export their foods to the U.S. before those foods would be permitted to enter the country. Could you give us the sense of the scope of accomplishing that task. For example, can you give me any estimate of how many Chinese facilities there are currently exporting foods or food ingredients to the United States, and what kind of resources would FDA need to be able to inspect each and every one of these firms? Dr. Acheson, do you have an idea of that?

Dr. ACHESON. Yes, based on the information provided on recent visits to China, there are about 400,000 food or feed manufacturers in China of various sizes. Currently about 12,000 to 15,000 of those are registered with AQSIQ who is the import/export authority in China. According to their law, they have to be registered in order to be a certified export. One of the problems is that foods are being exported from China that are not certified, and according to Chinese law they are essentially illegal exports. And at least a third of the exported food apparently is falling into that category.

Mr. WAXMAN. One would think if foods are being exported inconsistently with the law of China that even if we look to China to have in place a system like an FDA to inspect and review all the safety issues, there would probably be a lot of products that would go under that law, too, wouldn't it?

Dr. ACHESON. Well, to get to your point, if this is going to work, we have to ensure that it is meeting our standards. And you asked about resources. I think we would have to examine that, how many firms we are talking about, but it would be significant to ensure that number of firms were in compliance.

Mr. WAXMAN. Well, we are going to look forward to your recommendations, and I assume this is going to be part of the administration proposal because this is a huge undertaking if we work along this theory of making sure the country has in place a system, that they are enforcing it, and if they don't, we go facility by facility. Of course, China is only one of the countries that we are dealing with.

Dr. ACHESON. Right.

Mr. WAXMAN. FDA currently inspects only 1 percent of all imported food. This is quite a grim figure, but it is also true of the domestic food supply. Dr. Acheson, there has been a serious problem with leafy greens in the United States. There have been 20 outbreaks related to fresh produce alone in the past 12 years, and the number of food safety staff has fallen significantly in recent years; and funding for domestic food safety investigations has been dramatically reduced over the past 5 years. While we obviously have got serious problems on our hands because Americans are looking to FDA to restore their confidence in the safety of their food, has FDA formulated some ideas about how and what it needs to do to remedy this situation? We need to know how many more inspectors the FDA would need, whether your information technology infrastructure is adequate to effectively and efficiently monitor the life cycle of products as you indicated is necessary, what new authorities you need to deal with other countries as well as domestic firms to know that adequate safety procedures are in place. So I guess what I want to ask your personal assurances that you are going to work with Secretary Leavitt to give FDA's full and candid assessment of the needs of the agency in this area, and we need this assessment now. We can't wait for the next outbreak.

Dr. ACHESON. We are already working with the Secretary and others in HHS and FDA, and this essentially is what the food protection plan strategy that we are currently working on is all about, is to examine the changes that we are facing in 2007 that evolved over the last 10 years or so and put a plan in place that is going to begin to move forward. But I want to emphasize, this is not an overnight fix. We need to build a solid foundation of a plan adequately resourced and be looking for in the medium term to put this back on track. It is not something you can just throw money at, flick a switch, and the problem is solved.

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

Mr. PALLONE. Thank you, Mr. Waxman. It is not my intent to have a second round of questions because I want to move to the second panel, but Mr. Buyer said that he wanted to ask a question; so I will recognize him.

Mr. BUYER. I appreciate the gentleman's indulgence. This is a very complex and serious issue, so I appreciate the gentleman. On page 6 of your testimony, sir, you go into great detail how FDA, in order to comply with regard to imported drugs, your biologics, certain devices for pre-market approval with regard to authenticity to ensure that they comply with U.S. labeling requirements, et cetera. So earlier when I held up these two drugs, the Fosamax, and when you look at it, my gosh, it complies with everything. So what I look here is you are working very hard with regard to the authenticity, and these counterfeiters are getting better and better and better with regard to packaging and labeling. And obviously we have a great challenge ahead of us. So with regard to the proposed legislation that I am going to send to you, one of the things that I hate doing is studies. I don't want to create a commission, but I think there is one thing that we are going to have to really look at and that is whether to have FDA, in cooperation with our manufacturers, create a database that interfaces with your target-

ing system. And what I mean by that is if I am a manufacturer, I now disclose to you—you already know where their manufacturing facilities are but not only these are our manufacturing all around the world, but here are our approved wholesalers. Pick a company. This is who we work with. So if you are getting a particular product, so here is the legitimate product; and this runs through a legitimate wholesaler in Germany, and someone in Germany has purchased that product, they are sending it to a relative who is only visiting on a legal visa to the United States, you let that come through. But if your targeting system knows that this is coming from Singapore and I have no wholesalers licensed in Singapore, there ought to be some kind of alert system out there. So the more we get sophisticated and these computer systems are enablers for us, I think we have an opportunity here to zero in on the authenticity because right now, I just wanted to let you know, you can work very hard to comply with the law and do everything, but the counterfeiters seem and appear to be one step ahead of us. Do you have a comment with regard to any of these ideas?

Mr. LUTTER. We share very much your concerns about the threats to public health posed by counterfeit products, and the point that you are making about the inability to distinguish the counterfeit from the genuine product is one that I have actually made in this room on past occasions, and we agree very much with that. We have trained pharmacists and physicians who, confronted with the counterfeit, can't distinguish one from the genuine product. With respect to the opportunity to develop an electronic database that might facilitate the identification and the authentication of genuine products and permit the distinction of those from counterfeits, that is something we have explored repeatedly in the past in the context of a counterfeit task force. It was organized at FDA and has issued a series of reports. It is unclear who should own such a database or who should manage it. There are a variety of views on that, but the idea that electronic pedigrees and electronic track and trace technology would allow for a low-cost way of authentication so as to reduce the risk of counterfeits is something that we pointed toward, advocated in the past, and we think that is an appropriate way to implement mandates of past legislation and also the regulation on pedigrees that we have adopted. We think there are a lot of opportunities there, and we look forward to offering technical assistance to you.

Mr. BUYER. That is excellent, Mr. Chairman. That is going to put us here on the Hill on common ground with the administration with regard to this legislation. The last thing I would say is please recognize your front-line personnel for FDA. Your inspectors and your pharmacists, they are very challenged and frustrated; and they want the ability to destroy when they find these counterfeit drugs, rather than a return-to-sender policy. With that I yield back, and I thank the gentleman.

Mr. PALLONE. Thank you. I want to thank all of the panel and obviously we have got a lot of work ahead of us; and please get back to us with a lot of these questions that have been asked as quickly as possible.

Mr. LUTTER. Thank you very much for the opportunity to present our views, Mr. Chairman. Thank you.

Mr. PALLONE. Thank you. And I will ask the second panel to come forward if you can. Thank you all for being here, and let me introduce everybody from my left to right.

First we have Mr. William Hubbard who is senior advisor, Coalition for a Stronger FDA, and then we have my former colleague, Congressman Cal Dooley. I am really pleased to see you here today, and he is president and CEO of the Grocery Manufacturers Association. Then we have Jill Hollingsworth who is group vice president for food safety programs at the Food Marketing Institute. And then is Caroline Smith DeWaal who is food safety director for the Center for Science in the Public Interest; Dr. Alan Goldhammer who is deputy vice president for regulatory affairs with PhRMA, the Pharmaceutical Research and Manufacturers of America; and then we have Tom Kubic who is executive director of Pharmaceuticals Security Institute; and Mr. Hallock Northcott who is president and CEO of the American Association of Exporters and Importers.

You have 5 minutes for your opening statement. They will be made part of the record, and at the discretion of the committee, we may submit questions, ask you to get back to us, in which case we would ask you to answer those in writing for inclusion in the record at a later time. So I will start with Mr. Hubbard. You are recognized for an opening statement. Thank you.

STATEMENT OF WILLIAM HUBBARD, SENIOR ADVISOR, COALITION FOR A STRONGER FDA, CHAPEL HILL, NC

Mr. HUBBARD. Thank you, Mr. Chairman. Given the size of the panel, I will be very brief. I have a written statement. I will just point out that we like to think that our food supply is the safest in the world, but to some extent, the world's food supply is becoming ours. This country now imports $2 trillion worth of goods, and that will triple in the next few years. So we are being inundated by these foreign products, and you have pointed out the inadequacies in the current system, so I won't repeat all of that information. But I will say two main points, first, FDA is incapable of protecting the food supply vis-a-vis imports with its current resource staffing. They only have 450 inspectors to look at what is approaching 20 million imports. So they are simply inundated by that. Second, I believe a paradigm is broken or the process is broken. It is 100 years old. It once worked in the 1920s or 1930s, but it puts all of the burden on this one small agency to identify a problem. And so the producer, the exporter, and the importer essentially don't have that responsibility. We need to move toward a system where everyone is accountable.

Let me give one example. Let us say you have got a fish farm in China or Vietnam or Indonesia, and now he has got incentives to be as efficient as possible. He is crowding the fish into a pond, he is feeding them perhaps chicken livers, chicken droppings which are fairly high protein, and the water is becoming very polluted. The fish are getting fungal and bacterial infections. So he is adding drugs to keep the fish alive until they can be harvested. Well, that farmer is producing an unsafe food, and we see that all the time. The problem is no one is checking him. He has the incentive to produce this unsafe fish. His distributor in China has no respon-

sibility to do anything about that. The exporter, the importer in the United States, it all comes down to whether FDA will actually look at that fish and test it. And with an inspection rate of less than 1 percent, that is not going to happen. So we have the problem there that you can't depend on an inspection process at the very end of the food chain. You need it sooner.

So I am recommending that we consider much as your bill does and as section 7 of Mr. Dingell's bill does moving toward a system of prevention. Imagine that fish farmer now knows that the importer is taking some responsibility and saying, well, who am I getting that fish from? Is he producing safe fish? And then the exporter in China is doing that, and then the wholesaler in China is doing that. All the message down to that farmer is, if I don't produce safe fish, I am going to be checked by the people in the supply chain, and I am going to be out of business. We need to give FDA the authority to set up a process like that I believe and then fund it so that it can verify the system is working. And I believe with that we can have a safe food supply. In fact, many of the major food and drug companies do this now. Cargill, or someone like that, is already securing their supply chain. So we need to bring all the other guys who aren't doing that up to that standard, and then I believe we will have a safe food supply that everyone can agree is managed in an effective way.

With that I will pass onto the next witness.

[The prepared statement of Mr. Hubbard follows:]

STATEMENT OF WILLIAM K. HUBBARD

Mr. Chairman and members of the committee, I am William K. Hubbard. Before my retirement after 33 years of Federal service, I served for many years with the U.S. Food and Drug Administration, and for my last 14 years was an FDA Associate Commissioner responsible for, among other things, FDA's regulations and policy development. Although I have remained retired since my departure from FDA in 2005, I provide advice to The Coalition for a Stronger FDA, an organization comprised of patient, industry, and public interest groups whose mission is to urge that FDA's appropriations be increased. I will be providing comments on FDA's resource constraints on behalf of the Coalition, but my comments on specific legislative changes do not necessarily reflect the Coalition's views and are solely my own (as the Coalition does not take positions on non-appropriations issues). During my career at FDA, I was deeply involved in seeking improvements in FDA's ability to assure the safety of foods, drugs, medical devices and other products that are imported into the United States from around the world. Accordingly, I wish to thank the Committee for moving quickly this year to consider legislation that would strengthen FDA's ability to oversee imports of food and other products from other countries.

BACKGROUND

This committee has often raised concerns about our Nation's vulnerability to unsafe foods and drugs imported from abroad, and illustrated those concerns with examples of illegal pesticides on fruit from Latin America, deaths associated with raw drug ingredients from China, and other instances of unsafe goods produced in developing countries. FDA's scientists have agreed with you that imports were a growing concern, as they noted with increasing alarm the volume of imports moving from a trickle to a stream to a flood, with no new resources or authorities to deal with the problem. Perhaps the events of this year—the deadly pet food ingredients, toothpaste tainted with antifreeze, seafood laced with illegal drugs, and other examples of dangerous imports—will serve as the national wake-up call that is sometimes needed to get our institutions moving toward effective solutions. And solutions are indeed needed, for, Mr. Chairman, there can be no doubt that our current system for overseeing food and drug imports is broken, and therefore cannot protect us as it is currently structured.

THE CURRENT FDA IMPORT SAFETY SYSTEM

As was noted in July's Oversight and Investigations Subcommittee hearing on imports, the current FDA system predates the creation of the Food and Drug Administration. First established in 1896, the system was designed to authorize Federal inspectors to open and examine (and sample, if necessary) foods and drug imported into the United States. It was folded into the original Food and Drug Act that established the FDA in 1906. And when the current statute authorizing FDA to protect our foods and drugs was enacted by Congress in 1938, the import provision was the only one of the original 1906 authorities that were believed to have worked well (and were thus continued in the Food, Drug and Cosmetic Act that remains FDA's principal legal authority). Congress' judgment at the time was correct, as most imports were foods and FDA inspectors could generally oversee imports via technology of the early and mid–20th century—tools such as visual inspection, a well trained sense of smell, microscopic examination, and laboratory analysis. But as we neared the end of the century, it became increasingly apparent that changes in the nature of imports were overwhelming the ability of the FDA to assure their safety, namely:

• A huge increase in volume, for instance, from 2 million shipments of imported products regulated by FDA in 1993 to a level approaching ten times that today.
• A tremendous surge in foods, drugs, medical devices, cosmetics, animal foods, and dietary supplements from developing nations that have little or no established regulatory authorities overseeing production of those commodities.
• A shift in the types of commodities from "finished" products ready for consumption toward components that are used to make finished products in the United States, such as the active ingredients for our drugs from India and many of our basic food ingredients from China.
• A greater range of risks, such as new pathogens in food unknown to science in past years, and the intentional but dangerous addition of industrial chemicals and cancer-causing drugs in products produced overseas.

AN AGENCY OVERWHELMED

Several times in recent years, examinations by Congressional committees, the Government Accountability Office, the National Academy of Sciences, and other expert panels have concluded that FDA's ability to protect us from unsafe foods and drugs has been steadily deteriorating. No better example of that erosion exists than in the import area. Let me give you just a few measures of how FDA's capacity lines up with its responsibilities for imports:

The volume of imports, as I noted earlier, has grown to the point that it is nearing 20 million annual shipments of foods, drugs, medical devices and other FDA-regulated products. Yet the number of import inspectors has not been increased, and today the agency has only 450 inspectors to cover this massive inflow of products, which means that less than 1 percent of imports receive Federal inspection.

• Imports of FDA-regulated products enter the United States at many ports of entry. [Depending on how one counts a "port," between 300 and 400.] But inspector staffing is so low that they can man only about 40 ports, and many of those only part time.
• Despite the fact that there are thousands of facilities oversees making products for our medicine cabinets and dinner tables, the number of FDA inspections of those facilities is tiny. For example, only 125 inspections of foreign food manufacturers were conducted last year, and that was down from only 209 in 2001. This year, the agency will do even less, about 100. And for other products the numbers are even more dismal—two dietary supplement foreign inspections last year, zero animal food inspections, and zero cosmetics inspections.
• FDA's information systems, particularly those focused on imports, are old and out of date. They cannot interact directly with other agencies' systems, such as those at Customs, and cannot even distinguish imports of road salt from table salt.
• FDA inspectors lack modern scientific tools to make rapid assessments of imported goods for contaminants such as bacteria, viruses, heavy metals and industrial chemicals. They must undertake an expensive and time consuming process of collecting a sample and sending it to laboratory for analysis, often having to wait days for results.
• With so few inspectors, FDA's laboratories cannot be adequately used, and the agency has attempted to close some for that reason. The result is that only a small number of products even receive laboratory analysis. For example, only 20,000 samples of imported foods were sent for laboratory analysis last year, out of about 10 million shipments. There were about 200,000 shipments of food from China last

year, for example, so if ALL of the laboratory analyses were directed toward China alone, FDA would have been able to analyze just 10 percent of those imports.

• All in all, the parts of FDA that do not receive user fees (for new drug and medical device review) have been growing steadily weaker over the past decade, as the agency has lost a thousand scientists and inspectors who would have been protecting us from products on the market and those being imported from overseas.

A Broken Paradigm

If the signs of FDA's failure to adequately oversee imports are so clearly evident, then what can we say about how we got to this point? There are, in my opinion, two principal reasons for our current dilemma, both revolving around the paradigm that current exists for imports—namely, FDA inspection, at the border, to "catch" problems before they make it into our homes.

First, FDA's budget has not kept pace with its growing responsibilities. The agency has sustained either a flat appropriation or actual cuts in their budgets for more than a decade, at a time in which new problems and new regulatory challenges have been thrown steadily at the agency. The food safety program is a good example. It was almost half of FDA's budget in the 1970's, but today is only about one quarter.

Let me give you a more recent example. FDA's food safety budget was $407 million in 2003. If the agency had received sufficient funding since then just to stay even with inflation, the food safety appropriation for this year would be $626 million. But it was actually $450 million, which means that the agency lost $176 million in buying power for food safety in recent years. The result has been a loss of 20 percent of its food scientists, and over 600 inspectors, during that time.

One would think that with a growing domestic food industry, soaring imports of food from other countries, numerous new technologies (such as biotechnology) being used to produce food, an increase in food borne disease outbreaks associated with foods regulated by FDA, and declining public confidence in FDA, our leaders would be anxious to assure that the regulatory structure would be strengthened.

Similar analyses can be done for other FDA programs, such as drug and medical device safety, dietary supplements, and animal foods and drugs. These trends are alarming, and underscore the reasons for the creation of The Coalition for a Stronger FDA. While the Coalition's members often disagree on policy outcomes with respect to regulation, they are all concerned that a weak FDA is detrimental to domestic business, international trade, and, most importantly, public safety.

The second reason for our current vulnerability with respect to imports is that the regulatory paradigm for those products simply does not work in the 21st century. It is a system fraught with flaws in today's world:

• It is reactive system that looks for problems in foods and drugs after they're arrived in the United States, rather than preventing the export of contaminated products at their source

• It would need massive new resources to be significantly improved, requiring hiring thousands of new inspectors at a cost of billions of dollars, and even then may not be able to meet our expectations

• It continues to place all of the burden of assuring safety on this one small agency—the FDA—rather than requiring accountability by those who produce and import these commodities,

• It provides little incentive for foreign governments and foreign producers to be vigilant in producing safe goods for sale to the United States, and

• It does not take into account modern principles of product quality assurance that have recently been developed and proven to work effectively in the production of food and other products.In sum, Mr. Chairman, I believe we must re-engineer our system of import oversight in ways that will not only strengthen the FDA but also bring our trading partners and their producers into a comprehensive safety assurance system.

Building Quality In

Let me give a brief history that I believe will illustrate the concept of building safety into our food and drug supply. Many Americans do not know the name F. Edward Deming, but he is revered in Japan as one of the leaders in their post-World War II effort to rebuild their economy. Deming convinced the Japanese that traditional production methods, which relied on post-production inspection, would not assure product quality, and advocated instead a process whereby defects in a product's manufacturing are prevented from ever occurring. The Japanese embraced the concept and began a transformation in their production of automobiles, electronics and other consumer products that enabled Japan to shift from an image of

a producer of cheap, shoddy products—some would say analogous to China today—to an economic superpower with a reputation for product quality. American manufacturers eventually adopted Deming's quality assurance philosophy, which has been credited with improving quality in recent years of a host of U.S.-produced consumer products.

This quality assurance concept was implemented for food by the Pillsbury Corporation in 1960, when they were tasked by NASA to develop food for the U.S. manned space program. A food borne illness resulting in vomiting or diarrhea could be catastrophic in the weightless space environment, so Pillsbury developed a food production process to ensure that no contamination could occur as the food was being produced, thereby "building safety in" to the food as it was produced. This concept, known by the acronym "HACCP" (for Hazard Analysis Critical Control Points) was quickly used by FDA to solve a series of contaminations in the 1960's in canned foods, then used more recently to improve the safety of seafood and juice. Meanwhile, the Agriculture Department adopted the concept for improving meat safety in the United States, and the European Union has legislated HACCP into its food safety laws. FDA also developed regulations, utilizing the same quality control concept, for drugs and medical devices, to minimize production defects in those products.

An Emerging Consensus on a Solution—Build Safety In

As dismaying as the recent contaminations of seafood, pet food, toothpaste and other commodities have been, they have focused the various stakeholders in ways that would not have been likely a few months ago. I believe, Mr. Chairman, that we are seeing the development of the elements for needed change in the regulation of imports that could be a wonderful, even historic, opportunity to "fix" imports for the foreseeable future.

Two weeks ago, the Interagency Working Group on Import Safety created by the President this summer released a "strategic framework" that emphasizes a "life cycle" approach to the management of imports that builds prevention in upstream from the FDA. Last week, the Grocery Manufacturers Association/Food Products Association issued its "Four Pillars" for import safety, which emphasizes the need for all parties in the production and sale of imports to be accountable for the safety of foods. Consumer groups have long urged that a system of continuous quality controls over food production be adopted to reduce food borne disease. And your committee's draft import bill includes provisions that emphasize the need for safety assurance across the supply chain.

My point is that I believe you are all saying fundamentally the same thing—that the answer for import safety is a system based on prevention that requires producers, exporters, importers, U.S. purchasers "everyone in the chain of supply—to take greater responsibility for the safety of imports, and give FDA the authority and resources to implement and oversee such a system.

A System Based on Prevention

I urge you to accept this emerging consensus among the various stakeholders as a sign of a tremendous opportunity to re-engineer our import safety system in ways that will save lives, reduce illnesses, enhance our citizens' confidence in their government, and perhaps even improve some of our trade relationships. The elements of legislation that would focus on a system of prevention could include:

- An express requirement for a foreign supplier quality assurance program that importers would implement to provide greater assurance of the safety and quality of imported food products and ingredients;
- Enhanced international standard setting, for better consistency in safety standards across the globe;
- Agreements with exporting countries that would improve their capacity and willingness to better oversee producers within their borders;
- Procedures to assure that verification is made that safety standards are being followed, and
- A strengthened FDA, with resources to strengthen the agency's scientific base; to gather and utilize new technologies for screening imports; to create modern IT systems to track the movement of imports; and to recruit and train inspectors to oversee the new system—both by better, risk-based inspections at the border and by more frequent inspections of foreign facilities.

I believe it is entirely possible for the Congress to bring together the disparate interests involved in import safety and, keying off of the very basic concept of prevention throughout the supply chain, craft legislation that could be accepted by con-

sumers, the industry, and the current administration. Obviously, there would be many details to consider, but, in the end, the goal of a better, more effective import screening system is achievable. And, of course, there are other authorities that members of Congress have considered in the past, such as country of origin labeling, new recall authority and more. But those additional authorities would not, in my view, address the fundamental problem of why FDA cannot assure the safety of imports. Thus, I urge the committee to consider making a system of prevention your primary objective, and I thank you for allowing me to express my views on this subject.

Mr. PALLONE. Thank you. Congressman Dooley.

STATEMENT OF HON. CALVIN M. DOOLEY, PRESIDENT AND CEO, GROCERY MANUFACTURERS ASSOCIATION

Mr. DOOLEY. Well, thank you, Congressman Pallone, Congressman Buyer. It is a delight to be here. I have the honor and privilege of representing over 300 companies in the U.S. that manufacture food and beverage products. So every time you go into the grocery store and you see those brands on the aisles there, quite likely they were produced by my member companies; and they are absolutely committed in working in partnership with all of you and this committee to ensure that we can build upon what we consider the safest food supply in the world to make it even safer.

What we have proposed, the Grocery Manufacturers just recently, is what we call the four pillars for safer food; and we are trying to build upon that foundation of an incredibly safe food supply. But the underlying premise of this is much like Mr. Hubbard talked about is we can be most effective by focusing on prevention because while we know there is work to be done and there are improvements, when you look at all the food products that are in a grocery store today, we are fortunate that it is a small, a very, very small number of those that pose any health or food risk to a consumer. And so what we need to be focused on is that we understand we have a small problem, but it is not a large problem. It is almost like how do you find that needle in the haystack with that needle being that food safety concern? So our objective needs to be how do we limit the number of needles and also how do we reduce the size of that haystack so that it makes it easier for FDA to allocate their resources in order to make a difference.

Our pillar one is really to develop a mandatory foreign supplier quality assurance program, and under this pillar, all importers of record, which is a company that is importing a food product, would be required to develop mandatory protocols that would ensure that they have a greater confidence in the safety of those products that they are importing. We would ask FDA to develop guidance in terms of what would be the components for this mandatory foreign supplier quality assurance program. And the reason why we are going down this path is that every one of our member companies, the greatest equity that they have in their company is the brand of their product; and that brand of their product is what makes a difference in whether or not that consumer will take it off the shelf. And if that consumer has any concerns in terms of the safety of that product, they in fact, will not purchase it. And so we are totally committed, and we think we are in the best position to really make a difference in preventing contaminated food products.

The pillar two really works on the voluntary qualified importer food safety program, and this is really focused on how do we reduce the size of the haystack understanding that there are some food products that we are importing or ingredients that are in fact of lesser risk, and there are also opportunities for food producers and processors to work in cooperation with FDA to provide them with additional information which in fact can lower the risk of concern of a food safety problem.

And pillar three is something we think is absolutely critical is that this Government and FDA needs to be working to build the capacity of foreign governments to develop equivalent food safety programs within their countries.

And also pillar four is something that we have been working very closely with many of the organizations that are represented at this table, is that we have to expand the capacity of FDA. We are a part of the coalition for a stronger FDA which is asking for a doubling of the budget of the Food and Drug Administration over the next 5 years because we are not going to be successful in giving the FDA the resources to enhance their participation and partnership in this effort to achieve greater food safety if they do not have additional resources.

The one thing that I would like to spend just a moment in talking about some of our concerns with the legislation that was in fact implemented. The industry and my member companies have great concern about a user fee approach as we think that food safety is a public good, it is a responsibility of the Federal Government, and it should be paid for out of general fund dollars. We are concerned about whether or not you can actually in fact implement an equitable user fee approach that doesn't have unintended consequences. And I just brought two products, two little props here, which can kind of demonstrate that. If you have a line item, a user fee of $50 per line item, I have a product here that is Madras Lentis that is a product of India. This product would come in under one line item and thus would pay that one $50. We could have a very similar product coming in, a vegetarian chili product, that was manufactured in the U.S. that has a number of different ingredients in it. Those ingredients, many of which would be imported into this country, would be paying a separate line item or that user fee on each of those ingredients. You are creating a perverse incentive for many food processors and manufacturers to locate their processing facilities across the border in order that they could minimize the cost of a user fee that would be coming into this county.

There are also concerns similar to this on part of the country of origin labeling. All processed foods that are coming into the country today has to be labeled as to the country of origin where it had substantial or significant transformation. We are concerned, and there is a lack of detail on the country of origin labeling requirements, that again this product from India could be a product of India, but this product manufactured in the United States might be required to have separate line items in terms of where each of the ingredients was sourced, further complicating the marketing and the packaging of this product.

We also have concerns that have been articulated in terms of the port of entries. We do not think that you can restrict it to the 13

or so that have FDA lab facilities. We think that is of great concern to us. We also have concerns, too, with the certification process being prescribed. We think that just the testimony that Dr. Acheson gave, there are 400,000 food suppliers in China alone. There are almost that many in India. We are looking at millions of food suppliers throughout the world that we would have to be in the position to try to certify, and we think that would become such an onerous and costly burden and wouldn't be the best allocation of FDA funds. We think that our proposal will ensure the private sector can provide better information, that we can share that information with FDA in a manner that we can achieve the shared objective of enhanced level of food safety.

[The prepared statement of Mr. Dooley follows:]

STATEMENT OF HON. CALVIN M. DOOLEY

I am Cal Dooley, president and CEO of the Grocery Manufacturers /Food Products Association. I am here today to discuss an issue of paramount importance to our members—ensuring the safety of imported foods.

Food producers have an abiding interest in safe food. Maintaining consumer confidence in our products, our brands, and our companies is the single most important goal of the food, beverage, and consumer packaged goods industry, and product safety is the foundation of consumer trust. My industry devotes enormous resources toward this goal, and effective regulation and oversight by Federal regulatory agencies such as the FDA are critical and complementary elements of the fabric of consumer protection.

This month, GMA/FPA issued "Commitment to Consumers: The Four Pillars of Food Safety," a comprehensive proposal designed to protect consumers by strengthening, modernizing, and improving the system governing food imports. Our proposal envisions new mandatory requirements for the food industry to assure the adequacy of foreign supplier food safety programs and new responsibilities for FDA. Other elements include a new program to help identify and prioritize imports of potential concern, new efforts by FDA to help enhance the capacity of foreign governments to prevent and detect food safety issues, improvements to FDA's scientific capabilities and its use of information technology, and a significant increase in FDA resources.

Underlying this comprehensive set of proposals is a fundamental emphasis on prevention.

Let me put the challenge before us in plain terms. As the volume of imported food steadily increases, the FDA's job at the border can be compared to trying to find a needle in a haystack. We need to approach this task from different angles: (1) by reducing the number of needles to find; and (2) by reducing the size of the haystack in which to find them.

A complete copy of the "Four Pillars" proposal has been submitted with this written testimony. Before I provide comments on the Food and Drug Import Safety Act introduced last week, I will take just a few minutes to briefly outline each of the four pillars for you now.

Pillar One: Mandatory Foreign Supplier Quality Assurance Program—Under this pillar, all importers of record would be obligated to adopt a foreign supplier quality assurance program that assures that all imported ingredients and products meet FDA food safety and quality requirements. Food companies would utilize FDA guidance to adopt food safety programs and practices needed to ensure food safety, such as audits, testing, good manufacturing practices, good agricultural practices, HACCP plans, food defense programs, product management systems, and recall programs. Requiring importers of record to ensure the safety and quality of their supply chain—and giving FDA the authority to review the effectiveness of these programs—would reduce the number of needles in the haystack.

Pillar Two: Voluntary Qualified Importer Food Safety Program—To help prioritize FDA resources and to relieve congestion at ports, we further propose that importers of record who are able and willing to meet additional standards and conditions than those required under Pillar One could voluntarily participate in a program entitling them to expedited entry at U.S. borders. This is similar to the Safe and Secure Food Importation Program Chairman Dingell has proposed in the Food and Drug Import Safety Act introduced last week and builds upon the C-TPAT program currently in

place. In addition to demonstrating the presence of well-designed and implemented food safety systems, importers could demonstrate a secure supply chain and conduct and share additional testing and program data with FDA to be eligible for expedited entry. By permitting expedited entry for imported foods that pose no meaningful risk, Congress can reduce the size of the haystack needing closer scrutiny by the FDA.

Pillar Three: Build the Capacity of Foreign Governments—FDA would work with foreign governments to improve their capacity to prevent and detect threats to food safety. FDA would work with foreign governments to expand training, accelerate the development of laboratories, ensure the compliance of exports with U.S. regulations, permit appropriate FDA inspections of foreign facilities, and ensure adequate access to data and test results conducted abroad. In addition, FDA would be encouraged to use Codex to harmonize requirements among countries. The food industry has long supported international harmonization through Codex, and we believe that FDA must once again provide international leadership towards the adoption of strong, science-based international food safety standards. All of these foreign capacity building steps would further reduce the likelihood of contamination and thereby further reduce the number of needles for FDA to find at the border.

Pillar Four: Expand the Capacity of FDA—Expanding FDA resources—including personnel, equipment, laboratory capacity, and scientific expertise—is an essential component of an effective food safety system. FDA resources have not kept pace with the demands posed by rising imports and current food safety challenges. To meet these needs, Congress must provide significant new funds to dramatically improve FDA's analytical testing capabilities, to increase and target inspections conducted by FDA, to obtain real-time test results, and to enhance communications during crisis events. With additional resources that are well-deployed, FDA should be much better positioned to find any remaining needles before they cross the border and enter U.S. commerce.

We believe that the adoption of these four pillars of food safety will result in significant improvements in our food safety net. By focusing our efforts on prevention—and by expanding and improving our ability to detect threats to public health—we believe that our proposal will do far more to ensure the safety and quality of imported food products and ingredients than would the adoption of many of the provisions of the Food and Drug Import Safety Act and will build upon the partnership between FDA and the food industry.

Food companies recognize that growing food imports pose new challenges and we share the same goal as the committee: to continually improve the safety and quality of food products and ingredients. We are grateful for the opportunity to work with you to develop comprehensive imported food safety legislation which makes the prevention of contamination the cornerstone of our food safety net.

While inspecting products at the border is an important element of a comprehensive approach to food safety, we believe that inspections alone will not provide enough improvement to the safety of our food supply. We strongly agree with your desire to find more resources for FDA, which needs to restore its scientific base as well as its capacity to conduct an appropriate level of inspection and examination. However, we strongly oppose the user fee provision in the Food and Drug Import Safety Act. We have five significant concerns with the user fee.

One, we believe that the benefits of a safer food supply accrue to the public generally, much like the benefits of a strong national defense, and believe that the costs of providing FDA with sufficient resources to perform the various responsibilities to protect the public health that have been given to it by the Congress should come through taxes, not user fees. As you know, a user fee is appropriate when the benefits of the government service flow to an individual (such as postage stamps, recreation fees, or public transportation) or to a particular business (such as harbor maintenance fees, accelerated review of prescription drugs, or bankruptcy filing fees). The benefits of inspection and research clearly flow to all Americans, not simply to food companies.

Second, the proposed user fees would impose significant financial burdens on U.S. companies, not just on importers. This is especially true for companies with facilities in both the U.S. and Canada, for example, where there is a steady flow of ingredients and finished products, all of which would be subject to import user fees. We are in the process of collecting data to estimate the added costs to U.S. businesses, but we have reason to believe they would be substantial.

Third, the imposition of the user fee on imported products and ingredients could create an incentive for companies to locate production facilities outside the United States. Let me provide an example of why this is so. Suppose a company makes a product in the United States that consists of 20 ingredients, half of which are imported. Under the user fee proposal, a fee would be imposed on ten of those ingredi-

ents each time they are imported. If, on the other hand, the production facility was located in Mexico or Canada, for example, the fee would only be imposed once: when the finished product was brought into the United States.

Fourth, we are concerned that a user fee on imports would violate our trade commitments by creating a preference for domestic sources of food products and ingredients. We're also concerned that such a fee could invite other countries to place similar fees on our food exports. Finally, we are concerned by the mechanics of the user fee. By charging $50 per line of food, the user fee in the Food and Drug Import Safety Act places an unfair burden on importers of many distinct products.

We strongly agree that FDA needs more resources to increase inspectors, improve its scientific capabilities, and meet other critical needs. For the past year, GMA/FPA has worked with the Coalition for a Stronger FDA to substantially increase FDA funding. In our view, FDA does not simply need "more" resources, but needs the "right" resources. In particular, we believe that the agency needs additional resources for both its "science" and its "compliance" activities. The agency cannot operate effectively without both. Our goal is to double FDA's food-related spending over five years, and we applaud Chairman Dingell for his efforts to seek additional FDA spending.

We have other major concerns with the Food and Drug Import Safety Act and we look forward to working with the committee to address these and other challenges.

One, we are concerned that proposals to limit imports to certain ports and to require the development and implementation of certain tests could create havoc at the border and create costly and unachievable new burdens on FDA and the food industry. In particular, we are concerned that the proposal to limit food imports to ports of entry located in the same metropolitan area where FDA has a laboratory could unintentionally block food imports to many ports. While there are more than 300 ports of entry, there are only 13 FDA labs. As a result, many ports—including all ports in Texas and Florida—would no longer be able to import food products and ingredients. We believe a better course would be to expand and better target FDA inspectors, as we have proposed in our second "pillar" and Chairman Dingell has proposed in section 7 of the Food and Drug Import Safety Act, and to expand FDA's capacity to quickly analyze food products and ingredients.

We are also concerned about requirements to develop rapid tests within three years and to test all processed food products. While we share your desire to make rapid-tests and other sampling methods widely available, we are concerned that requiring the development of such tests within three years may be unrealistic. We are also concerned that a requirement, included in Section 12 of the Food and Drug Import Safety Act, that all processed food be tested to detect substances that make the food adulterated creates an impossible burden: there is simply no way to test for all potential causes of product adulteration. In our view, requiring every importer of record to implement a foreign supplier quality assurance program—and placing the focus of imported food safety efforts on prevention, rather than detection—would significantly improve the safety of imported food to a far greater degree and build upon the strong partnership between food companies, our suppliers, and FDA.

Two, we are also concerned about two new labeling requirements included in the Food and Drug Import Safety Act. First, packaged food products are already required to bear country of origin labeling. Second, we are concerned that the proposal to require country of origin labeling for all food could create huge new burdens on food companies while providing little or no benefit. Many of our food companies combine ingredients from dozens of countries to create a single product. Would the proposed country of origin labeling requirement mean that each ingredient has to be labeled with its country of origin? We are also concerned that a "safety notice" on meat, poultry or seafood that contains carbon monoxide to affect coloring would needlessly mislead the public. As you know, this practice has been subject to exhaustive testing and has been declared safe by FDA.

Three, we are also concerned that Food and Drug Import Safety Act violates our trade agreements and would invite retaliatory actions by our trading partners. As I mentioned, the adoption of user fees would create a clear preference for domestic food products and ingredients and would invite the adoption of similar fees on our exports. In addition, we are concerned that a requirement that all foreign facilities importing food into the U.S. obtain FDA certification would place enormous new burdens on FDA, would violate our trade agreements, and would invite reciprocal demands by our trading partners. Further, we do not believe that there are likely to be resources available—even with user fees—for FDA to certify tens of thousands of foreign facilities located in about 150 different countries.

Four, there is ample evidence that the current recall system works well. We are concerned that the due process protections that necessarily accompany the recall proposal in the Food and Drug Import Safety Act could actually delay, not acceler-

ate, efforts to address public health threats. As you know, food companies have powerful incentives to remove adulterated products from commerce as quickly as possible and have worked closely with FDA to implement recalls quickly and effectively. We strongly support efforts to expand FDA's ability to communicate the risks posed by adulterated foods.

In conclusion, we share your commitment to the improving the safety of imported food. We also share your commitment to increase FDA's resources, including resources to increase our ability to detect adulterated food at the border. However, we believe that far more emphasis must be placed on the prevention of threats to food safety throughout the supply chain and look forward to working with you to make a safe and secure supply chain the responsibility of every importer of record and to expand the capacity of foreign governments to detect and deter threats to public health.

Our "Four Pillars" proposal builds on the long history of public-private responsibilities and cooperation in ensuring food safety, while providing new and innovative approaches to the latest challenges to our Nation's food safety net. Its focus on prevention would be complemented by an enhanced ability to quickly detect and address public health threats. Meeting the challenges of the modern supply chain requires additional public resources for FDA and related agencies and demands an integrated approach that leverages the significant investment of the private sector in product safety. We look forward to working with the committee to fashion comprehensive legislation that will address the new challenges posed by rising food imports and will continually improve the safety of our food products and ingredients.

Mr. PALLONE. Thank you. I just realized, Calvin, you went over 5 minutes. I didn't pay attention. So I will ask the others to stick to the 5 minutes, even though he used twice the time; but that is all right, you are a Congressman, so we will allow it.

I do have to tell everyone, though, that we will have two votes; so I am going to try to get in one or two of you before we go vote, and you will have to wait until we come back.

So next is Dr. Hollingsworth.

STATEMENT OF JILL HOLLINGSWORTH, D.V.M., GROUP VICE PRESIDENT, FOOD SAFETY PROGRAMS, FOOD MARKETING INSTITUTE

Dr. HOLLINGSWORTH. Chairman Pallone and members of the committee, thank you for the opportunity to appear before you today to present our views and suggestions on H.R. 3610. I am Dr. Jill Hollingsworth, the group vice president at the Food Marketing Institute, FMI, where I have been head of the Food Safety Program for over 10 years. FMI is a national trade association with 1,500 member companies representing food retailers and wholesalers in the United States and abroad. Our members represent over 75 percent of all retail food store sales in the U.S., accounting for $340 billion in annual sales.

In my capacity at FMI I often have to draw upon my past experiences at USDA where I worked for 15 years. While I was there, I not only implemented the investigation of the *E. coli* outbreak at Jack-in-the-Box, but I was responsible for developing and implementing the public health and recall programs that exist today in the Food Safety and Inspection Service.

At FMI I worked closely with the supermarkets and their wholesalers to ensure that we are doing all that we can to achieve a safe food supply, but we are very concerned about the recent decline that we have seen in consumer confidence in the food safety system. In January 2007, FMI's own survey of consumers called U.S. Grocery Shopper Trends found that consumers' confidence in the

safety of the food purchased at supermarkets dropped from 82 percent down to 66 percent, and for restaurants that drop in confidence declined to 43 percent. Numerous recalls and the lack of confidence in both the food system and the Government have actually caused consumers to actually change their purchasing habits with over 38 percent of consumers saying they no longer buy certain items such as spinach because they are afraid of the safety of the food. Enhancing the safety of our food supply would require active effort and aggressive support of the business community such as food wholesalers and retailers working with the Government. This is a farm-to-table challenge, and it will take a farm-to-table solution; and it is both a domestic and an international problem that we must address together.

As the retailers and wholesalers of this country, we are working to improve safety through four focused programs. First, we want to ensure that our suppliers, whether they are domestic or international, are actively managing a science-based food safety program. We do that through our own Safe Quality Food Program, a global food safety training, audit, and certification system. Second, we train and certify our own supermarket employees in safe handling practices through education programs called SuperSafeMark, and we have trained this year alone over 15,000 food store managers.

Third, we provide consumers with practical science-based advice on food handling in the home through the cooperation for the Partnership for Food Safety Education. This is a public/private sector program that brings together consumer groups, FDA, USDA, CDC, and the industry sector. Our president, Tim Hammonds, is the founding chair and immediate past chair of this educational partnership.

Fourth, FMI's Board has appointed a food safety task force made up of chief executives from retail and wholesale companies. The task force is currently looking at ways that we can improve our Nation's food recall communication system to make it more effective and efficient. As I mentioned, there is a need to restore consumer confidence and to reduce food borne illnesses. To that end we would want to work with this committee, but we also want to be sure that we can do so without hindering the ability to serve our customers. To that end, any changes that we consider must be able to answer some questions: Can they be supported by science, do they in fact provide measurable benefits, are they affordable, realistic and practical, and can they be implemented without unintended consequences.

For example, in H.R. 3610, we support the concept of an expedited review process for those companies that comply with FDA guidelines. Here is an example of where the private sector can be of assistance. Through our safe quality food program, we are able to audit all of our suppliers as often as we need to, and we can grant them accredited certification when they meet the standards at or above FDA's. We also support the operation of the FDA field labs. Rapid tests should be developed based on the seriousness of the threat posed by the pathogen or chemical, and we also feel that these tests should be used to monitor the food safety system, not to inspect food. Another provision that we may be able to support

is mandatory recall. Under our current recall system, food companies have an outstanding history of compliance, and we do not want to change anything that would possibly slow down the recall system. However, if the Secretary had the option to mandate a recall, in the event that a company were to refuse, then we could consider supporting such a provision. This is slightly different from the bill language. We would be more inclined to supporting the Secretary with the authority to option, if a mandatory recall is necessary, rather than telling the Secretary he must issue a mandatory recall.

FMI cannot support the proposal for user fees on imported foods and drugs. Not only will this raise the cost of food for the American consumer but we also feel it presents a conflict of interest. FMI and its members are very concerned about the provision to restrict U.S. ports of entry. I think we have heard many examples of why the system will just be damaging to our country. Ultimately the consumer will be the loser with higher costs for food and less availability of quality, fresh foods. We also do not support the proposed provision for carbon monoxide labeling of meat, poultry, and seafood. Both FDA and USDA have recognized this technology as being safe, and it is not the only packaging system that is currently used to extend color of foods. We are not aware of any scientific basis for singling out one technology for a warning label.

The bill also contains a provision requiring country of origin labeling. FMI strongly objected to the mandatory Country of Origin Labeling Law created in the 2002 farm bill because it placed the entire burden for labeling on retailers. Retailers are the last link in the supply chain, and we should not, in fact we cannot, be accountable for ensuring the location of where food originated. The concept of certifying foreign governments and countries by FDA sounds very promising as we move toward a risk-based system and one that we can support.

That system is one that we would support, but there does need to be a more pragmatic approach as to how this could be accomplished. We look forward to working with you on these and other concerns. Thank you.

[The prepared statement of Dr. Hollingsworth follows:]

TESTIMONY OF JILL HOLLINGSWORTH, D.V.M.

Chairman Pallone and members of the committee, I am honored to appear before you today to present our views and suggestions on House bill 3610, the Food and Drug Import Safety Act. I am Dr. Jill Hollingsworth, group vice president of the Food Marketing Institute (FMI). I have been in charge of food safety programs at FMI for the past 10 years

FMI is a national trade association that has 1,500 member companies made up of food retailers and wholesalers in the United States and around the world. FMI members operate approximately 26,000 retail food stores with combined annual sales of $340 billion, representing three quarters of all retail food store sales in the United States. FMI's retail membership is composed of national and regional chains as well as independent grocery stores. Our international membership includes some 200 companies from more than 50 countries.

In my capacity at FMI, I often draw upon my past work experience at the U.S. Department of Agriculture (USDA). I spent 15 years there and led the investigation of the Jack-in-the-Box E. coli outbreak in 1992. I subsequently set up food safety and recall programs and a liaison program with the Center for Disease Control in Atlanta and the U.S. Public Health Service. While there I also served as a Veteri-

nary Inspector, Special Assistant to the Administrator of Food Safety and Inspection Service (FSIS) and Assistant Deputy Administrator of FSIS.

Presently, I work closely with supermarkets and their wholesalers to ensure we are doing all we can to guarantee a safe food supply—operating clean and safe stores; adhering to science-based best practices; responding to emergency situations; educating the public about safe food handling practices; and, working with our Federal, state and international partners to improve food safety programs.

In 2007, consumer confidence in the food supply reached its lowest point since 1989. FMI's own survey of consumers, U.S. Grocery Shopper Trends, found that consumer confidence in the safety of foods purchased at supermarkets dropped from 82 percent in 2006 to 66 percent in 2007. And for restaurants, the drop in confidence was down to 43 percent. Recalls and the lack of confidence in both the food system and government have caused consumers to actually change their purchasing habits, with 38 percent of consumers saying they have stopped buying certain food items because of food safety concerns. For example, in January of this year, 71 percent of consumers reported they no longer buy spinach.

We realize that restoring consumer confidence and strengthening our food safety system is of paramount importance. We understand and support your goals. Enhancing the safety of the food supply requires the active effort and aggressive support of the business community—such as food wholesalers and retailers—as well as government. This includes our work with suppliers, especially beyond our borders, our commitment to train our own people 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.

Accordingly, the retail food industry is actively involved in improving food safety in the U.S. We are doing this through four focused programs: SQF (Safe Quality Food program); SuperSafeMark; the Partnership for Food Safety; and, our Board Level Food Safety Task Force.

I would like to highlight a few of the retailer/wholesaler food safety initiatives in place. First, we work with our suppliers to ensure that they are following best practices. We have been aggressively implementing a new standard in food safety—one based on science, for all suppliers, from the smallest farm to the largest manufacturing plant. This program is called Safe Quality Food, or SQF. The SQF standard is one of only five programs in the world that has received recognition from the Global Food Safety Initiative, a group of international food safety experts. What makes SQF unique is that we require suppliers to carry out risk assessments, and after they have put their food safety program in place, we monitor their performance through third-party audits. Only those companies in compliance with this international standard can receive SQF certification.

Second, on the domestic front, we train and certify our supermarket employees in safe food handling through a program especially designed for retail called SuperSafeMark. Currently, we train and certify about 15,000 store managers a year and we train thousands of store employees so that they comply with the FDA Food Code.

Third, we provide consumers with practical, science-based advice on food-handling in the home. We do this through The Partnership for Food Safety Education. This is a joint private-public sector project that brings together consumer groups, the FDA, USDA, CDC and a wide variety of other industry associations. Our president, Tim Hammonds, is the founding chair and immediate past chair of the partnership. The Partnership is responsible for the FightBAC campaign to teach food safety to children and others; the Chill Out program to remind consumers about keeping their home refrigerators cold; and, most recently, the Be Food Safe promotion providing retailers with the tools they need to educate their customers about safe food practices.

Fourth, FMI's Board has appointed a food safety task force made up of the chief executives from retail and wholesale companies around the world. The task force is looking at how we can make our nation's food recall communications system more effective and efficient. We are working in concert with our trading partners and will be glad to communicate with this committee on our progress as we work toward improvements in the recall system.

As I mentioned earlier, there is a need to restore consumer confidence and to reduce the burden of foodborne illness; to that end we want to work with the committee to accomplish our shared goals but in a way that does not hinder our ability to serve our customers and ensure an affordable and abundant food supply. Many of the proposals in H.R. 3610 are well founded, but we must be sure that any changes to our current food safety system meet certain criteria. They must:

- Be supported by science,

- Have measurable benefits,
- Be affordable,
- Be realistic and practical,
- And, be implemented without unintended consequences.

MANDATORY RECALL AUTHORITY

Regarding mandatory recall authority, we realize that under our current voluntary system of recalls, a company has never refused to withdraw adulterated product at FDA's request or they have taken action on their own. However, if the Secretary is given the option to mandate a recall in the event a company did refuse, we can see where this would build confidence in the recall system. We note that this approach differs somewhat from the current bill language, which would require FDA to issue a cease distribution order upon a finding of food adulteration.

Rapid Testing Techniques for Use in Inspection of Imported FoodsAnother area of potential agreement is the development of rapid testing techniques for use in inspections of imported foods. We urge the committee to pursue this avenue as long as scientists and researchers prioritize this work. Developing rapid or screening tests should take into account: the seriousness of the threat posed by the pathogen or chemical; how frequently it occurs as a food contaminant; and, the likelihood that a rapid test methodology would be successful. We would also encourage FDA to work with USDA, CDC, and other public and private entities to share expertise, resources and laboratories in pursuing this.

SAFE AND SECURE IMPORTATION FOOD PROGRAM

The provision for a safe and secure importation of food program that recognizes those companies that comply with new FDA guidelines in exchange for expedited review of their product is a good idea. Here is an area where the private sector can be of assistance if companies demonstrate their compliance to a food safety standard through an accredited certification program such as SQF. SQF requires that a company be in compliance with the regulatory requirements of both the exporting and importing country, in addition to the standards set by the retail buyers. Although not intended to be a substitute for government oversight, the private sector can add an additional layer of "policing" for products entering into the U.S. food supply. We would need to see the details of FDA's plan as many factors such as tracking compliance, the security of the company's supply chain, etc., would need to be taken into consideration. It would also be important to coordinate these efforts with USDA, Customs and other Agencies.

CONTINUED OPERATION OF FDA FIELD LABORATORIES

We fully support the continued operation of FDA Field Laboratories. These labs provide needed scientific support and credibility. One consideration for reform would be to determine the capabilities at each of the labs and designate certain ones as a "center of excellence" for a selected type of test or procedure.

USER FEES ON IMPORTED FOODS AND DRUGS

Although we strongly agree that FDA and its food safety programs are underfunded, FMI cannot support the proposal to impose user fees on imported foods and drugs. Not only will this raise the cost of food, but we also consider such fees to be a conflict of interest by the Agency in charge of inspecting and raising money for its own budget. We are unsure what direct impact user fees on food will have on our retailers and have asked them to review this.

RESTRICTING THE PORTS OF ENTRY FOR IMPORTED FOODS

FMI and its members are very concerned about the provision to restrict U.S. ports of entry for imported foods. We understand that the provision is modeled on the USDA system, but when applied to the broad spectrum of products under FDA supervision, it becomes unworkable and prohibitively expensive.

Mr. Chairman, U.S. ports are already busy to the point of congestion. And there is increasing concern in the retail community that the growth in port capacity is simply not keeping pace with the growth in demand. Limiting the number of ports food can enter into through legislation will not only aggravate congestion and delays, it could also increase the cost of food for the American consumer.

As you know, quite a bit of food that enters the country is perishable and needs to be shipped, sold and consumed in a limited period of time. A shipment of apples

or pears cannot be left sitting on a dock for an extended period of time. As delays increase, so does shrinkage, waste and—unfortunately—costs.

FMI is particularly concerned about the ability of these ports to handle the spike in imports of perishable commodities during the winter months, when the U.S. growing season for a number of products is over. The only way to meet demand for certain fruits and vegetables during this period is through imports. But again, delays at the port-level threaten our ability to bring these products to market in a timely manner and increase costs. And unfortunately, it is the American consumer who bears the brunt of this increase, particularly poorer Americans. As prices rise, consumers do not just pay more, they often consume less. When talking about fruits and vegetables, this is clearly not the desired outcome.

I would also note that there are significant costs involved with closing ports of entry and shifting freight elsewhere. Food importers that have distribution centers at or around the ports that will no longer accept food will have to move their operations and face the expense of building and setting up new centers. Long-established supply lines will have to be reworked, which can be both expensive and costly. And the impacted districts are likely to see a decline in employment and tax revenues as the importers shift employees to their new operations.

As an example of the disruption of trade, ninety percent of seafood shipments enter through 14 ports (Los Angeles; New York; Miami; Portland ME; Seattle; Boston; Norfolk; Tampa; Savannah; San Francisco; Houston; Philadelphia; New Orleans; and, Nogales, AZ), according the National Fisheries Institute. Of the 14 ports, only four are co-located with FDA laboratories: New York, Seattle, Savannah (Atlanta laboratory) and San Francisco. This would render states such as Florida unable to accept seafood products.

Country of Origin Labeling

Section 6of the bill would require labeling to identify the country of origin of food, drugs, and medical devices and would require FDA to promulgate final regulations within 180 days of the law's enactment that would likewise take effect within 180 days of enactment. We have several concerns with this provision in terms of timing, necessity and efficacy.

In terms of timing, based on our experience with the regulations for country of origin labeling for seafood alone, we can report that the development of regulations for the 80 percent of the food supply that falls within FDA's jurisdiction within 180 days would be virtually impossible. Moreover, the Tariff Act already requires imported food products to bear country of origin labeling, leaving open the question of what additional service this provision would apply and what standard the bill intends for the industry to use. That is, given the breadth of countries that may be involved in sourcing ingredients (and ingredients of ingredients) for processed foods, what country should be listed as THE country of origin for any given food product if a different standard is to apply? More importantly, however, identifying one—or twenty—countries from which food or its ingredients derives does not enhance the safety of the underlying food product. The resources that would be required to develop and implement the complex system that such labeling would entail would be far better spent on measures that would actually have the potential to improve the safety of the product.

Certifying Foreign Governments and Companies

The concept of certifying foreign governments and companies by FDA sounds promising as a nod toward a risk-based system, but it gives rise to many questions. For example, how would FDA implement a mandate of this magnitude? FDA does not have the financial or personnel resources to take on this endeavor even with the $300 to $500 million projection from the user fee provision of the bill. Before moving forward with this, FDA, USDA and others should map out a plan for how such a system might work.

We would also encourage the committee to remember that a number of developing countries may face severe difficulties in meeting the requirements of any certification programs. At the very least, both FDA and USDA need to be prepared to provide both technical and monetary aid to support capacity building in those areas.

We agree that foreign governments should be held accountable for demonstrating that they have regulatory systems in place equivalent to those in the U.S.; evaluating other government programs might be a more realistic starting place. We would also suggest using some of the existing resources of USDA, APHIS and others who are already in those countries and ask them to take part in inspections and possible certifications.

Adequate Testing of Processed Food Products

Providing adequate testing of processed food products post-production presents challenges because there is no objective way to ensure testing is truly "adequate." It is more effective to implement and monitor prevention programs, and use testing as a measure of how well those food safety programs are performing. This approach supports risk-based systems where resources are directed toward making sure products are safe through process control, such as HACCP (Hazard Analysis Critical Control Points) and certified third party audit programs.

CARBON MONOXIDE LABELING FOR MEAT, POULTRY AND SEAFOOD

We do not support the proposed provision for carbon monoxide labeling of meat, poultry and seafood. Both FDA and USDA have recognized that carbon monoxide is generally recognized as safe for its intended purpose. We are not aware of any scientific basis for singling out this one technology for labeling.

Thank you for the opportunity to testify. We appreciate the efforts set forth in H.R. 3610 to help restore confidence in the food safety system and reduce foodborne illness. We remain available to the committee for further discussion and information should you need it.

Mr. PALLONE. I think we only have about 6 minutes left, so I am going to recess. We only have two votes, so it should be about maybe 15, 20 minutes. Thank you. The subcommittee is in recess.

[Recess.]

Mr. PALLONE. The subcommittee will reconvene, and we left off with Ms. DeWaal.

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

Ms. DEWAAL. Thank you, Mr. Chairman. I am Caroline Smith DeWaal, and I direct the Food Safety Project for the Center for Science in the Public Interest. We represent over 900,000 consumers, both in the U.S. and Canada; and I need to tell you that last year consumer confidence in the safety of the food supply declined dramatically by 16 percent in just 1 year. Concerns about imported food was also very pronounced; and in July, 83 percent of shoppers expressed concern about food from China, and 61 percent were concerned also about food from Mexico. This concern is really, totally understandable given the fact that we have so many outbreaks and recalls last year from contaminated food.

For years CSPI has advocated for new, legal structure to modernize FDA's Food Safety Program, and we really congratulate the chairman on his leadership in introducing the Consumer Food Safety Act. Recently, the Bush administration and the food industry both agreed that the systems in place today are not sufficient to ensure the safety of imported foods. In fact, the food industry's Four Pillars Reform Proposal recognizes several essential areas for modernization. Such broad agreement clearly signals that the time is right for Congress to act on reforming the country's food safety laws.

Congress also appears poised to address this problem and to fund it adequately as just last week in the PDUFA legislation, you passed a sense of Congress that talked about the need to do this and Congress' commitment to it. And the emergence of coalitions like the Coalition for a Stronger FDA including groups which are traditionally estranged or on opposite sides of the table, consumer and industry organizations, this gives Congress a unique opportunity to appeal to many constituencies as it creates a modern food safety system.

Change is hard, but it has been done before and in many other countries. The United Kingdom reformed its food safety program and established the Food Standards Agency in 1999; and this agency has proven effective in reducing the incidents of food borne illness and in rebuilding public confidence. In fact, food borne illnesses declined 18 percent within the first 3 years of the new agency, and public confidence in the safety of the food supply rose from 44 percent to 60 percent. This change came after food scares, most notably from mad cow disease in the 1990s which led all sides to recognize both the need for change and built the momentum to reach workable compromises.

I believe that we are at the same nexus of crisis and consensus in this country that Britain faced in the 1990s and that the momentum for building a stronger food safety system is growing.

I have a number of specific comments with respect to Chairman Dingell's legislation, and they are mostly included in my written testimony. I do want to mention that the certification procedure in the bill has greatly improved from what was originally announced in August, but it does need to probably be fine tuned with some regular audits of foreign national programs, including inspections of facilities.

In addition I am concerned that the user fee proposal may distract from many important questions about legal authority, so I would hope that the user fees, if they are going to move forward, doesn't bog down the process.

The bottom line though is while this bill contains many excellent components, we believe that really to restore consumer confidence, Congress must go further and enact comprehensive legislation to address today's food safety hazards, both foreign and domestic. Preventive control systems implemented by the food industry and performance standards monitored and enforced by the Government must form the heart of needed reforms to FDA's legal structure. Only such comprehensive reforms will protect the food supply and restore consumer confidence.

U.S. food safety laws are more than 100 years old and were never designed to deal with the modern issues such as escalating imports, bioterrorism, or tainted produce. Legislation is needed that creates a program that puts public health at the forefront of food safety. We urge Congress to take action before the next congressional election to modernize food safety laws and to fully fund our National Food Safety Program. Thank you.

[The prepared statement of Ms. Smith DeWaal follows:]

H.R. 3610, the Food and Drug Import Safety Act

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

Washington, DC
September 26, 2007

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 the 900,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Thank you for the opportunity to address this committee on H.R. 3610, the Food and Drug Import Safety Act. Last year, consumers' confidence in the food they purchase at restaurants and grocery stores declined by 16 percent, according to an annual survey of the Food Marketing Institute.[1] USA Today reported in July that 83 percent of shoppers were concerned about food from China, and 61 percent about food from Mexico.[2] And today the Food and Drug Administration's ability to protect the food supply is being questioned by consumers and Congress alike.

---

[1] Food Marketing Institute, *U.S. Grocery Shopper Trends 2007*, 66.
[2] Weise, E. *Buying only U.S. food is a tall order*, USA TODAY. July 10, 2007.

Each year 76 million Americans get sick, 325,000 are hospitalized, and 5,000 die from foodborne hazards in the United States, according to the Centers for Disease Control and Prevention (CDC). And with responsibility for 80 percent of food supply, FDA's food program is a critical element in reducing this public health burden. Since September 2006, a number of nationwide outbreaks and recalls exposed gaping holes in the safety net guarding U.S. consumers from contaminated food. Spinach contaminated with a deadly strain of *E. coli*; peanut butter with *Salmonella*; pet food with toxic chemicals – each of these tragedies has demonstrated a different problem with our system of regulating the food supply. It is time for Congress to take action to better ensure food safety and to protect Americans from these preventable illnesses and deaths.

Americans Are at Risk From Imported Foods

In recent weeks, both the Bush Administration and the food industry itself have admitted that the systems in place today are not sufficient to ensure the safety of imported foods. Yet the average American eats about 260 pounds of imported foods, accounting for about 13 percent of our annual diet.[3] U.S. food imports for 2006 reached a record value of $65.3 billion, roughly $6 billion higher than the year before.[4] Overall, U.S. imports of agricultural and seafood products from all countries have increased by nearly 50 percent over the last decade, and certain countries and commodities are showing exponentially greater increases. U.S. imports of Chinese agricultural and seafood products, for example, have increased almost 350 percent in the same time period—an increase in value from $880 million in 1996 to over $4 billion in 2006.[5]

---

[3] Bridges, A. *Imported food rarely inspected*, USA TODAY, April 16, 2007.
[4] Nora Brooks, *U.S. Agriculture Ends Calendar Year 2006 with Record Trade: Exports at $71 billion, Imports at $65 billion*, U.S. Agricultural Trade Update Electronic Outlook Report from the Economic Research Service, Feb. 15, 2007, at 1.
[5] CRS Memorandum, *Food and Agricultural Imports from China*, June 6, 2007.

China is the sixth leading foreign supplier of agricultural products to the U.S. When seafood imports are considered, China rises to the third ranking supplier of all food products to this country—startling placement considering the spate of recent Chinese food safety scares. But China is not alone. U.S. agencies cannot depend on a large number of countries to ensure the safety of imports because many countries have inadequate regulations and under-funded food safety agencies that do not have the ability to regulate food entering the global market.[6]

The announcement in June banning certain farmed seafood products from China was hardly surprising. Evidence of contamination from state testing had been reported in the media for some time.[7] Moreover, the Food and Drug Administration (FDA) admitted at its June 28, 2007, press briefing that "investigators have found consistent problems with farmed fished products produced in China and exported to the U.S."[8] In fact, products from Chinese importers have been placed under periodic alert for the last six years.[9]

In May, FDA issued a consumer warning for pufferfish, mislabeled as monkfish, from China.[10] After two people in Chicago were sickened by eating fish soup made with the purported monkfish, laboratory testing confirmed that the fish contained life-threatening levels of tetrodotoxin, one of the most hazardous toxins found in food. In fact, poisoning by tetrodotoxin is one of the most violent intoxications from marine species. Pufferfish can contain levels of

---

[6] World Health Organization, *General Information about FOS Capacity Building Activities,* at http://www.who.int/foodsafety/capacity/general/en/index.html.

[7] *Dangers of Imported Shrimp*, CBS NEWS, Sept. 17, 2004. (Last accessed Sep. 23, 2007, at http://www.cbsnews.com/stories/2004/09/17/eveningnews/consumer/main644203.shtml.) In addition, several states—including Louisiana and South Carolina—introduced legislation calling on the federal government to improve food import restrictions after testing in five southern states detected chloramphenical in samples of imported shrimp from China. For an example see H. 3708, 115th Gen. Assemb., (S.C. 2003-04).

[8] Transcript of FDA Press Conference on Seafood Imported from China (June 28, 2007) at 5 (quoting Margaret Glavin, Associate Commissioner of Regulatory Affairs), *available at* http://www.fda.gov/bbs/transcripts/transcript062807.pdf.

[9] *Id.* at 13 (further quoting Glavin, "The most - in recent years the longest alert was put on in 2001 which was an import alert for products from certain processors in China. So that's - it - this goes back before 2001 because we were gathering data before that that led to that alert.")

[10] Press Release, FDA Warning on Mislabeled Monkfish, (May 24, 2007) *available at* http://www.fda.gov/bbs/topics/NEWS/2007/NEW01639.html.

tetrodotoxin sufficient to produce rapid and violent death, as quickly as 20 minutes after consumption.[11] It appears that lethal pufferfish were illegally imported to the U.S. from China mislabeled as monkfish.

These events followed soon after the most-widely discussed food safety catastrophe this year. Beginning in March 2007, pet food manufacturers recalled more than 100 brands of cat and dog food after receiving complaints about cats and dogs developing sudden kidney failure from eating pet food. For weeks after, new brands were pulled from shelves as processors tracked the tainted wheat gluten.

FDA investigations revealed that the pet food that sickened so many pets was contaminated with melamine and cyanuric acid, two industrial chemicals. These toxins were found in wheat gluten imported from China and used in many pet food and animal feed products manufactured in the U.S. Chinese wheat gluten producers are thought to have intentionally contaminated the product with melamine to give the appearance of increased protein content. According to an investigation by *The New York Times*, cutting grain products with melamine to fool protein tests is apparently common practice among producers in China, yet the contaminated wheat gluten passed across our borders without being found or stopped by the FDA.[12]

While these problems with Chinese imports have been profiled most recently, China is certainly not the only example of FDA's failure to guard against contaminated food imports. Many human illnesses have been linked to imported produce. Americans enjoy a variety of fresh fruits and vegetables year-round, and supplying this demand is done by importing produce from around the world. In fact, one-quarter of our fruit, both fresh and frozen, is imported. But lack

---

[11] U.S. Food and Drug Administration *Bad Bug Book*, referenced June 11, 2007, *at* http://www.cfsan.fda.gov/~mow/chap39.html.
[12] Barboza D and Barrionuevo A. *Filler in Animal Feed Is Open Secret in China*, N.Y. TIMES, April 30, 2007.

of adequate border controls has lead to numerous large and occasionally deadly outbreaks linked to imported food. Here are some examples:

- In Fall 2003, a major Hepatitis A outbreak linked to raw green onions used in restaurant salsa sickened 555 people in Pennsylvania, killing three of them. Preliminary traceback by FDA indicated that green onions supplied to the restaurant were grown in Mexico under conditions where contamination with human waste was likely. Green onions from this area were also linked to outbreaks in Georgia, Tennessee, and North Carolina that occurred earlier that fall.[13]

- Three multistate outbreaks of *Salmonella* serotype Poona infections associated with eating cantaloupe imported from Mexico occurred in the spring of consecutive years during 2000-2002. FDA conducted traceback investigations and determined that the cantaloupes were from farms in Mexico. FDA conducted on-farm investigations in Mexico and found many possible sources of contamination, including sewage-contaminated irrigation water; processing (cleaning and cooling) with *Salmonella*-contaminated water; poor hygienic practices of handlers; pests in packing facilities; and inadequate cleaning and sanitizing of equipment that came in contact with the cantaloupe.[14]

- In 1997, over 256 cases of Hepatitis A were associated with the consumption of frozen strawberries. The strawberries were harvested in Mexico and processed and frozen in southern California before they were distributed by U.S. Department of Agriculture (USDA) to school lunch programs in several states, including Michigan, Wisconsin, Louisiana, Maine and Arizona.[15]

- In 1996 and 1997, thousands of people became ill in both the U.S. and Canada from a parasite, *Cyclospora,* on raspberries grown in Guatemala.[16] Illness associated with *Cyclospora* includes watery diarrhea and persistent fatigue, which can persist for a month or longer if untreated.[17] *Cyclospora* is chlorine-resistant and can be transmitted through water or from infected handlers.

---

[13] V Dato et al., *Hepatitis A Outbreak Associated with Green Onions at a Restaurant—Monaca, Pennsylvania, 2003*, 52 MMWR 1155-57 (2003).

[14] SM Anderson et al., *Multistate Outbreaks of Salmonella serotype Poona Infections Association with Eating Cantaloupe from Mexico—United States and Canada, 2000-2002.* 51 MMWR 1044-47 (2002).

[15] Centers for Disease Control, *Hepatitis A Associated with Consumption of Frozen Strawberries—Michigan, March 1997*, 46 MMWR 288-95 (1997).

[16] J Hoffman et al., *Update: Outbreaks of* Cyclospora *cayetanensis Infection – United States and Canada, 1996*, 45 MMWR 611-12 (1996).

[17] CDC Fact Sheet for Health Professionals, Cyclospora *Infection—Information for Healthcare Providers, available at* http://www.cdc.gov/ncidod/dpd/parasites/cyclospora/healthcare_cyclospora.htm.

A Broken Food Inspection System Doesn't Do Enough to Ensure the Safety of Imported Foods

As I noted in my testimony before the Subcommittee on Oversight and Investigations in July, twelve federal agencies share responsibility for regulating food, resulting in a chaotic and inefficient system.[18] The two principal inspection agencies, FDA and USDA, each operate import programs purportedly responsible for ensuring the safety of imported foods, but the programs are not comparable, not adequate, and, in many ways, not reliable. Further, import programs sometimes overlap, but resources are not shared. For example, USDA and FDA inspect food imports at 18 ports, but they do not share inspection resources at these locations. In fact, according to a recent GAO report, some USDA-approved import inspection facilities store FDA-regulated products, and although USDA maintains a daily presence at these facilities, FDA products can languish at the port waiting for FDA inspectors.[19]

While USDA has a fairly intensive program for ensuring the safety of imported meat and poultry products, the FDA program is anything but comprehensive. FDA's procedures are much less stringent and much less effective. FDA does not evaluate national programs to determine equivalence or visit foreign countries to verify compliance with food safety procedures. FDA's Import Program System Information website does not delineate an audit system for imported product and directs users to cross-reference the U.S. Customs Office for additional requirements.[20]

It is currently estimated that FDA only inspects one percent of food at the U.S. border, so it is frankly surprising that catastrophes like the recent pet food contamination haven't happened

---

[18] National Research Council, *Ensuring Safe Food From Production to Consumption*, 26 (1998)
[19] GEN. ACCT. OFF. REP. NO. GAO-07-449T, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Needed Attention to Fragmented System*, (Statement of David M. Walker, Comptroller General of the United States) (Feb. 8, 2007).
[20] FDA OFFICE OF REG. AFFAIRS, IMPORT PROGRAM SYSTEM INFORMATION, (Sept. 21, 2004), *at* http://www.fda.gov/ora/import/ora_import_system.html.

more often. Although imports of FDA-regulated foods have more than doubled in the last 7 years—from 4 million shipments in 2000 to approximately 9 million shipments in 2006—the rate of inspections has remained woefully low.[21] Of these 9 million shipments, only 0.2 percent were analyzed in a laboratory as part of their inspection process.[22]

Although products enter the U.S. through 361 ports, at the peak of its funding, FDA had inspectors on-site at only 90 of these ports. Today the agency likely covers half that number.[23] To increase inspections of FDA-regulated imports to 10 percent (still a strikingly low figure) would require an additional 1,600 full-time inspectors. To double that figure to 20 percent import inspection would require 3,200 full-time inspectors, according to FDA estimates given to the House Agriculture Appropriations Subcommittee in 2001.

Food Industry Recognizes Need for Stronger Preventative Program

Last week, the food industry issued "Four Pillars", a reform proposal that calls for a multi-tiered approach to ensuring the safety of imported foods.[24] Its formula—establishing mandatory and voluntary import quality assurance programs, improving oversight programs in the countries of origin, and providing FDA with better resources and clearer authority—signals areas of agreement on which solutions to our food safety problems can be built.

Change is hard, but it has been done before, and in many different countries. The United Kingdom reformed its food safety program to establish a single Food Standards Agency in 1999. That agency has proven effective in reducing the incidence of foodborne illness and building public confidence. Foodborne illnesses declined 18 percent within the first three years of the

---

[21] *Food Imports Often Escape Scrutiny*, N.Y. TIMES, May 1, 2007.
[22] *Id.*
[23] *The State of American Labor,* CNN: Lou Dobbs Tonight (Sept. 3, 2007) (Transcript available at http://transcripts.cnn.com/TRANSCRIPTS/0709/03/ldt.01.html).
[24] *A Commitment to Consumers To Ensure the Safety of Imported Foods: Four Pillars of Public-Private Partnership*, Grocery Manufacturers Association, Sept. 18, 2007, *at* http://www.gmabrands.com/news/docs/newsrelease_p.cfm?DocID=1773.

new agency, with a reduction from 37 percent to 6 percent in the occurrence of eggs and poultry infected with *Salmonella.* Public confidence in the safety of the food supply rose from 44 percent to 60 percent.[25] The change came after food scares in the 1990s led all sides to recognize the need for change and that built momentum to reach a workable compromise. I believe we are at the same nexus of crisis and consensus in this country that Britain faced in the 1990's and that the momentum for reform is building.

Congress also appears ready to adopt a modern regulatory oversight program and fund it adequately to fulfill its mission and in fact, just last week passed a Sense of Congress, stating this intent. And the emergence of coalitions of traditionally estranged consumer and industry organizations, like the Coalition for a Stronger FDA and the FDA Alliance, gives Congress a unique opportunity to appeal to many constituencies as it rebuilds the agency. But the need is great. In fact, the industry 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 today.

Food and Drug Import Safety Act Is the First Step to a Solution

The Food and Drug Import Safety Act of 2007 is an important contribution to addressing the problems in the food import system. Designed to bolster FDA resources in the area of import inspection, the bill directs FDA to create and implement more rigorous import controls. Additionally, it increases funding for research, limits the number of ports of entry for food items, and continues the operations of field laboratories. These are steps that improve the security and safety of the food supply. Even so, there are three areas of the bill—the user fee, recall and certification provisions (sections 3, 10 and 11)—that need additional attention.

---

[25] John Krebs, *Establishing a Single, Independent Food Standards Agency: The United Kingdom's Experience*, 59 Food & Drug L.J. 3, 390-91 (2004).

The Coalition for a Stronger FDA, consumer groups and the food industry have all recognized the need to provide FDA with more resources. The user fee in section 3 authorizes $500 million in additional resources for import inspections. That could support inspecting over 10 percent of imports, which would be a considerable improvement over the current practice of inspecting only one percent of food items crossing the border. The money cannot be accessed for other components of FDA's program, as it is fenced off for increases in import inspections and research. The user fee funding mechanism, therefore, does not address FDA's inadequate inspection of the domestic food supply resulting in last year's major outbreaks from spinach, peanut butter and pet food ingredients. The Committee should ensure that FDA has the flexibility to direct resources beyond the user fee collections where needed for domestic as well as import food safety activities.

In general, industry and consumer advocacy groups oppose user fees,[26] albeit for different reasons.[27] CSPI does not take a position on the user fee, but does have concerns about the timing and impact of this provision on efforts at achieving comprehensive reform of the food safety system. We should be conscious of the potential for defusing the consensus for reform by changing the focus from food safety onto a fight over user fees. Also, if user fees are going to be the funding mechanism for reform, they would be better applied to a more comprehensive bill.

The lack of mandatory recall authority at FDA has been a long-standing concern of food safety advocates. Therefore, the mandatory recall provided in section 10 is a welcome improvement to the food law. Most Americans do not realize that the agencies responsible for

---

[26] Anna Edney, *Energy and Commerce Dems Introduce Food Safety Bill*, CONGRESSDAILYAM, Sept. 21, 2007, at 15.

[27] *See* Anna Edney, *Senator to try incremental overhaul of food safety laws*, CONGRESSDAILY, June 1, 2007 (quoting Susan Stout, vice president of federal affairs for the Grocery Manufacturers Association, that "the jury is still out on user fees for inspections because the industry does not directly benefit from inspections"), and Anna Edney, *DeGette Looks to Add Food Safety Bills to Dingell Measure*, CONGRESSDAILYAM, Sept. 5, 2007 (stating consumer groups "fear user fees give industry too much influence over inspectors").

ensuring the food they eat is safe do not have the authority to order unsafe food removed from the market. CSPI would like to work with the Committee to strengthen the recall authority further by requiring notification to consumers in affected areas.

As originally drafted the Food and Drug Import Safety Act required each foreign food facility to be certified by FDA as meeting United States' standards. More than 188,000 foreign food facilities have registered with FDA under the Public Health Security and Bioterrorism Preparedness and Response Act as of July 3, 2007.[28] Certifying and reviewing so many importers could be unmanageable for FDA. The approach taken in the final version of the bill permits FDA to certify countries that have food safety standards at least as protective as United States standards, and an effective program to monitor and enforce those standards. Missing from the certification procedure, however, is a regularly scheduled auditing requirement. The bill provides authority to conduct inspections of foreign facilities, but does not mandate an on-site audit of foreign programs, including the inspection of facilities, prior to certifying that countries meet United States' standards. In-country inspections before meat and poultry exporters can enter are part of USDA's process for verifying a country has implemented the food safety protocols it claims to have in place. Requiring FDA to conduct similarly stringent evaluations is essential to preventing unsafe foods from ever arriving at the border.

Modernizing the Law: The Safe Food Act

While the Food and Drug Import Safety Act contains many excellent components, to restore consumer confidence, Congress must build upon the growing consensus and enact comprehensive legislation at least comparable to the Safe Food Act.[29] The Act would streamline

[28] FDA REGISTRATION OF FOOD FACILITIES, July 3, 2007, *available at* http://www.cfsan.fda.gov/~furls/ffregsum.html.
[29] H.R. 1148, The Safe Food Act of 2007, 110th Cong. (2007). This bill was introduced February 15, 2007 by Senator Durbin and Representative DeLauro

food safety at the federal level by consolidating multiple federal agencies at FDA, USDA, and EPA that currently oversee food safety to create a unified, science-based Food Safety Administration. Most importantly, the bill would modernize the outdated inspection system and give clear authority for on-farm programs. It relies on preventative control systems implemented by the industry and performance standards monitored and enforced by the government.

The Safe Food Act gives the Food Safety Administration the authority to evaluate and certify a country's food safety program to ensure that it is "at least equivalent to the food safety program in the United States."[30] The Administration would have the authority to audit the certified countries and would ensure continued compliance at least every five years.[31] The proposed law also requires routine inspections of foreign food imports to ensure that the food is safe and properly labeled. Under the Safe Food Act, foods would no longer have an "open visa" to enter the U.S. without inspection or regulation.

The Safe Food Act further mandates the establishment of a national system for "tracing food and food producing animals from point of origin to retail sale."[32] The Act would allow companies to issue voluntary recalls should their product be deemed unsafe, but also grants authority for the Food Safety Administration to issue a mandatory recall if the company fails to do so. This will ensure quick removal of contaminated products from the market and increase consumer confidence in the food supply.

The Safe Food Act creates a food agency with the necessary authority to fulfill its mission to put safe food on America's tables, a recommendation made by the National Academy of Sciences in 1998. It is a comprehensive approach that would modernize our antiquated food

---

[30] *Id.*
[31] *Id.*
[32] *Id.*

laws. It would address each of the problems we experienced last year, from tainted spinach and peanut butter to contaminated imports.

The Act would help to restore consumer confidence through a strong national program, science-based decision making, and effective, honest public communication. The food industry remains the first line of defense, but the Act recognizes that effective industry programs require government monitoring and oversight.

U.S. food safety laws are more than a century old and were not designed to deal with modern issues such as escalating imports, bioterrorism, or tainted produce. The September 11, 2001, terrorist attacks demonstrated the need for enhanced national security, and the recent outbreaks serve as a reminder that much more must be done to protect the food supply. The Safe Food Act draws from these recommendations and creates a program that puts public health at the forefront of food safety in America. We urge Congress to take action this year to modernize food safety laws in the U.S. and to fully fund federal food safety programs.

Mr. PALLONE. Thank you. Dr. Goldhammer.

STATEMENT OF ALAN GOLDHAMMER, DEPUTY VICE PRESIDENT, REGULATORY AFFAIRS, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Mr. GOLDHAMMER. Thank you very much, Chairman Pallone. It is a pleasure to return to the subcommittee and talk about this important issue. PhRMA looks forward to continueing to work with the full committee to ensure patient safety because patients and their healthcare providers quite reasonably expect that our medicines will safely and effectively treat the diseases that they are diagnosed with. American patients trust that the drugs dispensed for their conditions are not counterfeit, and our companies obviously don't want patients getting counterfeit medicines because such medicines could result in effectual or even dangerous medical outcomes.

The Prescription Drug Marketing Act which originated with this committee was a critical piece of consumer legislation passed as a result of Congressional concerns regarding the integrity of the drug distribution system that existed at that time. The passage of this legislation established the closed distribution system that we have today. The PDMA, coupled with the exacting regulatory requirements of the FDA helps to minimize the possibility of a consumer receiving a counterfeit drug. The pharmaceutical industry is already intensively regulated. Our companies manufacture products following exacting standards that have been reviewed and approved by the FDA. They employ extensive quality systems to assure that innovative medicines provide consistent, positive health outcomes. However, even the most effective medicines cannot help patients if those medicines were compromised by loopholes or breakdowns in the pharmaceutical distribution system which could provide opportunities for diversion or counterfeiting.

The remainder of this testimony will focus on the FDA regulatory system that assures quality, steps that manufacturers take to implement quality systems, and finally some thoughts about what policymakers might consider to further secure the pharmaceutical supply chain.

Throughout the drug development process, our companies focus on the quality of the product and put into place manufacturing controls that result in a medicine that is consistent from lot to lot with respect to purity and potency. Information is collected on the product's stability so the patient may be assured, the expiration date is based on sound science, and that the medicine, if used within this period of time, will provide the therapeutic dose the doctor has prescribed. All of this information is submitted to the FDA for review in the license application. FDA not only reviews all this data but conducts the preapproved inspection in the manufacturing facility to ensure that it is in compliance with good manufacturing practice regulations.

These GMPs cover the quality control unit, buildings and facilities, equipment, control of components and drug product containers, enclosures, production and process controls, packaging and labeling control, clothing and distribution, laboratory controls, record and reports, and finally, returned and salvaged drug products.

When companies use outside vendors or contract manufacturers for any components or parts of the finished medicine, extensive qualification and standards testing regimes are put in place to ensure the materials received meet the standards established by the pharmaceutical company. Companies regularly audit these suppliers to make sure that source materials are produced in a manner consistent with the specifications outlined in the manufacturing agreements. Quality assurance is also an ongoing part of the business. It does not stop when the NDA is approved and production commences. Companies have a regulatory responsibility to continuously monitor so that each lot released in the commercial distribution system meets the FDA approved specifications.

While PhRMA believes the United States drug distribution system is the safest in the world, there are some steps we have advocated that will further secure the pharmaceutical supply chain. First, we need increased requirements for repackagers. PhRMA believes that FDA should reassess its policies and procedures regarding repackaging operations. Repackaging has been identified as a weak spot in the drug distribution system that can be used as an entry point and distribution center for diverted and counterfeited drug products. Repackagers remove drug products from their original packaging and labeling thereby destroying any counterfeit-resistant technologies employed by the original manufacturer. Consequently, additional oversight is necessary to ensure that repackaged drug products are authentic and not compromised by such repackaging operations.

Second, we believe the Federal requirements for wholesalers and distributors should be strengthened. We support efforts to strengthen licensure requirements for wholesalers and distributors. Recent investigations in Florida have identified systemic weaknesses in the oversight of the wholesale drug industry, and there have been many newspaper articles detailing this as well. These weaknesses permit individuals, even those with prior felony convictions, to obtain wholesale licenses for operations that deal in diverted and counterfeit drug products.

Third, we believe that there should be increased criminal penalties for counterfeiting activities. We believe that the criminal penalties for counterfeiting prescription drug products must be significantly increased. The current penalty under the Federal Food, Drug, and Cosmetic Act, a maximum of 3 years' imprisonment, does not reflect the serious public health risks associated with counterfeit drugs or serve as an adequate deterrent to prospective counterfeiters. We thus support increasing the maximum criminal penalty for counterfeiting drug products from 3 to 20 years imprisonment.

We look forward to working with the committee as you move forward with this important legislation. Thank you very much.

[The prepared statement of Mr. Goldhammer follows:]

STATEMENT OF ALAN GOLDHAMMER

Thank you Mr. Chairman and members of the Energy and Commerce Committee. My name is Alan Goldhammer, Ph.D., and I am the deputy vice president for regulatory affairs at the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade association representing the leading research-based pharma-

ceutical and biotechnology companies. We are pleased to have been invited as part of this discussion, and look forward to continued work with the committee to ensure patient safety.

PhRMA members alone invested an estimated $43 billion in 2006 in discovering and developing new medicines, and patients and their health care providers quite reasonably expect these medicines to safely and effectively treat the diagnosed medical condition. America's patients trust that the drugs dispensed for their conditions are not counterfeit. Pharmaceutical companies obviously don't want patients getting counterfeited medicines, because such medicines could result in ineffectual or even dangerous medical outcomes.

The Prescription Drug Marketing Act of 1987 (PDMA), was a critical piece of consumer legislation passed as a result of Congressional concerns regarding the integrity of the drug distribution system that existed at the time. The passage of this legislation established the closed distribution system that we have today. The PDMA coupled with the exacting regulatory requirements of the Food and Drug Administration (FDA) helps minimize the possibility of a consumer receiving a counterfeit drug.

Pharmaceutical companies manufacture products following exacting standards that have been reviewed and approved by the FDA. They employ extensive quality systems to assure that innovative medicines provide consistent positive health outcomes. However, even the most effective medicines cannot help patients if those medicines are compromised by loopholes or breakdowns in the pharmaceutical distribution system, which could provide opportunities for diversion and counterfeiting. The remainder of this testimony will focus on the FDA regulatory system that assures quality, the steps manufacturers take to implement quality systems, and finally some thoughts about what policy makers might consider to further secure the pharmaceutical supply chain.

Throughout the drug development process, pharmaceutical companies focus on the quality of the product and put in place manufacturing controls that result in a medicine that is consistent from lot to lot with respect to its purity and potency. Information is collected on the product's stability so that the patient can be assured that the expiration date is based on sound science and that the medicine if used within this period of time will provide the therapeutic dose the doctor has prescribed. All of this information is submitted to the FDA for review in the New Drug Application (NDA) (or Biologics License Application (BLA) for biologics and biotechnology products). FDA not only reviews all of this data but also conducts a pre-approval inspection of the manufacturing facility to insure that it is in compliance with Good Manufacturing Practice (GMPs) requirements as outlined in 21 C.F.R. Parts 210 and 211.

The GMPs cover the quality control unit; buildings and facilities; equipment; control of components and drug product containers and closures; production and process controls; packaging and labeling control; holding and distribution; laboratory controls; records and reports; and finally returned and salvaged drug products. When companies use outside vendors or contract manufacturers for any components of the finished medicine, extensive qualification and standards testing regimes are put into place to assure that the materials received meet the standards established by the pharmaceutical company. Companies regularly audit their suppliers to make sure source materials are produced in a manner consistent with the specifications outlined in the manufacturing agreement(s).

Quality assurance is an ongoing part of the business; it does not stop when the NDA is approved and production commences. Companies have a regulatory responsibility to continuously monitor so that each lot released to the commercial distribution system meets the FDA approved specifications.

While PhRMA believes that the Unites States drug distribution system is the safest in the world, there are some steps that we have advocated that we believe will further secure the pharmaceutical supply chain.

1. Increase Requirements for Repackagers. PhRMA believes that FDA should reassess its policies and procedures regarding repackaging operations. Repackaging has been identified as a weak spot in the drug distribution system that can be used as an entry point and distribution center for diverted and counterfeit drug products. Repackagers remove drug products from their original packaging and labeling, thereby destroying any counterfeit resistant technologies employed by the original manufacturer. Consequently, additional oversight is necessary to ensure that repackaged drug products are authentic and are not compromised by repackaging operations. PhRMA believes that FDA could better regulate the authenticity and quality of repackaged drug products if it had authority to require prior approval of repackaging operations. At a minimum, FDA should increase its inspections of repackagers and, where appropriate, initiate enforcement action. In addition, repackagers

should be subject to the same requirements regarding overt and covert counterfeit resistant technologies as original manufacturers.

2. Strengthen Federal Requirements for Wholesalers/Distributors. PhRMA supports efforts to strengthen the licensure requirements for wholesalers and distributors. Recent investigations, particularly by the Florida Grand Jury and the Washington Post, have identified systemic weaknesses in the oversight of the wholesale drug industry in many states. These weaknesses permit individuals, even those with prior felony convictions, to obtain wholesaler licenses for operations that deal in diverted and counterfeit drug products. PhRMA supports efforts by Florida and Nevada to strengthen requirements for the licensure of wholesalers by, for example, requiring the posting of a substantial performance bond (e.g., $100,000) and conducting detailed pre-licensure background checks and facility inspections. PhRMA believes, however, that licensure requirements should be strengthened consistently across all states to prevent diverters and counterfeiters from re-locating to states without strong licensure requirements. This can best be accomplished through revisions to 21 U.S.C.0 § 503(e)(2) specifying higher minimum standards for state licensing of drug wholesalers and distributors similar to those currently in place in Florida and Nevada. FDA also should review state requirements for the licensure of wholesalers to ensure that they meet any enhanced minimum Federal regulatory requirements.

3. Increase Criminal Penalties for Counterfeiting Activities. PhRMA believes that the criminal penalties for counterfeiting prescription drug products must be significantly increased. The current penalty under the Federal Food, Drug, and Cosmetic Act (FFDCA)—a maximum of three years imprisonment—does not reflect the serious public health risks associated with counterfeit drugs or serve as an adequate deterrent to prospective counterfeiters. PhRMA thus supports increasing the maximum criminal penalty for counterfeiting drug products from three to twenty years imprisonment. PhRMA also believes that criminal penalties should be imposed against entities that create a market for diverted and counterfeit drug products by purchasing drug products without adequate due diligence into the source and authenticity of such drugs. PhRMA thus supports making it a prohibited act under the FFDCA to purchase prescription drugs from a wholesale distributor without first obtaining and verifying the information provided on a drug pedigree.

Mr. PALLONE. Thank you, Doctor. Mr. Kubic.

STATEMENT OF TOM KUBIC, EXECUTIVE DIRECTOR, PHARMACEUTICALS SECURITY INSTITUTE

Mr. KUBIC. Thank you for this opportunity to provide comments concerning an issue of growing importance to all Americans, the safety and security of their medicines as well as their food.

Today there are trans-national criminal organizations who ignore regulations formulated by drug regulatory authorities and who regularly violate laws designed to ensure the integrity of medicines that are widely available here in the United States. They manufacture, they distribute counterfeit medicines indiscriminately without any regard to the current good manufacturing processes.

I hope that these discussions today will help lead to a better understanding that the risks facing the public today are indeed real. My name is Tom Kubic, and I am the executive director of the Pharmaceutical Security Institute. PSI is comprised of 24 security directors of the major manufacturers of pharmaceuticals. They have operations in more than 160 countries.

The goal of PSI is to support our members in their efforts to ensure the distribution of pharmaceuticals that are safe and effective. PSI's mission is to collect, to analyze, and to disseminate information about counterfeiting, theft, and the illegal diversion of medicines. This information is then shared with the authorities so that they can initiate appropriate investigations and activities. In my opening remarks, I just want to make a few statements about the

nature and extent of counterfeiting, the counterfeiting facts, if you will.

PSI conducts an annual assessment of the worldwide situation regarding counterfeit medicines. In the Fifth Annual PSI Situation Report, we found that many individual criminals and criminal organizations continue to be actively engaged in pharmaceutical crimes. The support of this statement is the fact that last year PSI reported 1,371 new incidents, roughly 22 percent as an increase over calendar year 2005. Throughout the year we added another 150 incidents that actually occurred in 2005, and the 2-year total exceeded 2,494, roughly 100 incidents around the world each and every month.

The increases in 2005 and 2006 were not an isolated trend. In fact, the 5-year trend line includes generally speaking double-digit increases in counterfeiting incidents around the world. Some would say this number of incidents is small. In fact, what we see is an increase in quantity of medicine and an even wider variety of medicines that being counterfeited. For example, in November 2006, in Mexico City itself at 14 locations, 11 tons of counterfeit medicines were seized. In July 2007, in Jakarta, Indonesia, 4½ tons of illegal medicines were seized. In contrast to 2006, when each incident had either one to 45 different drugs found that were counterfeit, in 2007 the Jakarta seizures, for example, 88 different types of medicines were counterfeited.

The numbers of countries experiencing counterfeiters remain about the same in 2006. There were 100, the preceding year it was 101. However, we have seen a concentration on fewer numbers of drugs with the exception of 2007. In 2006, 560 different types of medicines were counterfeited, and then in 2005, it was 687 different products.

Counterfeiting is no longer limited to the so-called lifestyle drugs. In fact, virtually every type of medicine has been determined to be counterfeited.

So what has been the law enforcement response? In calendar year 2006, worldwide there was an actual 10 percent reduction in counterfeit arrests. There were a total of 755 documented individuals arrested for this activity in over 56 different countries. While it was encouraging to see that the majority of these arrests occurred in the Asian region, fully 33 percent of the worldwide arrests, it was also important to note that those arrests, the largest category, was for manufacturing of counterfeit medicines versus the sale or distribution of counterfeit medicines.

In summary, the challenge of counterfeits, stolen, and diverted pharmaceuticals is fairly clear from the Situation Report. More incidents have occurred, fewer arrests have been made. Americans need to know that the U.S. markets have been, is now, and will continue to be an area that is of keen interest to these organizations. Their safety today is endangered whenever they venture outside of the closed system of acquiring their pharmaceuticals and they move into such bizarre places such as the Internet. Thank you.

[The prepared statement of Mr. Kubic follows:]

Testimony of Thomas T. Kubic
Executive Director of the Pharmaceutical Security Institute

Counterfeit Medicines - The Risks Are Real

I am pleased to have this opportunity to provide comments concerning an issue of growing importance to all Americans. I thank the Subcommittee members for devoting their valuable time to these hearing as together we explore the hidden aspects of the illegal counterfeiting of pharmaceuticals.

Today, there are transnational criminal organizations successfully ignoring regulations and violating laws designed to insure the integrity of the many life saving medicines widely available here in the United States. They easily manufacture and distribute counterfeit medicines indiscriminately and without regard to current good manufacturing practices. I hope these discussions will lead to a greater understanding that the risks facing the public are, indeed, real.

My name is Thomas T. Kubic and I am the Executive Director of the Pharmaceutical Security Institute, (PSI), a non-profit association based in the Washington D.C. area. The PSI members are the Security Directors from twenty-four pharmaceutical manufacturers with business operations in more than one hundred and sixty countries.

Prior to my association with the Institute, I acquired substantial investigative experience during my thirty year career as an FBI agent, supervisor, chief, inspector and Agent in Charge. As the Deputy Assistant Director, Criminal Division, I was responsible for the development

and implementation of the FBI's financial crimes and health care fraud programs which at that time, involved over 3,500 agents in the field.

The goal of PSI is to support its members in their efforts to insure the distribution of pharmaceuticals that are safe and effective. PSI's mission is to collect, analyze and disseminate information about the counterfeiting, theft and illegal diversion of medicines. This information is then shared with authorities so that they can initiate appropriate enforcement activities.

Because of the limited time, I want to focus my comments on defining for the Subcommittee the nature and scope of counterfeiting.

Counterfeiting Facts

PSI conducts an annual assessment of the worldwide counterfeiting situation. In the fifth annual report, "PSI - 2006 Situation Report," the Institute found that during 2006, many individual criminals and criminal organizations were actively involved in the counterfeiting, illegal diversion and theft of pharmaceuticals.

In support of this statement is the fact that PSI documented a record number of new incidents last year. There were 1,371 incidents of counterfeiting, illegal diversion and theft identified – a twenty-two percent (22%) increase in incidents reported to the Counterfeiting Incident System (CIS).

Also, continued collection identified 150 additional incidents from CY 2005, with a resulting revised total for that year of 1,123. Thus, for the first time the combined two-year total of incidents surpassed 2,400 – more than 100 incidents a month, as the incident total reached 2,494.

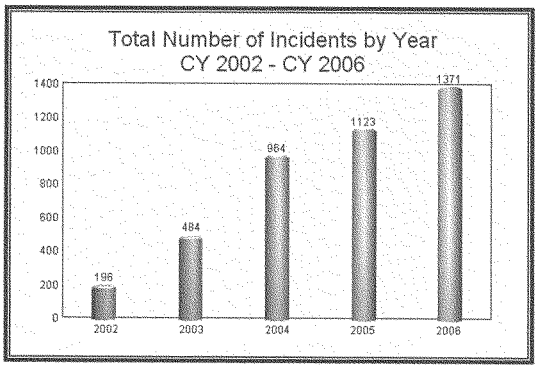


Chart One – "PSI 2006 Situation Report"

The increases seen in 2005 and 2006 were not isolated events. A five-year trend line has been graphically represented in my formal statement as Chart One. In general, since 2002, there has been at a minimum, an annual double digit increase in the recorded incidents.

While the number of incidents seems small, many involve an increasing quantities and wider varieties of medicines. For example, in November 2006, in Mexico City, eleven tons of counterfeit, stolen, expired and/or smuggled medicines were seized from fourteen locations.

In July 2007, four and one-half tons of illegal medicines were seized in Jakarta.

During 2006, the number of products found in a single incident ranged from one drug to forty-five drugs. In the Jakarta seizure, eighty-eight different drugs were seized. These seizures uncovered drugs from virtually every therapeutic category as the number of therapeutic categories detected ranged from one to eleven.

The analysis of CIS data reveals other trends which can be identified from the information collected.

First - the counterfeiting of pharmaceuticals was the most common type of incident documented in CIS. Counterfeiting was involved in eighty-six percent (86%) of the incidents. Ten percent (10%) involved illegal diversion of drugs and the remaining four percent (4%) concerned pharmaceutical thefts.

Second - the number of countries experiencing counterfeiting, theft and illegal diversion remained about the same at one hundred. The top three countries in terms of counterfeiting, illegal diversion and theft incidents were the China, Russia, and the United States. When considering only counterfeiting incidents, the top three countries were Russia, China, and Uzbekistan.

Third - counterfeiters appear to have concentrated their efforts on fewer types of drugs in 2006, a trend which was reversed during the first nine months of 2007. In the

1,371 incidents, 560 different pharmaceutical products were identified. This represented a reduction of nearly twenty percent (20%) from the 687 products identified in CY 2005.

The largest number of incidents occurred in the same therapeutic categories as last year – genito-urinary, anti-infectives and central nervous system.

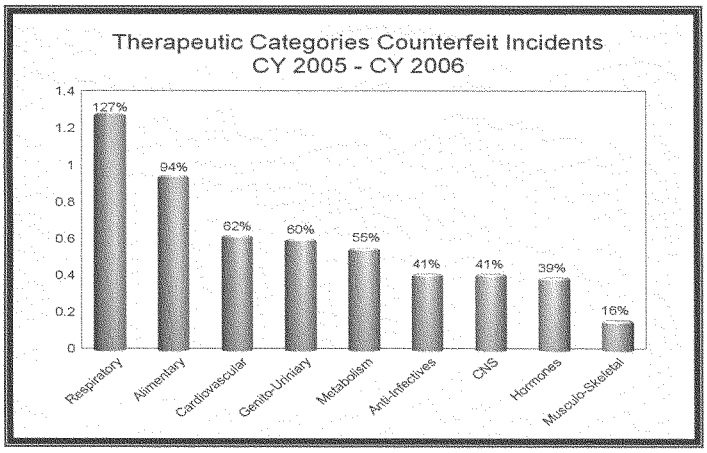


Chart Two – "2006 PSI Situation Report"

However, as illustrated in Chart Two, in terms of percentage increases, the respiratory therapeutic category led with the largest percentage increase at one hundred twenty-seven percent (127%). Alimentary medications were second with an increase of ninety-four percent (94%) and cardio vascular at sixty-two percent (62%).

Counterfeiting is no longer limited only to the so called "life style drugs" as virtually every type of medicine has been counterfeited.

Finally, CIS data disclosed that during CY 2006, reported law enforcement activity, when measured by "number of arrests made" decreased by ten percent (10%), when compared to CY 2005. There were 755 individuals arrested in fifty-six countries for crimes relating to counterfeiting, illegal diversion, and theft incidents.

While these reductions concerned us, there was a noticeable increase in arrests in the manufacturer category. If sustained, this trend will lead to diminished supplies of counterfeit medicines in the international marketplace.

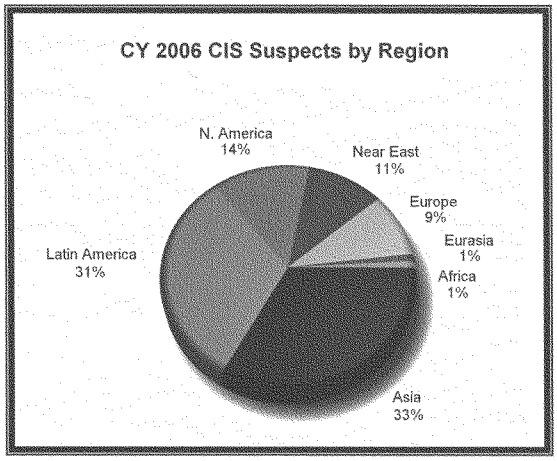


Chart Three – "PSI 2006 Situation Report"

In my written statement is a pie chart, designated Chart Three, which illustrates the relative percentage distribution of arrests by region. This chart shows that for the second year, the Asia region lead with thirty-three percent of the worldwide arrests; this is a particularly important fact since much of the counterfeit medicines are sourced to this region.

Trends in the Worldwide Response

The Institute analyzed two hundred and five public reports from a wide variety of sources to supplement CIS data concerning the extent of counterfeiting and to gauge the response by international organizations, national governments and manufacturers. In 2006 and continuing during 2007, the following major trends were identified:

Increased efforts at improved international coordination in the fight against counterfeits were initiated.

A greater number of international anti-counterfeiting events were sponsored by an increased number of organizations engaged in assessing the problem and devising strategies to address it. The World Heath Organization (WHO) emerged as the clear leader in the development of a major anti-counterfeiting effort, known as the IMPACT initiative, along with twenty international partners. Taking a broad approach, the WHO launched a comprehensive scheme to help national authorities safeguard their populations from counterfeit medicines. This effort was clearly the most significant endeavor of the

year and holds the promise of stemming the tide of counterfeit medicines.

The U.S. FDA, European Commission and the European Medicines Agency (EMEA) have agreed to increase cooperation in the area of pharmaceutical regulation. Additional public health priority areas, including counterfeit medicines, are high on their agenda.

Multi-lateral efforts progressed under the leadership of national drug regulatory authorities. In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) entered into an agreement with the government of the People's Republic of China and Sweden to stem importation of fake and substandard pharmaceuticals through their ports.

A better understanding of the global nature and extent of the sale and distribution of counterfeit products over the internet emerged.

The Austria-based International Narcotics Control Board (INCB) highlighted the threat of rogue online pharmacies which were found to be engaged in smuggling unlicensed drugs using bogus prescriptions.

The European Commission issued a warning that counterfeit weight loss drugs were being sold via several websites in March 2006. The warning underscored the European Commission's concern that criminals are taking advantage of the anonymity of the internet to sell fake,

adulterated and unlicensed medicines to an unsuspecting public.

The Irish Medicines Board (IMB) confirmed that forty percent of the enforcement cases undertaken in the preceding year involved illegal importation of medicines, many of which were purchased over the internet.

In August 2006, the U.S. Food and Drug Administration issued a warning that U.S. patients should be aware that counterfeit medicines were being sold by a major internet pharmacy in Canada. Ten specific drugs were listed in this advisory.

Individual countries began prioritizing their efforts to more closely monitor the market place and committed additional resources to these projects.

The authorities in China initiated a major effort to increase drug inspections at the provincial level. By placing state of the art testing equipment in vans, these mobile laboratories are fully equipped with drug registration data, drug instruction information, adverse drug reaction records and chemical "fingerprinting" information.

The Korean Customs Service formed a special task force with 446 officials to improve their efforts against the importation of illegal medicines.

The U.K. Royal Pharmaceutical Society (RPS) collaborated with the MHRA and provided pharmacist with new guidance which identified the causes and consequences of counterfeiting. RPS gave practical advice on detecting and reporting suspected counterfeit medicines.

Summary

The challenge of counterfeit, diverted and stolen pharmaceuticals is clear from the Situation Report. While more incidents have occurred, fewer arrests have been made. Counterfeiters have modified their activities and now seem to be concentrating on fewer types of drugs. The international community has begun to recognize the need to better coordinate their efforts, to address the problem of internet sales of pharmaceuticals and to more closely monitor the market place.

Americans need to know that the U.S. market has been, is now and will continue to be a tempting target for counterfeiters. Their safety is endangered when they venture outside of the current closed system – and the risk to their health and welfare is real.

More than ever before, it is essential to work together to protect public health, share information and initiate investigations with drug regulatory authorities and law enforcement officials in order to stem this illegal trade.

Mr. PALLONE. Thank you. Mr. Northcott.

STATEMENT OF HALLOCK NORTHCOTT, PRESIDENT AND CEO, AMERICAN ASSOCIATION OF EXPORTERS AND IMPORTERS

Mr. NORTHCOTT. Good afternoon, Chairman Pallone, members of the committee. My name is Hal Northcott, and I am here representing the American Association of Exporters and Importers, and we very much appreciate this opportunity to speak on H.R. 3610.

AAEI is a cross-section of the Nation's supply chain in that we are made up of manufacturers, distributors, retailers, freight forwarders, insurers, brokers, foreign trade zones, and ports all across the country, both large and small business. Each of these businesses is engaged in actively getting stuff in and out of the United States. That is what they do, that is who we represent.

With this background, let me say that we are here today to address by section only those portions of the bill on which our trade, security, and logistics knowledge may be of some benefit to the community.

So if I might, let me begin with section 2 on port inspection, which for brevity, we will comment on in linkage with section 7 covering restricted ports of entry. Here I would like to make three points. First, the use of a tried and true inspection system like that of the USDA is very initially appealing. However, taking that model which has been applied to a comparatively small scope and volume of meat, poultry, and eggs and then trying to apply it across the enormous volume of imports, food in particular, nationwide creates a whole new logistical ballgame. Frankly, it is highly problematic.

Second, the application of the restricted port inspection system will have predictable but significant impact nationwide in that there will be clearly perceived winners and losers. That would make 313 ports losers and 13 winners. However, let me assure you that even the perceived winners will face some serious new problems and we believe unintended consequences.

Third, we would urge the committee to take a serious look at the enormous volume of data that has been referenced over and over again during this testimony. In this we commend to you CBP's developing ITDS, or International Trade Data System, which for rough purposes is roughly comparable to the air scoop on the hood feeding crucial data to the engine block which in this case is the automated commercial environment. This is a good thing, and frankly it enables the very important drive toward one face at the border which our friends at CBP are also spearheading. And may I note here that CBP, like FDA, is badly lacking necessary resources, and we encourage your action in that regard.

So separately, we ask that you appreciate that while a successful import safety program with its data must have transparency, data is private property and it is highly valuable. It must not be given away to the bad guys in a world filled with foreign government-owned and subsidized industries and extensive industrial espionage. In the name of American competitiveness, data protection is crucial.

Now let us turn briefly to section 6, the rules or origin, and here frankly we have two requests, both very short. We ask that you please do not permit this Congress to confuse rules of origin labeling with an effective safety program. It is certainly a useful consumer element, but it doesn't do much if anything to solve the real world's import food safety problems. And second, in looking at rules of origin, we suggest that the Congress please do not impose yet another country-of-origin standard upon your import/export industries. Believe me, with the further proliferation of new and differing rules of origin found in existing and forthcoming FTAs, it is sufficiently confusing for industry already. Please look to existing standards.

I am going to go briefly to section 7 and say that we endorse the concepts here and have been actively engaged with the FDA in trying to create this type of program for the last four years. The personnel with whom we have worked do a fine job. The low-risk model will go a long way in promoting America's huge food export markets. But all of the above, I would say as a final point, one fundamental springs to the top of any supply chain list, and here we would ask that you recognize, despite important similarities, that trade, security, and product safety are not the same. They are fundamentally different. They may look and feel the same on the surface, but they are truly worlds apart. At its most basic, trade security is concerned with the integrity of the supply chain, ensuring that the box or container and its contents have not been tampered with in packaging or transport. Thus, it is secure. In direct contrast, what you are addressing today, food product safety, is focused on the individual item inside those boxes. Product safety targets the composition, functionality, quality, and overall integrity of the food product. It is inside versus outside, the two must not be confused.

And with that, thank you very much. We would like to conclude our testimony and offer again our appreciation.

[The prepared statement of Mr. Northcott follows:]

STATEMENT OF HALLOCK NORTHCOTT

A. INTRODUCTION AND OVERVIEW

Chairman Dingell, Ranking Member Barton, Ranking Member Deal, and members of the committee, my name is Hall Northcott and I am president and CEO of the American Association of Exporters and Importers (AAEI). AAEI appreciates the opportunity to offer its comments on your effort to address import product safety in the Food and Drug Import Safety Act of 2007 (H.R. 3610)

AAEI is a trade association comprised of U.S. and multinational manufacturers, distributors, retailers, freight forwarders, insurers, brokers, foreign trade zones and ports across the country, each engaged in the import and export of merchandise to and from the United States. In one fashion or another we truly represent the scale and scope of America's supply chain. We have helped educate and then externally represented the trade community in domestic regulatory, legislative, and public policy arenas since 1921 and in recent years have moved to assertively represent American import and export interests in multiple international forums.

AAEI's primary focus has long been "getting things in and out of the United State in the most efficient, practical and responsible manner seen worldwide." In this we have long been a strong supporter of supply chain integrity and security as well as facilitation throughout the full-range of trade community issues affecting customs and international commerce. In short, AAEI believes that it is vital for the government and the trade community to work closely together and coordinate supply chain security, facilitation and import product safety for the United States to maintain a

critical balance between the free flow of legitimate trade and safe and secure goods. However, we are not expert in food product safety matters and thus are to here to support the committee in its efforts impacting supply chains, trade processes and those multiple aspects of today's global trade reality with which we are very familiar. It would be our pleasure to support, assist and encourage the committee in these efforts.

It is indeed a privilege to appear before you on behalf of Chairman Charlene Stocker, our Board of Governors, and our members, found in every industry nationwide. Our testimony reflects the trade community's eagerness to work with the committee to ensure that the Nation's product safety measures work—for consumers, the government, manufacturers, importers and exporters. In particular, we hope that we can assist you in your efforts to advance product safety by both fully exploring and thus utilizing all the current trade related statutory and regulatory tools available.

Since 9/11, AAEI and the U.S. business community have worked diligently with the Department of Homeland Security, U.S. Customs and Border Protection and multiple government agencies at the Federal, state and local levels to develop programs designed to maximizing homeland security protection primarily through reducing the likelihood that the global supply chain could be used by terrorists as a delivery system for weapons of mass destruction. Frankly, we have long been and remain concerned that many important trade facilitation functions can be relegated to secondary status in the press of today's critical security environment. Thus, it has been our intent to assist in ensuring that robust security practices enhance the flow of legitimate trade such that the twin goals of trade security and trade facilitation are mutually complementary. In this, while we often have significant disagreements as to details and applications, we would strongly commend the efforts and personnel of the CBP and related DHS leadership for their commitment to vital national goals.

In relation to the above trade and supply chain concerns, we have recently begun to explore, in depth, related product safety issues and believe that ensuring product safety and integrity should be viewed as an important "third leg of a stool" which strengthens the other two legs—security and facilitation. Although balancing these interests is unquestionably a difficult task, we believe that H.R. 3610 has provisions of great value in further structuring the overall framework. We look forward to working with you to safeguard achieving this productive balance between these roles is a vital national interest and those U.S. policies and programs critically important for the United States to remain competitive in the global marketplace. In this we will support your efforts to further encourage the growth of our nations reliable, efficient and successful international trade system. This system must remain healthy if our Nation is to retain and enhance its position at the head table of global commerce.

B. Setting a Framework for Import Product Safety Difference

AAEI's testimony on Setting a Framework for Import Product Safety touches upon four topics which we understand to be of particular interest to this committee 1. Low risk and account-based management works and can be used to enhance import product safety; 2. trade security and product safety are different and are based on divergent principles including different risk tolerances; 3. Interagency cooperation, particularly data exchange through the International Trade Data System (ITDS), is essential; and 4. Enhancement of manpower and resources for multiple agencies both directly and through third parties should be approached with an eye to significantly enhanced capabilities.

Frankly, at some point in the future, we would welcome the opportunity to discuss with the committee a number of subjects including 1) the multiple impacts, since 9/11 upon commerce and, in particular, small and medium business of the substantial number of security programs launched, as stand alone efforts, 2) the cumulative affect of proliferating Federal agency actions outside of CBP jurisdiction which increases the complexity and cost of the import process, 3) Federal agencies movement towards harmonizing U.S. regulations with international standards, 4) additional compliance requirements, 5) ongoing pressure on agencies to impose new user fees on importers that are, at best, "toll booth taxes" rather than fees for additional government services, and 7) new proposals each year seeking market data demands as well as more transparency and resilience from the global supply chain than can be digested and implemented by the trade community in the short period of time required by statutory deadlines.

LOW RISK AND ACCOUNT-BASED MANAGEMENT IS HIGHLY EFFICIENT

Account-Based Management. For many years, the trade community has partnered with CBP and DHS to develop low risk importer programs for both trade security and trade compliance purposes. In regulating over 825,000 importers, CBP had to make strategic choices in deploying its already scarce, and increasingly depleted, resources while the volume of trade continued to increase. CBP's strategy, going back to the 1980's, incentivizes companies with good security procedures and internal controls to join voluntary programs for mutual advantage and, dependent upon the program, a menu of trade facilitation advantages through reduction of processes or complexity of steps required. A critical part of this strategy, as directed earlier by the Congress, is treating importers as an "account" by reviewing the companies" record of compliance for all their importations, rather than individual transactions. By treating importers as an account, CBP is able to quickly determine a company's compliance profile and work with the company to remedy any deficiencies. CBP can then concentrate its resources on companies which do not demonstrate a high level of compliance and present the great risk for violations. In these efforts, CBP serves as an excellent model.

One example of a flourishing public private partnership at work today is found in the risk management operations of a widely accepted account based program now in its 6th year. This is the Customs Trade Partnership Against Terrorism (CTPAT) program which today, while truly voluntary, has, in many industries become the acknowledged standard upon which business is done. C-TPAT is a government-business initiative to strengthen and improve overall international supply chain and U.S. border security. Those businesses that choose to apply are making a commitment to work toward the goal of creating a more secure and efficient supply chain in partnership with CBP.

One key feature, that we would specifically note for the committees consideration is that, after multiple discussions with industries and congressional committees committed to this program's success, CBP did not fall prey to the easy answer of imposing a "one size fits all" approach in this wholly new effort. Instead of the "one size fits all" approach, CBP and DHS succeeded in developing a successful program by recognizing that different products, sourcing regions, and supply chains have different operations and levels of risks. We would strongly urge the committee to explore the many reasons for adopting this approach. In this effort, one vital aspect is the ongoing verification and recertification program. Here, for instance, they issued and used extensively in the ongoing verification process, a Supply Chain Security Best Practices Catalog to provide importers with a compendium of the optimum and most effective efforts developed by other companies. This catalog has helped promote CTPAT's wide acceptance in the trade community as evidenced by the fact that there are over 7,500 certified participants in C-TPAT. As of today, approximately, 5,000 validations have been completed and we expect the remainder will be validated by the end of the year. However, we would hope that any efforts that the committee might wish to initiate would from date of implementation be adequately staffed for efficiency in implementation.

In a significant precedent, Congress has already accepted and enhanced C-TPAT's risk management approach to security by providing statutory recognition of this program in the Security and Accountability for Every (SAFE) Port Act. In this legislation, they sanctioned its voluntary nature, and tiered levels of participation linked to specific benefits. For most U.S. companies with global supply chains, C-TPAT membership is a requirement in today's business environment. C-TPAT has also serves as a model for the European Union's Authorized Economic Operator certification for security and the World Customs Organization's (WCO) adoption of the "Framework of Standards to Secure and Facilitate Global Trade" (the Framework of Standards). Here we see an international strategy, based upon clearly established U.S. principles to secure the movement of global trade in a manner that does not impede it, but instead, facilitates the movement of global trade. In this, AAEI has been privileged to support various initiatives in multiple international forums.

TRADE SECURITY AND PRODUCT SAFETY ARE DIFFERENT

AAEI recognizes that though there are important similarities, trade security and product safety are fundamentally different. We have noted and attempted to incorporate those differences in our now four year effort to assist FDA in the development of low risk importer programs which, in our opinion, would have substantially benefited all parties. We remain hopeful that important progress towards this goal can be made through both the regulatory and legislative processes.

It is fair to say that, at its most basic, trade security is primarily concerned with the integrity of the supply chain and ensuring that the "box" (i.e., the cargo con-

tainer) has not been tampered with during transport so that no weapons of mass destruction or other harmful substances are surreptitiously placed in the box after sealing at the point of stuffing. On the other hand, product safety is focused on the integrity of commodity in the box. Specifically in FDA jurisdiction, we understand there needs to be focus on microorganisms, toxins, pathogens, pesticides and problematic chemicals. In this effort, there is clear recognition that regulated food testing requires examination outside of the containers. In other words it is our understanding your product safety effort is specifically directed to ensure for the Nation the quality, functionality, safety and overall integrity of the product. This is not even comparable. Frankly, with apologies, in the contrast of "inside the box" and "outside the box," we must point out that these are, as my niece has said, simply apples and zebras. One element which this committee could appropriately explore is an import safety is current company or independent testing policies at FDA. Currently, AAEI is unaware of any variety or method of internal testing which a company can do to reduce processing and inspection time for food, drugs and medical devices. However, it is important to note that would be a fundamental change in culture and resource requirements for FDA to fully implement a programs which take advantage of ongoing extensive domestic industry efforts. Thus, any efforts which the company makes do not help without agency facilitating product delivery. Perhaps the nearest match to product safety requirements in today's business environment is in the quality assurance process (QA)—which so many American companies excel in and can help by providing valuable lessons for the committee's use in crafting language.

INTERAGENCY COOPERATION IS ESSENTIAL—ITDS IS A VITAL TOOL

In fostering necessary interagency cooperation, and thus effective and efficient import and export programs, the Congress made an important first step in strongly encouraging what has become known as "One Face at the Border." The effort has been designed to eliminate lack of coordination and even agency cross purposes, at our land, air and sea ports. Achievement of this goal was initiated in the creation of the Department of Homeland Security. Over the past several years, AAEI has testified to the importance of both preventing restoration of and further eliminating the extraordinarily burdensome and inefficient processes which have been suggested by a variety of special interests.

Increasing the government-wide focus on product safety, including CPSC leadership and multiple agency participation in the enforcement of Intellectual Property Rights protection, along with tracking financial transactions that may be financing terrorism are extremely worthy goals. Unprecedented cooperation and formal coordination of efforts, whether legislative or administration driven, would make all the difference.

In this, AAEI and the trade community have long supported the government's multi-agency automation efforts and the use of data to provide more transparency to the supply chain and import clearance process. One of our top priorities in the passage of the SAFE Port Act was the inclusion of a provision mandating Federal agency participation in the International Trade Data System (ITDS). ITDS is intended to be a "single window" of trade data for government agencies to advance electronic access trade data provided by the importer in order make the import clearance process a seamless process for importers, CBP, and other Federal agencies that license imported products or have "release and hold" authority for regulated imports. In a rough analogy, ITDS is the air scoop on the hood feeding vital data to the engine of the Automated Commercial Environment System (ACE).

We continue to believe that interagency cooperation and, at minimum, data exchange through the ITDS is essential. While full data sharing may not always be possible, alignment of agency goals with our nation's regulatory framework is crucial. In sum, use of the ITDS tool, if fully supported by vital agencies and bureaus, is highly beneficial for all involved and its maturation should be a much higher priority. We are gratified that the President's Interagency Working Group on Import Safety highlighted the importance of ITDS by recommending the acceleration in the development of ITDS in its initial report to the President, "Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety," issued on September 10, 2007. We hope the committee can take advantage of this important tool in development of its overall legislative strategy to improve product safety.

A. U.S. BUSINESS DATA CONFIDENTIALITY

Among the emotionally charged issues that the U.S. trade community and AAEI's member companies have confronted in today's evolving environment are the exten-

sive and substantial concerns regarding the confidentiality of proprietary business data submitted to government agencies. In crafting this testimony, we wish to recognize the committee's dedication to preserving and even expanding individual data privacy and we hope that the committee will recognize that for business this is an effort which should be preserved with equal vigor. Frankly, commercial data is property and inadequate protection is a "give away" to the bad guys. We need not look far to see a repugnant record of foreign firms and interests engaging in grand scale industrial espionage. In trade policy terms, these concerns are driven both by private sector competitiveness issues and international business ownership and management. In addition, we are deeply concerned about some Federal agencies" dismal record of compliance with the Federal Information Security Management Act (FISMA). We would ask that the committee carefully examine the breadth of concerns we convey today and support further study in this area.

The immediate issues which we ask you to consider exploring and incorporating into your efforts are driven by several "real world" competitiveness concerns. Among business community concerns are: 1) the increasing range, depth and amount of total data that is being requested by multiple Federal, state and local agencies often without cooperation and certainly without integration; 2) the Federal sharing of "sensitive" data with an ever widening range of domestic and international trade bodies where neither a devotion to crafting future program requirements nor a tradition of confidentiality (or record of advanced training programs) or have even been apparent to the private sector; and 3) the Federal Government's increasing reliance on unproven electronic systems to manage confidential commercial data including product entry and risk assessments about products based on such data.

In today's environment, we are quite concerned with the development of policies within international bodies where multiple U.S. data streams are provided to merge and commingle with other Nation's data. In this we applaud recent Department of Commerce's initiatives toward data security for the Automated Export System (AES). In any instance, sharing of data regarding "risk analysis" must be done in such a fashion so as to avoid commercial implications as much as is humanly possible.

Notably, it is the practice of a number of foreign governments, which are traditional and significant U.S. trade partners, to subsidize certain industries which compete directly with their U.S. counterparts. In many of these governments, both in developed and developing nations, it has been AAEI's experience that the US tradition of data confidentially and specific agency retention of data, is both absent, and frankly, unwelcome. This is particularly true of a significant number of competitive nations which have neither sufficient customs nor enforcement capacity. Thus, internationally, we particularly encourage the committee to explore development of policies to address the sharing of sensitive information with other governments, in particular foreign customs and business promotion agencies.

In noting that a variety foreign governments have substantially invested finances, national pride and whole industrial development strategies in industries and specific business enterprises that compete directly with the U.S. private sector, we must also note that, as the committee is well aware, significant commodity supports are found globally. Clearly our concern here is in the impact of government subsidies and credits among other financial commitments may have upon the absence of appropriate prohibitions, or regrettably the apparent "blind eye" to data misuse or abuse.

In addition, a significant concern here is, the apparent lack of controls or restrictions to be imposed upon these foreign governments by any international body on a commerce driven mandate, particularly, as noted, those which may have a financial interest in such a competitor to a U.S. company or which lack important legal safeguards restricting the use and dissemination of trade data belonging to U.S. companies necessitate AAEI's concern. To be candid, those FDA regulated U.S. businesses which are of interest to you today must have firm assurances that information potentially to be supplied to foreign governments for safety, and related, purposes would not be used against them in a competitive business context. At present, AAEI member companies are not sufficiently convinced that their proprietary trade data in multiple industrial sectors will be secure.

Allocation of Manpower and Resources—Both Direct and Through Third Parties

Among vital areas the significant enhancement of manpower and resources for multiple Federal, and perhaps state and local, agencies through third parties should be carefully considered by the committee. As noted earlier, this may be the time to review existing FDA lack of recognition or benefit from internal testing and controls.

We look to you, in those areas of your concern, for potentially significant changes in the way government provides for and otherwise supports import safety, risk management and control and thus imports writ large. We would be happy to discuss CBP's significant under funding and lack of sufficient manpower in the face of expanding responsibilities, but this is not the proper forum. In specific program terms, our experience has demonstrated that the CBP model for gaugers and, more recently third-party validations for C-TPAT certified partners" shipments from China, may prove useful to the committee along with the Environmental Protection Agency's long-standing program of licensed importers and Coast Guard's periodic regulatory inspections. AAEI believes that a fundamental element in the design of such systems must be the economic impact upon small and medium size enterprises. However, the overall impact upon small businesses nationwide; of implementing multiple trade-related approaches to enhanced product safety is subject to the unforgiving rule of unintended consequences. "To do no harm" is a difficult mission when, even for a vital purpose, modifying long-established importation and distribution patterns and requirements will be part of the mission. It is indeed necessary, but the committee may wish to explore the use of an incremental approach.

CONCERNS WITH H.R. 3610

AAEI's testimony on specific provisions of H.R. 3610 touches upon the following seven topics: 1. Inspection at Port of Entry; 2. User Fee on Imported Food and Drugs; 3. Restricted Ports of Entry; 4. Country of Origin Labeling; 5. Safe and Secure Food Importation Programs; 6. Penalties; and 7. Recall Authority; and 8. Inspections.

1. SECTION 2—INSPECTION AT PORT OF ENTRY

We believe that emphasis on inspection at the border goes against the current administrations "push out the border" policy that has been embraced by Congress with respect to trade security and must be considered in development of this approach to food safety. However, those amendments which have already been suggested to simply adopt the pattern of current homeland security policy, i.e. to push the borders back- to foreign soil is problematic in foods. It is our belief that to prevent any or all FDA regulated product from ever being loaded into U.S. bound containers- to certify the safety of products- has huge supply chain implications for customer access and pricing.

In addition, though we are not experienced in USDA matters, we certainly appreciate the value of their current system of labs and import safety. However despite this appreciation,, we suggest that trying to take a limited volume and scope "system" which works well for certain kinds of goods and apply it across the board, sends U.S. policy in altogether new directions. As we will discuss shortly, we find a number of these possible directions problematic.

1. SECTIONS 3 AND 4—USER FEE ON FOOD AND DRUGS

AAEI is concerned about this proposed user fee on imported food for the following four reasons:

AAEI is opposed to user fees levied against the retail community and other importers when we know that global trade has a positive effect on the United States as a whole. We believe that both existing user fees imposed upon certain commodities (such as medical devices) and future fees under consideration are problematic. We consider that their impact frequently appears to be the kind of unequal burden created when the government agency in procurement or resource allocation among others chooses to treat products differently. The assessment of fees (or tariffs) upon retailers and importers of only specified commodities is said to limit the opportunities to cost effectively bringi9ng in goods of all genres. Frankly though this witness is certainly not an expert on fees versus tax policy it has been our analysis that such fees can unfairly burden certain industries, commodities and communities. Here we note disparate treatment of food and drugs, which are already highly regulated commodities.

It is our observation that the disparate treatment of imported product safety and domestic product safety is highly problematic in terms of U.S. industry's ability to trade internationally. To prevent serious, unnecessary damage to our huge export economy, U.S. interests must be understood in today's complex WTO environment and our growing framework of trade agreements. With the enormous degree of international competition in food commodity production already facing our companies and industries, we are extremely concerned, as noted earlier, that reciprocal ac-

tions, particularly in countries with our U.S. traditions of fair trade, could prove very difficult trade barriers to overcome.

From conversations with our retailer members, it is our impression that fees assessed per line item will disproportionately impact small and medium enterprises (SME's), particularly those that import a wide variety of products currently regulated under the Food Drug and Cosmetics Act. We are informed that these would, as one example, specifically impact, specialty food retailers who may cater to traditional "geographically" based consumers. However, we believe that such data is not yet available and anecdotal evidence is all that we can rely upon at this point.

The possibility exists that the fee amount per line item may actually exceed the value of the good. In this case, importation of the product is likely to dry up regardless of the lack of any domestic production. This diminishes the value of our global economic power in directly benefiting the American consumer and penalizes importers who currently provide low cost food to the average American household.

One fine example of this has been provided by an allied trade association in which they pointed out that(MR I think that here we can just Insert NCBFFA Mexico example

2. SECTION 4—USER FEE ON IMPORTED DRUG

a. AAEI is concerned about this proposed user fee on imported drugs for the following four reasons:

AAEI is opposed to user fees levied against importers when we know that global trade has a positive effect on the United States as a whole. Again, this witness is not expert in the arena of fees assessed.

However, to prevent serious, unnecessary damage to our huge export economy, U.S. interests must be understood in today's complex WTO environment and our growing framework of trade agreements. Prominent among these have been both the nature of the assessment (tax on value) and constitutional limitations (tax on exports). Frankly, from our preliminary review, it appears that each of the methods commonly discussed does appear to require extensive review so as to avoid unanticipated economic and trade repercussions. To assist in this effort, we suggest that the committee consider an annual report of all such revenue collected from the spectrum of Federal customs-related fees and their allocation in the budget would be of value to the committee.

The possibility exists that the fee amount per line item may actually exceed the value of the good. This diminishes the value that our global economy has the power to bring to the American consumer and appears to penalize importers who provide low cost food and drugs to the working class families and senior citizens who live on a fixed income. As referenced earlier in this testimony, the impact upon specific niche but very important marketplaces could be profound.

It is our understanding that utilization of user fees to pay for government programs and projects reportedly undertaken in the public good, rather than applying primarily or exclusively for the benefit of a specific and defined set of users, would be a significant departure from widely accepted policies. It appears to us that it is simply a tax imposed upon this segment of American industry. Yes, we as a Nation need to gather the resources required, but this is not the way to do it. From our perspective, it is highly prejudicial against imports, falls disproportionately on a variety of industries and impacts most heavily on the ultimate U.S. consumer.

3. SECTION 5—RESTRICT PORTS OF ENTRY

AAEI believes that restricting ports for entry of food is an unwise choice because our industries trade and logistics providers must always be prepared to adjust to the dynamic economic environment. In fact, any major corporation's supply chain team can provide you with—virtually on demand—multiple alternate methods and location of delivery with minimal product cost or availability implications. In fact, we all need to keep in the front of our minds the all too real possibility that any number of occurrences (i.e., natural disasters, labor strikes or terrorist attacks) could cripple any one of our major ports for weeks or months. Under this proposal, if that port or ports, since many are located in relative proximity, in the case of natural disasters among other factors were to be closed the options available are markedly reduced and the impacts, while negative, are highly unpredictable.

In a global environment, it is unwise to place insurmountable restrictions on either specific imported products or individual ports due to the need to maximize the limited remaining flexibility that still exists in the US trades overcrowded and aging infrastructure.

For Example, as noted above, if an incident of any kind occurs, it will be extremely difficult to adjust the import clearance and distribution of food product in

a timely manner. The lack of pathways, in our current and emerging multimodal environment will restrict the flow of necessary food items to localities that need such products and will inevitably create a backlog in processing shipments through food specific imports.

Today, such adjustments for multiple perishable and time sensitive products are routine and often occur overnight.

With respect to the food industry, both a necessity and highly perishable commodity, this is a very dangerous shackle to burden our country with at a time when the need might be at a crescendo. Industry's ability to adjust current import and distribution methodologies in the event of an incident is an essential and highly supported element of today's Homeland Security Strategic planning at the Federal, state and local levels. We would urge members of the committee to consult with those local and state officials most familiar with these concerns to fully evaluate the repercussions.

It is our understanding that application of the USDA restricted port model for individual product imports, food and otherwise, would mean, in very simple terms, that specified kinds of products can only be imported and distributed through certain ports—both land and sea. The impact upon the 50 states and literally hundreds of ports, out of roughly 300, can only be calculated with full understanding of the consequences of economic dislocation in Congressional districts nationwide as well as the anticipatable impact upon land ports along either border. It is important to note that the Congress has, since the Second World War, repeatedly resisted such plans for multiple products and industries. It is our experience that, to date, proposals of such policy for multiple product and industry imports have often been offered by those whose primary concern would appear to ease and simplicity of government processing without equal regard for economic impact.

Under such a proposal the added logistical costs for an importer, even assuming that nothing catastrophic occurs, can be prohibitive particularly when—as is very common in this country—a product enters a given port, is transported to a second relatively convenient location for packaging or modification and then delivered to a third perhaps distant market for final distribution and consumption. The implications for the small and medium business owner unable to compete with the large retailers for inexpensive product would be substantial. In terms of industry, as we know there are multiple highly competitive pharmaceutical and food products where profits, under normal circumstances may range for one to four percent. The impact upon these, often generic or house brand products could be highly problematic, if not prohibitive, based upon location of established facilities and long term distribution patterns.

As noted earlier, the reported over-crowding, current massive infrastructure requirements and highly limited expansion or even rebuilding of a number of the ports specified has another side to it. Here, we must be concerned about the impact upon those areas where labs currently exist or where one of a limited number may be added. As noted, we are looking at the immediate need for substantial infrastructure costs—official structures, roads, tracks, additional docks and many other elements. We are facing immediate and significant congestion and citizen disruption in that virtually all of these ports are contained with major metropolitan areas. We are also looking at potentially substantial overall environmental impact and quality of life concerns. To understand this, we ask that you simply note the enormous volume of product where, at the largest ports, of which these are, roughly 20,000 containers arrive a day. With total current national meat, poultry and egg importation of 2.6 million containers a year being absolutely dwarfed by projected totals coming through each of these ports.

Among many, one particular example of definite concern to the import community would be the Port of Los Angeles. Here the infrastructure requirements, increased congestion and projected, environmental disruption would obviously be of lifestyle concern to those citizen groups and policy leaders already actively engaged in operations and planning.

I would like to note, finally, one additional item which may be of interest to the committee. In conversations with some of our historically minded members I am reminded that, when it was first discussed here in the late 1700s, this concept, apparently known as "Port Goods Selection", might have been a viable option when there were fewer ports around the country, a dearth of well established industries at highly diverse locations and far less global trade flowing through interior ports,. However they suggest that it is certainly not feasible for 2007.

4. SECTION 6—COUNTRY OF ORIGIN LABELING

AAEI is concerned with the burden being placed on the trade with respect to the further development of multiple agency Country of Origin rules. This is, for instance, evident with respect to CBP and FDA. Today's situation can be roughly described as CBP being harmonized internationally though the WTO and multiple FTA's and FDA having an independently developed and implemented system that lacks even a nexus of compatibility or overlap with CBP's regulatory regime.

5. SECTION 7—SAFE AND SECURE FOOD IMPORTATION PROGRAM

AAEI wholeheartedly supports voluntary programs for security and safety, and was an enthusiastic participant in the development of C-TPAT. As a result, AAEI would, in terms of trade facilitation and security concerns, be pleased to both support and assist in the development of voluntary programs for product safety. However, such a program should be based on risk management principles that are compatible with and enhance both the current and future food security programs.

Foreign exporters of product to the U.S. utilizing non-performance of voluntary standards as a competitive tool against U.S. manufacturers who do adhere to these essential standards—pose a growing problem which must be firmly and quickly addressed. While complex legal issues will arise, the idea that "voluntary" means that any one player, by virtue of geography, doesn't have to pay attention to them is just plain wrong. Equally, the merits of our current system permitting export of U.S. made products failing to meet domestic agency safety standards will need to be fully explored and addressed.

The committee should be aware of the enormous complexities, as well as range of other the difficulties, that AAEI members have encountered in dealing with the multiple Federal agencies whose regulatory jurisdiction and oversight for certain imported goods overlap with other Federal agencies. As mentioned, our member companies have been at the forefront of cooperating with CBP by joining its trade security and trade facilitation partnership initiatives, such as C-TPAT and the Importer Self-Assessment (ISA) Program. We believe that these programs have a valuable role in achieving AAEI's often stated goal of a productive balance between trade security and trade facilitation, which AAEI believes will be achieved on regulatory issues only when Federal agencies work in close partnership with one another and the U.S. trade community.

Regretably, today, many AAEI member companies tell us that they do not receive the full benefit of these partnership programs because they are indeed regulated by multiple Federal agencies that neither recognize nor accept the risk-based methodologies of existing partnership programs. They continue to face the kind of d hurdles which should be a thing of the past in today's security environment. Such reluctance affects nearly 36 percent of the entries for imported goods that are subject to the "release and hold" authority of the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the U.S. Fish and Wildlife Service (FWS), which are the primary Federal agencies that impact most of our members potentially impacted by the current proposals.

As you can see the Congress' design for "One Face at the Border" was well founded and based upon concerns to serve land, air and sea port traders with full and equal rights. If successfully implemented it should, and hopefully will, eliminate much of the perceived inequities which have been reported in the past.

In this pursuit, AAEI has worked closely with the Congress and has spearheaded private sector efforts to initiate and develop a dialogue and working relationship with these other Federal agencies. AAEI is particularly pleased that the earlier referenced industry dialogue with FDA has resulted in some recent initial successes. Most notably, AAEI has provided comments to FDA on its Secure Supply Chain Pilot Program which builds upon the investment U.S. companies have made in C-TPAT since FDA's program requires applicants to be C-TPAT certified at Tier 2 or higher.

In the same vein, we are also working with FDA concerning possible adoption of proven and practical risk-based methodologies. One which we believe is worthy of consideration, as a purely voluntary element, is the Importer Self-Assessment program where the foundation of the ISA program is CBP's finding that U.S. companies which have good internal controls are highly compliant with U.S. customs laws. It is AAEI's experience that ISA member companies are pro-active in meeting their compliance responsibilities for all Federal regulatory agencies, not just customs. However, as with other items mentioned, making this program mandatory would have difficult impacts upon the competitiveness of small and medium sized enterprises. Overall, AAEI believes that the committee's interest in FDA and CBP coordination is an important step toward encouraging coordination and integration of

other Federal regulatory agencies in maintaining and demonstrably enhancing our efficient and reliable import process.

SECTION 8—PENALTIES

Again this is not an area where AAEI has specific expertise but we comment based upon the strong belief of our members that significantly increased and burdensome monetary penalties levied against manufacturers and importers will do little in today's international marketplace to effect change and enhance product safety without implementation of a firm correlation to the level of culpability found during an investigation. We would urge that the apparent lack of delineation in the varieties and levels of company involvement in the introduction of a product for introduction should be carefully evaluated by the committee. We do not understand the reasoning behind the apparent intent to make no differentiation between those supply chain participants who had no reason to know and those willing and knowingly participating companies. We believe that the bad actors should be punished. Examples of perhaps more useful deterrents which the committee may choose to explore include tying the fines to certain thresholds of negligence and/or intentional violations.

SECTION 10—RECALL AUTHORITY

AAEI supports providing FDA with necessary recall authority. However, as before, we cannot comment upon the specifics of such a provision in light of our focus on import, export and supply chain matters. Nonetheless, we are obviously familiar with domestic distribution networks and would urge the committee to examine the full implications of such a proposal. It is, frankly, the velocity with which those products under discussion move through the global supply chain from manufacturer to often independent distribution to multiple retail facilities and ultimately to the consumer that causes our concern. It seems to us that today's rapid and efficient distribution system could well place the importer in the untenable position of chasing down every shipment transported long after delivery to retailers and probable consumption. We suggest that the committee may wish to recognize that FDA regulated products often move in very different patterns than consumer electronics or automobiles or apparel but are often facilitated by the same players. In this regard, we ask that you examine recall policy, a necessarily reactive remedy for the government, with an eye toward economy wide impact.

. SECTION 11—INSPECTIONS

AAEI remains concerned that merely increasing random inspections, sampling and testing of food imports will not sufficiently enhance food safety because such actions will be done at our borders. We suggest that there are other ways which the committee could consider in devising solutions. In this effort, one vital step to the ultimate goal of protecting the American consumer from harm will likely lie in the prevention of tainted food and drugs entering the supply chain. However, we believe that the committee will wish to indicate that the importer's failure to find and obtain products once released, and not "caught by regulators" at entry, will not lead to penalties upon the importer—in particular if there is no finding of intentional distribution . Thus, something that must be done outside the supply chain to ensure that the supply chain does not end up as the dumping ground for any and all catch-all provisions aimed at regulating this complex and sensitive area of trade.

Though the committee may wish to fully explore providing additional U.S. certification of foreign facilities, it could choose to both augment and take advantage of the strength of ongoing U.S. efforts to concentrate on development of international harmonization standards. Such efforts, pursued by both the public and private, sectors could provide a model that the committee could use to assist the promotion of U.S. foods and FDA regulated products.

In addition to our export interests we suggest judging the real world impact, upon U.S. consumers. It is vital to note that there are today tens of thousands of foreign shippers to the U.S. which provide critical products and substantial price competition in marketplaces nationwide. We believe that, with the tremendous growth in multiple overseas marketplaces which may not yet or ever choose to impose similar certification regimes upon these very same exporters, American retailers and the consumer could suffer a significant diminution in quality and variety. Despite our attraction as a marketplace the growing sophistication of worldwide consumers could have a major impact.

During our 85 year history, AAEI has a long record of working together with those Federal departments and agencies, which have had jurisdiction over customs, trade policy, ports, transportation, tariffs, security, and immigration regarding the variety of other issues that impact the import and export of goods and services to and from the United States. We actively participate in multiple international forums and in support of excellence in this arena. In this light, it is our view that effective models for FDA and trade cooperation should include a wide variety of private sector perspectives—particularly those trade related organizations which have not always been part of the current food and drug related equations. Though independent organizations provide vital information and perspective, one highly instructive model can be based on the foundations of the well regarded Commercial Operations Advisory Committee (COAC). COAC authorized under the Federal Advisory Committee Act (FACA) is a key mechanism to foster and encourage public and private sector interaction. While significant aspects have evolved over time, COAC remains extremely useful and its mission is vital to assisting CBP and DHS craft appropriate trade security and compliance programs that not only do not interrupt the flow of legitimate trade but serve to facilitate trade in many ways. It is worth noting that the operations and reach of COAC itself were significantly enhanced in last session's passage of the SAFE Port Act and this effort may prove helpful to the committee.

From our perspective, dedicated private sector organizations and individuals, where appropriate, assisting FDA and related agency consultative efforts could highly productive and organizations can be encouraged which are specifically devised to incorporate the breadth of private sector consumer and trade related voices in their consideration of policy development and implementation. In addition to these groups and other beneficial multiple channels of communications between the public and private sector regarding vital import safety, trade security and trade facilitation issues for both U.S. importer and exporters, a body comprised of private citizens authorized under FACA to confer with FDA modeled on COAC would be a constructive initiative. Such a COAC like body could provide vital support and assist in making these programs both robust and effective. We would ask the committee to examine options and consider its options in imitating utilization of a Federal advisory committee in the development of vital Executive and Legislative branch coordination and direction for these vital trade related issues.

In conclusion, we wish to thank the House Subcommittee on Health of the Committee on Energy and Commerce for its invitation to provide our observations, comments, and suggestions about "H.R. 3610, the Food and Drug Safety Import Act." We greatly appreciate the committee's efforts and hope that we can assist it to ensure that consumer confidence in our product safety regime serves as the third leg of a stool balanced partnership with trade facilitation and security. We strongly believe that the committee's continued oversight and active promotion of import safety with recognition of existing trade security and trade facilitation programs and initiatives can make an enormous difference.

We hope that our testimony will prove useful as the committee considers measures to enhance FDA's capabilities in handling imported food and drugs. AAEI looks forward to both supporting this committee's active involvement and to continuing our partnership with FDA in pursuit of these goals.

Mr. PALLONE. Thank you very much. Let me start the questions with the panel. I wanted to start with Congressman Dooley. I had a couple of questions I wanted to ask you, Cal. In your testimony, you speak about GMAFPA's four pillars, one, mandatory foreign supplier quality assurance program; two, quality import food safety program; three, build the capacity of foreign governments; and four, expand the capacity of FDA. Now, when I look at Mr. Dingell's bill, some of his provisions include, one, a new requirement that imported food meets the same standards as domestic foods; two, a voluntary program for companies that import food to agree to abide by specific safety guidelines; three, significant new resources for food drug safety via an importation fee, I mean the question I have, Cal, is that you state that your proposal will do more to ensure the safety and quality of imported food products and ingredients than with the adoption of many of the provisions

of the Dingell bill, but I don't see the difference on how your plan is superior. You want to just tell us why you think it is better or why you think it would do more to ensure safety and quality?

Mr. DOOLEY. Sure. The way I would respond to that is that the proposal that we have tabled really relies much more on prevention than from inspection. Our assessment of Chairman Dingell's bill is that it really is looking at how do you enhance the level of inspection capacity and resources of the FDA to try to enhance a level of food safety. We think that we need to approach this by defining what the private sector can do most effectively and complementing that with the defined role where FDA can best utilize its resources. And so where the Dingell proposal would rely on perhaps a certification of what is, by FDA's testimony today, would literally be hundreds of thousands of foreign suppliers of ingredients which we don't think they have the capacity to do, that our approach would be to have a partnership with the private sector where the private sector would have to develop these mandatory supplier import programs that would embody almost without question audits of those facilities and those suppliers, and that would be a private sector approach that would mitigate the need for FDA to have to go out and certify again these literally hundreds of thousands of facilities. And we think that would be a role that would be more effective and certainly more pragmatic with our approach.

Mr. PALLONE. Well, you mentioned about the different models the FDA could adopt to strengthen their efforts to regulate food safety, but are there things your members are doing to mirror those FDA efforts at this point?

Mr. DOOLEY. Well, what you find is that the reason that we really have a limited number of food safety incidents even as it relates to imported food products is that most importers of products today do in fact have best practices in place that are including the supplier audits, they do have the chain of custody that they can account for throughout the supply chain, do have testing protocols to ensure that there's not an adulteration of a product. They have those practices in place, but unfortunately there are limited number of people in the industry that aren't deploying that same level of best practices. What our proposal would suggest is that we need to mandate that those best practices apply to any company that is importing a food ingredient or food product, and they would have to be in compliance with those guidelines and guidance that would be developed by FDA.

Mr. PALLONE. I wanted to ask you about the import user fee because you are pretty critical of that, and you have a number of reasons for your opposition. For example, you said user fees are generally appropriated when the benefits accrue to individuals or individual companies and that the benefits of import inspections and research go to all Americans. Of course, I don't agree with you on this because we just went through the PDUFA process and the MDUFMA process, and it is very similar where you have the industry paying for a user fee that essentially helps all Americans or all consumers; and I don't really see how a user fee on imports would be any different than a user fee on drugs or device applications. So I guess my question is what is your answer to that? I mean, it is no different in my opinion. Do you think it is?

Mr. DOOLEY. Yes, I think it is dramatically different because when a pharmaceutical company is working with FDA to gain approval of a product that they are going to provide into the marketplace, they have a proprietary interest. They get a protection of a product that is going to have a patent protection for a period of time which derives financial benefits to that company who is paying that user fee. In this case, we have no proprietary interest on what we could be paying for, is that we are paying for basically a public good in terms of an inspection of a food ingredient that we have no proprietary interest in it. Even if we go in and we have a food additive that a member company in the food industry might be requesting that FDA approve, that food additive immediately goes into public domain and we have no financial benefit from that. So we think it is a dramatically different approach.

Mr. PALLONE. Of course, a lot of what we just passed in PDUFA was post-market, too. In other words, that was the big issue, that it is not just for the approvals, a lot of what we are doing in the new bill is post-market. I don't want to argue with you. I mean, I do but you know where I stand.

Ms. DeWaal or Mr. Hubbard, did you want to comment on that, and I am already over the time. I wanted to give the loyal opposition or whatever they are the opportunity.

Mr. HUBBARD. Ms. DeWaal may differ with me, Mr. Chairman, but I was very much involved in the creation of the original user fees for drugs in 1992. The downside has been as the drug program has gotten wealthier, the appropriators and the budgeteers and the OMB have seen an opportunity to cut back on appropriations, and the problem is because the drug money had to be kept up, based on provisions in the law, they cut it out of foods in the field and inspectors. So the FDA has lost 1,000 people in the food safety and inspection area since PDUFA was created.

So my fear here is that if you do this user fee, they will find a way to use that to supplant appropriations, and we won't be any better off for it. So, if you could find a way to prevent that, great, but I am pessimistic about user fees.

Mr. PALLONE. I understand. Ms. DeWaal?

Ms. DEWAAL. Thank you. We don't have a fundamental problem with the concept of user fees, but in this context we are very concerned that the user fee proposal in this narrow construct where it is only applying to one segment, the imported food, and also there may be some restrictions in how that money is used, it could actually distract from the important work the committee needs to do in terms of looking at the authority. So while we are happy to work with the committee on what the overall structure might look like, I think it is just vitally important that you really focus on what authorities are needed today that will improve the safety of the products, both domestic and imported, going to consumers tomorrow.

Mr. PALLONE. Sounds like the same arguments that we heard in PDUFA and MDUFMA, and of course, we ended up doing it anyway because we didn't know where the money was going to otherwise come from. Mr. Buyer?

Mr. BUYER. Thank you very much. I am focusing on the drug side, so I apologize to the witnesses here with regard to food. Mr. Dooley, it is good to see you again, and I appreciate your testimony.

I will go back to our ideal, the ideal being safety and efficacy of drugs that come into the United States through legal means. Our challenges are these that come through illegal means, and so I have some questions here for Messrs. Hubbard, Kubic, and Dr. Goldhammer. There are some givens. One of the givens is that the mail facilities are overwhelmed, that there appears to be an inadequacy of FDA personnel and of resources that due process is becoming extraordinarily burdensome with regard to the 30 days; and this 30-day process or giving notice of due process I highlighted because what I am learning here is that the, quote, by exception of FDA policy is becoming the rule of the day and being exploited by these counterfeiters. So I would ask the three of you to comment on my assessment.

Mr. HUBBARD. That is right, Mr. Buyer. The FDA created an exception for compassion in cases of people who had a serious disease and could not get the drug in the United States, a very small number of people. These Web sites use that and say to people, you can buy prescription drugs like Viagra or something over the Internet using this exception from the FDA. So first of all, that is a lie to begin with. Then the drugs arrive in these mail facilities, thousands of packages a day. The FDA has no place to store them. They might have the size of a high-school locker to store things. Customs is saying, we got to move this stuff out of here, there is more coming tomorrow; and the FDA has the choice of either taking each package, sending a letter to the addressee and waiting 30 days for them to explain that the drug should come in usually unsuccessfully or just letting it in. And unfortunately, that means they are just letting it in, and that is a bad outcome for everybody because people are getting all kinds of drugs from all kinds of countries all over the world that can be counterfeit, expired, or otherwise unsafe; and FDA really has no choice in my view than to let it in under current law.

Mr. BUYER. So you would endorse my initiatives to have FDA——

Mr. HUBBARD. We actually proposed that when I was there. Just give Customs the authority. If it's a pill, burn it which is what they do for controlled substances.

Mr. BUYER. Thank you. You are right. Dr. Goldhammer?

Mr. GOLDHAMMER. Our position on it is very simple. A patient should only buy drugs through the normal supply chain, and if they go on the Internet they should only buy through verified Internet pharmacies that have been certified by National Association and Boards of Pharmacy. We believe any other Internet Web site is not an Internet pharmacy site, it is simply an Internet drug seller that is trafficking in illegal drugs.

Mr. KUBIC. Your observations are entirely correct, and I share the views expressed by my colleagues on the panel. I would say, however, that there is another thing that needs to be done here, and rather than try to stop the flood of these drugs that are arriving at the mail centers on a daily basis, which is frankly overwhelming, I think there needs to be a refined investigative effort

on a national basis to go after the people who are really behind the Web sites. Earlier, sir, in your statement you mentioned a specific site that the FDA had identified. That particular investigation is ongoing, and I won't go into a lot of details; but suffice it to say that they are into their third Assistant U.S. Attorney who has had that case in the particular Federal District Court, the prosecution has not even begun. So there seems to be some rhetoric about the importance of these things, but when it gets down to it and cases are made and cases are presented by the FDA, their Office of Criminal Investigations, they seem to somewhat fall by the wayside.

Mr. BUYER. On page 6 of your testimony, you spoke about the counterfeiting, legal diversion, products, that arrests have decreased by 10 percent, even though we have double-digit increases of activity. So what is your explanation of this dissonance?

Mr. KUBIC. Well, what we saw law year, for instance, is that there was a shift of law enforcement effort. Early on in our initial reporting, we saw a lot of arrests that were being made at the point of sale. This is kind of a low-hanging fruit. I mean, it doesn't take a very extensive investigation to go to an open-air market anywhere in the world and conduct an enforcement action. In contrast, if you are going to identify a manufacturer of counterfeit medicines in China, you are going to have to spend some time and effort. The private sector does some of this with their security staffs in concert with ICE, CBP, and the FDA. So as you look at the higher-level targets, it will certainly take more time; and I think that is one of the reasons why there has been a dimunization of the number of arrests. It is in fact a reduction, but we see a different person being arrested over the last year at least.

Mr. BUYER. Thank you, Mr. Chairman.

Mr. PALLONE. Ms. DeGette.

Ms. DEGETTE. I guess I will try to cover food and drugs somehow because I think we should be concerned about both of them. So I would start by asking Mr. Kubic and if any of the other drug representatives have anything to add. I agree with you, I think that the counterfeit drugs are a huge problem. We have been having a number of hearings over the years in Oversight and Investigations Subcommittee about this issue, and I think greater enforcement is needed but when you look at the pictures of the vast quantities of these drugs that are coming in through our points of entry, it almost seems like it is a barrage that is just coming in. I am wondering if there are independent efforts by any of your organizations to educate consumers about what you just said which is that you should only buy drugs from approved sites, and my other question is how are consumers going to know what the, and maybe that is a question for Dr. Goldhammer, what are the sites that would be safe for them to buy drugs on the Internet from?

Mr. GOLDHAMMER. The National Association Boards of Pharmacy actually has a seal. I believe the acronym is "VIPPS" that goes on those Internet sites that they certify.

Ms. DEGETTE. And how do consumers know that that is the way they can tell that those——

Mr. GOLDHAMMER. Well, we have been doing a number of education campaigns over the last several years in this area. There is

a Web site *BuySafeMedicines.org* which we are part of. There are a number of consumer groups that are a part of this as well that has a lot of information. Also the Food and Drug Administration, on their Web site has their own independent page on safe purchasing of pharmaceuticals over the Internet.

Ms. DEGETTE. Well, Mr. Kubic, do you have any ideas what else we could do?

Mr. KUBIC. Sure. I could add, just to expand a little bit on Dr. Goldhammer's comments, there is a Partnership for Safe Medicines where anyone, any person who has got a prescription drug medicine that they are taking can sign up for free and they get an e-mail alert if there is in fact then an official announcement made by the FDA about a counterfeit medicine here in the United States.

Ms. DEGETTE. About how many alerts are going out every year, do you know?

Mr. KUBIC. By the FDA? I would have to defer to the FDA. I am not quite sure of the specific number, but that would direct a person who is taking a specific medication that has been found to be counterfeit to that site. So, the FDA does a fine job of alerting professionals, the doctors, pharmacists and so forth. But the partnership is designed for the target audience to be the person who takes the medication.

Ms. DEGETTE. I am wondering if any of you think it would be a good idea for us to do an idea that Mr. Dingell and I disagree with, but a lot of our other colleagues on this side of the aisle agree with, which is drug reimportation. Seems to me that it would make the problem worse. Mr. Hubbard, why don't we hear from you?

Mr. HUBBARD. Well, when I was with the FDA, we certainly opposed reimportation because drugs that have been made here and gone elsewhere could have been contaminated, but more likely, they didn't really start here to begin with.

Ms. DEGETTE. Right.

Mr. HUBBARD. So the FDA is very much opposed on safety grounds.

Mr. GOLDHAMMER. I think you know that is the PhRMA physicians——

Ms. DEGETTE. Right. Yes, yes. I just want to turn quickly to Ms. DeWaal and ask her a couple of questions about food safety because as you know, I have two pieces of legislation, one for mandatory recall and one for traceability. And you mentioned very briefly in your testimony that the language in the Dingell bill could be improved significantly on mandatory recall. I am wondering if you can briefly talk about how you think that could be improved?

Ms. DEWAAL. First of all, all recalls done, both the USDA and FDA, are voluntary; and one of the problems we are finding in that system is actually getting information into the hands of consumers who need it. So we would have specific proposals to actually extend that portion of the bill down to the consumer level to ensure they get effective recall notice. But also Congresswoman DeGette, I think your issue of traceability is also vital here. To have an effective recall, we need to know where that food went, and in a recent recall actually that the FDA handled, it wasn't effective down at the retail store level, and they had to actually send out otherwise

fully employed food, drug, and medical device inspectors to retail stores to pull back cans of foods that may have contained botulism.

Ms. DEGETTE. And as I understand it, it is not from a food distribution standpoint, it wouldn't be difficult to do, traceability. You could actually do that in both the foods under the FDA purview and the USDA purview, correct?

Ms. DEWAAL. That is right. And part of a comprehensive bill which we are urging this committee to consider, I think traceability would be a critical element.

Ms. DEGETTE. Thank you. We will keep working with you on those issues. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Before I recognize Mr. Matheson, I know Mr. Buyer had a unanimous consent request.

Mr. BUYER. Yes, Mr. Chairman. I would move that all Members may have 10 legislative days to ask questions for witnesses to answer for the record and insert additional material.

Mr. PALLONE. Yes, so ordered. Didn't you have a request to include this document from the American Free Trade Association? Mr. Matheson?

Mr. MATHESON. Well, thanks, Mr. Chairman, and thanks to the panel. I want to address first a question to my former colleague, Mr. Dooley. It is good to see you again. As you know, the Ways and Means Committee already had a mock markup but the House will begin consideration of this trade agreement with Peru, and one of the issues that has been raised in relation to this agreement has been food safety. And I am hoping you might be able to clarify to folks on the committee how the standards included in the Peru free trade agreement affect existing U.S. safety standards as well as whether this agreement would limit the ability of the U.S. to raise food safety standards.

Mr. DOOLEY. Congressman Matheson, there is nothing in the Peru FTA agreement that would in any way pose any jeopardy to the existing food safety regulations that we have in the United States. And in fact, there is nothing in the Peru FTA agreement that would preclude the United States from even developing more stringent science-based food safety standards as long as they applied to domestic and imported products in a similar manner.

Mr. MATHESON. And beyond Peru, is it also not true that under the WTO standards that exist today, even without a bilateral free trade agreement, those capabilities exist for the U.S. in dealing with any other country that is a member of the WTO?

Mr. DOOLEY. That is absolutely correct.

Mr. MATHESON. The next question I wanted to ask you is you have testified that the focus of our efforts to improve food safety ought to be placed on prevention in your words to reduce the number of needles in the haystack. How much of this burden should be placed on the food industry and how much should be placed on the public sector?

Mr. DOOLEY. Well, I think, clearly we are going to be most effective at one that is a partnership, but it is clearly the private sector that can make the biggest difference. And what we are suggesting that if we really are objective and we look at the scope of this problem, the vast majority of our food products are safe, those that are imported as well as domestic. And the reason for that is that most

manufacturers are currently today deploying best practices that provide that level of food safety. So what we are suggesting is that, there might be some folks out there that need to change some of their operation protocols, and why don't we work again in partnership with FDA and the consumer groups to help develop some mandatory guidance that would ensure that those best practices are being deployed by anybody that is importing a food product into this country. And then in fact we think, well, further enhance and build upon the already safe food supply that we have today. Where we are somewhat concerned in terms of the difference between Congressman Dingell's approach is on relying more on an inspection approach. People were talking today we are inspecting 1 percent of the food that is coming into this country. OK. So if we inspect 10 percent, is that going to give us that much greater margin of safety? We would argue it might help on the margins, but your greatest difference is going to be by finding that effective partnership with the private sector to ensure that these best practices are being put in place.

Mr. MATHESON. As I said in my opening statement, while the issues are not completely the same, when we are talking about the toy safety issue in another subcommittee on this committee, we are talking about doing preventive measures back at the source along the manufacturing chain, whereas on the food safety, the proposed legislation seems to be focusing more on the back end, and I think it might be healthy for us to consider the benefits of looking at the overall supply chain. I suspect you probably agree with that. Dr. Hollingsworth, quick question for you. The proposed legislation seeks to give FDA the authority to recall products. Since this would be a new authority as I understand it for FDA, I am interested to hear ideas on what would make recalls more effective from the retailers' perspective.

Dr. HOLLINGSWORTH. I think from a retailers' perspective, the biggest issue that we are challenged with is the communication system of recalls, getting the information from the manufacturer who is initiating the recall, whether it was mandatory or voluntary. It is getting that information down to the retailers so they know what products need to be recalled and also allowing retailers to be involved in the initial discussions. Retailers are excluded from any discussions about possible recalls until that information is given to the media. And so we are always trying to play catch-up on a recall. We would like to be engaged earlier, and we are working to find better ways to help those communications and also ways that we can be sure that the word gets out to the customer, if in fact they have bought that product.

Mr. MATHESON. I was going to ask you, also you talked about communication to the retailer, and I was also going to say how does it work for communication directly to the consumer? Do you think there are better ways in the public and private sector to partner in this communication?

Dr. HOLLINGSWORTH. I think there are ways we can do better, and that is one of the things that our board task force is looking at now, having more uniformity in the announcements and the messages so that people will understand what is being recalled and what to do with that product.

Mr. MATHESON. Mr. Chairman, I know my time expired but I just would emphasize I think this issue of communication is one that would merit our review of it on the committee. I think that is a really relevant issue both communication with the retailer and on down to the consumer level. I think that is a healthy issue for us to discuss. I will yield back.

Mr. PALLONE. Thank you. I am going to ask a couple more questions, too, so if you want to you can. I just had two questions of Mr. Hubbard. In your testimony you talk about building safety into products, and you specifically cite Hazard Analysis Critical Control Points as a model adopted by the FDA and the Department of Agriculture in the 1960s. But given all the recent contaminations we have had with spinach, peanut butter, and other products, I am wondering why this model no longer appears to be effective? What has changed exactly?

Mr. HUBBARD. Well, it is not in place for those products. It is only in place for meat and poultry at USDA and for seafood and juice at FDA. In fact, I understand there have been press reports that the FDA leadership requested that the Secretary allow him to move to adopt that for produce, meaning in February, but was denied. So, I think it has been proven first by the industry and later by FDA regulation that the concept of HACCP does work because it builds in safety and it is much as Mr. Dooley was describing, you have got the people in the supply chain now taking some responsibility rather than putting it all on the FDA to inspect a product at the end which has proven not to work. You don't want to rely on that inspection at the end because it will fail. You need to have everyone producing safe food and then letting FDA be the regulator that comes in and verifies that folks are in fact building safety and keeping records so that you know that they are doing that and keeping them honest. And then you have in my opinion a safe process.

Mr. PALLONE. OK. And then the second question, in your testimony you state that you think that reengineering our import safety system could actually improve some of our trade relationships, but there are Members who are looking at this legislation, especially the import user fee, and see it as a possible trade barrier. Can you elaborate on why you think this may be good for trade?

Mr. HUBBARD. Well, let us take the case of China. They have been hit pretty hard by this. They produce a tremendous amount of goods for our country. Most of it is very safe. We have got a small problem here. One would hope that if processes are in place that say to the producers in China, produce safer food, then the overall Chinese export economy will improve. I am told by experts on China and a number of them that the Chinese Government does not have the wherewithal to assure the safety of exports to us, that they don't have the reach into the hinterlands of China, they don't have the regulatory structure. It could take years to develop such a thing. So if by putting into place the preventative system we are talking about to have the Chinese producers producing safer food, the sense I get is the Chinese Government would say we win in that because then products coming out of China are safer products. And then they have a better reputation in the world market. I

would defer to a trade expert on that, but I would argue that in the end they win, too.

Mr. PALLONE. OK. Thank you. Did you want to ask anything else? All right. Let me just remind everybody that Members may submit additional questions for the record to be answered by all of you, and those questions should be submitted to the clerk within the next 10 days, and then the clerk will notify you if we have any. And again, I just want to thank you all. I know it has been a long day here with the interruptions from the floor, but that is the way things go. Mr. Dooley is certainly familiar with it. And without objection, this meeting of the subcommittee is adjourned.

[Whereupon, at 3:40 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

I

110TH CONGRESS
1ST SESSION

H. R. 3610

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food and drugs imported into the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 20, 2007

Mr. DINGELL (for himself, Mr. PALLONE, and Mr. STUPAK) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food and drugs imported into the United States, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Food and Drug Import Safety Act of 2007".

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

SEC. 2. RESEARCH ON TESTING TECHNIQUES FOR USE IN INSPECTIONS OF IMPORTED FOOD SAFETY; PRIORITY REGARDING DETECTION OF INTENTIONAL ADULTERATION.

Section 801 of the Federal Food, Drug, and Cosmetic Act (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.—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. In providing for research under paragraph (1), the Secretary shall under the preceding sentence give priority to conducting research on the development of tests for detecting the presence in food of the pathogens E. coli, salmonella, cyclospora, cryptosporidium, hepatitis A, or listeria, the presence in or on food of pesticide chemicals and related residues, the presence in or on food of chemical toxins, and the presence in or on food of 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. The Secretary shall establish the goal of developing, by the expiration of the

3-year period beginning on the date of the enactment of the this subsection, tests under paragraph (1) for each of the pathogens and substances receiving priority under the preceding sentence.

"(3) PERIODIC REPORTS.—The Secretary shall submit to the Congress periodic reports describing the progress that has been made toward the goal referred to in paragraph (1) and describing plans for future research toward the goal. 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. The first such report shall be submitted not later than March 1, 2008, and subsequent reports shall be submitted semiannually after the submission of the first report until the 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. 3. USER FEES REGARDING INSPECTIONS OF IMPORTED FOOD SAFETY.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended by inserting after section 801 the following:

"USER FEES REGARDING FOOD SAFETY

"SEC. 801A. (a) IN GENERAL.—

"(1) ASSESSMENT.—Beginning in fiscal year 2008, the Secretary shall in accordance with this section assess and collect fees on food imported into the United States.

"(2) PURPOSE OF FEES.—

"(A) IN GENERAL.—The purpose of fees under paragraph (1) is to defray the costs of carrying out section 801 with respect to food over the costs of carrying out such section with respect to food in fiscal year 2007 multiplied by the adjustment factor. Fees under paragraph (1) may be used to pay for overseas inspection with respect to food by the Department of Health and Human Services.

"(B) ALLOCATIONS BY SECRETARY.—Of the total fee revenues collected under paragraph (1) for a fiscal year, the Secretary shall reserve and expend amounts in accordance with the following:

"(i) The Secretary shall reserve not less than 90 percent for carrying out section 801 with respect to food, other than research under section 801(p). In expending the amount so reserved, the Secretary shall give priority to inspections conducted at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

"(ii) The Secretary shall reserve not more than 10 percent for carrying out research under section 801(p).

"(C) LABORATORY TESTING.—In this paragraph, the term 'costs of carrying out section 801' with respect to food being imported or offered for import includes the costs of laboratory testing of such food, including laboratory personnel costs.

"(3) AMOUNT OF FEE; COLLECTION.—A fee under paragraph (1) shall be assessed on each line item of food, as defined by the Secretary by regulation. The amount of the fee shall be based on the number of line items, and may not exceed $50 per line item, notwithstanding subsection (b). The liability for the fee constitutes a personal debt due to the United States, and such liability accrues on the date on which the Secretary approves the food under section 801(c)(1). The Secretary may coordinate with and seek the cooperation of other agencies of the Federal Government regarding the collection of such fees.

"(b) TOTAL FEE REVENUES.—The total fee revenues collected under subsection (a) for a fiscal year shall be the amount appropriated under subsection (f)(3).

"(c) ADJUSTMENTS.—

"(1) INFLATION ADJUSTMENT.—With respect to the amount of total fee revenues referred to in subsection (b), the amount authorized in subsection (f)(3) for a fiscal year shall be adjusted by the Secretary (and as adjusted shall be published in the Federal Register) to reflect the greater of—

"(A) the total percentage change that occurred during the preceding fiscal year in the

Consumer Price Index for all urban consumers (all items; U.S. city average); or

"(B) the total percentage change for such fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

"(2) ANNUAL FEE ADJUSTMENT.—Not later than 60 days after the end of each fiscal year beginning after fiscal year 2008, the Secretary, subject to not exceeding the maximum fee amount specified in subsection (a)(3), shall adjust the amounts that otherwise would under subsection (a) be assessed as fees during the fiscal year in which the adjustment occurs so that the total revenues collected in such fees for such fiscal year equal the amount applicable pursuant to subsection (b) for the fiscal year.

"(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of a fee assessed under subsection (a) where the Secretary finds that the fee to be paid will exceed the anticipated present and future costs incurred by the Secretary in carrying out sec-

tion 801 with respect to food (which finding may be made by the Secretary using standard costs).

"(e) ASSESSMENT OF FEES.—

"(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless 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 the Food and Drug Administration for fiscal year 2008 multiplied by the adjustment factor applicable to the fiscal year involved, except that in making determinations under this paragraph for the fiscal years involved there shall be excluded—

"(A) the amounts appropriated under subsection (f)(3) for the fiscal years involved;

"(B) the amounts appropriated under section 801B(f)(3) for such fiscal years; and

"(C) the amounts appropriated under section 736(g) for such fiscal years.

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect

such fees, without any modification in the rate of the fees, at any time in such fiscal year notwithstanding the provisions of subsection (a)(3) relating to the time at which fees are to be paid.

"(f) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for carrying out section 801 with respect to food, and the sums are subject to allocations under subsection (a)(2)(B).

"(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized in subsection (a)—

"(A) shall be collected in each fiscal year in accordance with subsections (a)(3) and (b); and

"(B) shall only be collected and available for the purpose specified in subsection (a)(2).

"(3) AUTHORIZATION OF APPROPRIATIONS; ALLOCATIONS BY SECRETARY.—Subject to paragraph (4) and subsection (c)(1), there is authorized to be appropriated for fees under this section $500,000,000 for each of the fiscal years 2008 through 2012.

"(4) OFFSET.—Any amount of fees collected for a fiscal year under subsection (a) that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

"(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

"(h) CONSTRUCTION.—This section may not be construed as requiring that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in carrying out section 801 with respect to food be reduced to offset the number of officers, employees, and advisory committees so engaged.

"(i) DEFINITION OF ADJUSTMENT FACTOR.—For purposes of this section, the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April 2007.".

SEC. 4. USER FEES REGARDING INSPECTIONS OF IMPORTED DRUG SAFETY.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.), as amended by section 3, is further amended by inserting after section 801A the following:

"USER FEES REGARDING DRUG SAFETY

"SEC. 801B. (a) IN GENERAL.—

"(1) ASSESSMENT.—Beginning in fiscal year 2008, the Secretary shall in accordance with this section assess and collect fees on drugs imported into the United States.

"(2) PURPOSE OF FEES.—

"(A) IN GENERAL.—The purpose of fees under paragraph (1) is to defray the costs of carrying out section 801 with respect to drugs over the costs of carrying out such section with respect to drugs in fiscal year 2007 multiplied by the adjustment factor. Fees under paragraph (1) may be used to pay for overseas inspection with respect to drugs by the Department of Health and Human Services.

"(B) PRIORITY.—In expending the fee revenue amounts collected under paragraph (1), the Secretary shall give priority to—

"(i) inspections conducted at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration or misbranding of drugs; and

"(ii) inspections of good manufacturing practices conducted abroad.

"(C) LABORATORY TESTING.—In this paragraph, the term 'costs of carrying out section 801' with respect to drugs being imported or offered for import includes the costs of laboratory testing of such drugs, including laboratory personnel costs.

"(3) AMOUNT OF FEE; COLLECTION.—A fee under paragraph (1) shall be assessed on each line item of drugs, as defined by the Secretary by regulation. The amount of the fee shall be based on the number of line items, and may not exceed $1000 per line item, notwithstanding subsection (b). The liability for the fee constitutes a personal debt due to the United States, and such liability accrues on the date on which the Secretary approves the drugs under section 801(c)(1). The Secretary may coordinate with and seek the cooperation of other agencies of the Federal Government regarding the collection of such fees.

"(b) TOTAL FEE REVENUES.—The total fee revenues collected under subsection (a) for a fiscal year shall be the amount appropriated under subsection (f)(3).

"(c) ADJUSTMENTS.—

"(1) INFLATION ADJUSTMENT.—With respect to the amount of total fee revenues referred to in subsection (b), the amount authorized in subsection (f)(3) for a fiscal year shall be adjusted by the Secretary (and as adjusted shall be published in the Federal Register) to reflect the greater of—

"(A) the total percentage change that occurred during the preceding fiscal year in the

Consumer Price Index for all urban consumers (all items; U.S. city average); or

"(B) the total percentage change for such fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

"(2) ANNUAL FEE ADJUSTMENT.—Not later than 60 days after the end of each fiscal year beginning after fiscal year 2008, the Secretary, subject to not exceeding the maximum fee amount specified in subsection (a)(3), shall adjust the amounts that otherwise would under subsection (a) be assessed as fees during the fiscal year in which the adjustment occurs so that the total revenues collected in such fees for such fiscal year equal the amount applicable pursuant to subsection (b) for the fiscal year.

"(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of a fee assessed under subsection (a) where the Secretary finds that the fee to be paid will exceed the anticipated present and future costs incurred by the Secretary in carrying out sec-

tion 801 with respect to drugs (which finding may be made by the Secretary using standard costs).

"(e) ASSESSMENT OF FEES.—

"(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2008 unless 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 the Food and Drug Administration for fiscal year 2008 multiplied by the adjustment factor applicable to the fiscal year involved, except that in making determinations under this paragraph for the fiscal years involved there shall be excluded—

"(A) the amounts appropriated under subsection (f)(3) for the fiscal years involved;

"(B) the amounts appropriated under section 801A(f)(3) for such fiscal years; and

"(C) the amounts appropriated under section 736(g) for such fiscal years.

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect

such fees, without any modification in the rate of the fees, at any time in such fiscal year notwithstanding the provisions of subsection (a)(3) relating to the time at which fees are to be paid.

"(f) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for carrying out section 801 with respect to drugs.

"(2) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized in subsection (a)—

"(A) shall be collected in each fiscal year in accordance with subsections (a)(3) and (b); and

"(B) shall only be collected and available for the purpose specified in subsection (a)(2).

"(3) AUTHORIZATION OF APPROPRIATIONS; ALLOCATIONS BY SECRETARY.—Subject to paragraph (4) and subsection (c)(1), there is authorized to be appropriated for fees under this section $300,000,000 for each of the fiscal years 2008 through 2012.

"(4) OFFSET.—Any amount of fees collected for a fiscal year under subsection (a) that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

"(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

"(h) CONSTRUCTION.—This section may not be construed as requiring that the number of full-time equivalent positions in the Department of Health and Human Serv-

ices, for officers, employees, and advisory committees not engaged in carrying out section 801 with respect to drugs be reduced to offset the number of officers, employees, and advisory committees so engaged.

"(i) DEFINITION OF ADJUSTMENT FACTOR.—For purposes of this section, the term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for April of the preceding fiscal year divided by such Index for April 2007.".

SEC. 5. AUTHORITY TO RESTRICT FOOD IMPORTATION TO SPECIFIC PORTS OF ENTRY.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended by section 2, is further amended by adding at the end the following:

"(q) AUTHORITY TO RESTRICT FOOD IMPORTATION TO SPECIFIC PORTS OF ENTRY.—

"(1) IN GENERAL.—The Secretary shall restrict the importation of all food to ports of entry that are located in a metropolitan area with a laboratory of the Food and Drug Administration for testing such food.

"(2) WAIVER.—The Secretary may waive the requirement of paragraph (1) and authorize the im-

portation of food to a port of entry not described in such paragraph if the Secretary certifies that—

"(A) the importation of such food through such port will not increase the probability that such food will cause serious, adverse health consequences or death; or

"(B) there is a reasonable probability that the type food involved will not cause serious, adverse health consequences or death.

"(3) IMPLEMENTATION.—The Secretary shall implement this subsection beginning not later than 5 years after the date of the enactment of this subsection.".

SEC. 6. COUNTRY OF ORIGIN LABELING.

(a) FOOD.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

"(z) If the labeling of the food fails to identify the country of origin of the food.".

(b) DRUGS AND DEVICES.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

"(y) If it is a drug or device and its labeling fails to identify the country of origin of the drug or device.".

(c) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall promulgate final regulations to carry out sections 403(z) and 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), respectively.

(d) EFFECTIVE DATE.—The requirements of sections 403(z) and 502(y) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), respectively, take effect on the date that is 180 days after the date of the enactment of this Act.

SEC. 7. SAFE AND SECURE FOOD IMPORTATION PROGRAM.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (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—

"(1) persons importing food into the United States voluntarily agree to abide by the food safety and security guidelines developed under subsection (b); and

"(2) the Secretary agrees to expedite the movement of such food through the inspection process.

"(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.—The guidelines developed under paragraph (1) 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.".

SEC. 8. CIVIL PENALTIES.

Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

(1) by redesignating subsection (g) (relating to civil penalties) as subsection (f): and

(2) in subparagraph (A) of paragraph (2) of subsection (f), as so redesignated, by striking "Any person who introduces" and all that follows through the end of the subparagraph and inserting the following: "Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of—

"(i) not more than $50,000 in the case of any individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding; or

"(ii) notwithstanding clause (i), if such person is the manufacturer or the importer of the food, not more than $100,000 in the case of any individual and $500,000 in the case of

any other person for such introduction or delivery, not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.".

SEC. 9. 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 subsection (a) to the Comptroller General, 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 180 days after the date on which the Comptroller General submits the report required by subsection (c).

SEC. 10. RECALL AUTHORITY.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by section 6 of this Act, is amended by adding at the end the following:

"SEC. 418. RECALL AUTHORITY.

"(a) ORDER TO CEASE DISTRIBUTION.—

"(1) IN GENERAL.—If the Secretary finds that a food may cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the food) to immediately cease distribution of the food.

"(2) INFORMAL HEARING.—An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing,

to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of the food involved. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(b) ORDER TO RECALL.—

"(1) IN GENERAL.—If, after providing an opportunity for an informal hearing under subsection (a)(2), the Secretary determines that the order should be amended to include a recall of the food with respect to which the order was issued, the Secretary shall, except as provided in paragraphs (2) and (3), amend the order to require a recall. The Secretary shall specify a timetable in which the food recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

"(2) CERTAIN ACTIONS.—An amended order under paragraph (1) shall not include recall of a food from individuals.".

SEC. 11. INSPECTION AND OTHER STANDARDS; APPLICABILITY, ENFORCEMENT; CERTIFICATIONS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 10 of this Act, is amended by adding at the end the following:

"SEC. 419. INSPECTION AND OTHER STANDARDS; APPLICABILITY, ENFORCEMENT; CERTIFICATIONS.

"(a) IN GENERAL.—Notwithstanding any other provision of law, all food that is offered for importation into the United States shall be subject to the food safety standards applied to such food produced in the United States.

"(b) ENFORCEMENT.—Any food that appears to not meet all the standards referred to in subsection (a) shall be considered adulterated and shall not be permitted entry into the United States.

"(c) RANDOM INSPECTIONS.—The Secretary shall enforce this section through appropriate random inspections, sampling, and testing.

"(d) CERTIFICATIONS REGARDING FOREIGN FACILITIES.—

"(1) REQUIREMENT.—No food shall be permitted entry into the United States from a foreign facility in a foreign country unless there is—

"(A) a certification for such facility in effect under paragraph (2)(A); or

"(B) a certification for such country under paragraph (2)(B).

"(2) CERTIFICATION.—

"(A) FOREIGN FACILITY.—Each foreign facility seeking to import food into the United States may obtain a certification by the Secretary stating that the facility maintains a program using reliable analytical methods to ensure compliance with all the standards referred to in subsection (a).

"(B) FOREIGN COUNTRY.—A foreign country may obtain a certification by the Secretary stating that—

"(i) the country has in effect and is enforcing food safety standards at least as protective of food safety as the standards applicable to food in the United States; and

"(ii) the country has a program in effect to monitor and enforce its food safety standards with respect to food being exported from such country to the United States.

"(3) PERIODIC REVIEW.—The Secretary shall periodically review certifications under paragraph (2)

and shall revoke any certification if the Secretary determines that the foreign facility or foreign country involved is no longer meeting the requirements described in such paragraph.

"(4) INSPECTION.—The consideration of any application for a certification under paragraph (2) and the review of any such certification, by the Secretary, may include the inspection of foreign facilities to ensure that the inspection program of the foreign facility involved is meeting such standards.

"(5) FOREIGN FACILITY.—In this subsection, the term 'foreign facility' means a foreign facility (as defined in section 415(b)(3)) that is required to be registered under section 415.

"(6) EFFECTIVE DATE.—This subsection takes effect beginning on the date that is 5 years after the date of the enactment of the Food and Drug Import Safety Act of 2007.".

SEC. 12. REGULATIONS ON ADEQUATE TESTING OF PROCESSED FOOD.

Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 11 of this Act, is amended by adding at the end the following:

"SEC. 420. REGULATIONS ON ADEQUATE TESTING OF PROCESSED FOOD.

"(a) IN GENERAL.—Not later than 2 years after the date of the enactment of the Food and Drug Import Safety Act of 2007, the Secretary shall by regulation require that, as good manufacturing practices, processed food undergo testing to detect substances in the food that may render the food adulterated, including microbial pathogens, toxic chemicals, and such other substances as the Secretary determines to be appropriate.

"(b) REVIEW OF TEST RESULTS.—Regulations under subsection (a) shall require that the results of tests under such subsection be provided to the Secretary upon demand.".

SEC. 13. RECORDS OF INTERSTATE SHIPMENT.

Subsection (a) of section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

(1) by striking "upon the request" and inserting "upon the written or oral request"; and

(2) by striking ", except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food,

drugs, devices, or cosmetics in the usual course of business as carriers, except as provided in subsection (b)".

SEC. 14. LABELING REQUIREMENT FOR MEAT, POULTRY PRODUCTS, AND SEAFOOD THAT CONTAIN CARBON MONOXIDE.

(a) LABELING REQUIREMENT.—

(1) IN GENERAL.—Paragraph (t) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(t)) is amended by adding at the end the following new paragraph:

"(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 finfish, molluscan shellfish, crustaceans, and other forms of aquatic animal life) intended for human consumption as food within the meaning of section 201(f) of this Act (referred to collectively in this subsection 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: 'SAFETY 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 or safety of the product. Discard any product with an unpleasant odor, slime, or a bulging package.' ".

(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)(1), 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.

○

October 30, 2007

The Honorable Calvin Dooley
President and CEO
Grocery Manufacturers Association
Suite 300
1350 I Street, N.W.
Washington, D.C. 20005

Dear Mr. Dooley:

Thank you for appearing before the Subcommittee on Health on Wednesday, September 26, 2007, at the hearing entitled "H.R. 3610, The Food and Drug Import Safety Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached is a question directed to you from a certain Member of the Committee. In preparing your answer to this question, please address your response to the Member who has submitted the question and include the text of the Member's question along with your response.

To facilitate the printing of the hearing record, your response to this question should be received no later than the close of business **Friday, November 9, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your responses should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

November 9, 2007

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

Dear Chairman Dingell:

Thank you again for the opportunity to appear before the Energy & Commerce Committee's Subcommittee on Health on September 26th. Attached please find my responses to your additional questions regarding my testimony.

Sincerely,

Cal Dooley
President and CEO

Cc: Melissa Sidman

1350 I Street, NW :: Suite 300 :: Washington, DC 20005 :: ph 202-639-5900 :: fx 202-639-5932
www.gmaonline.org

Responses to Questions for the Record

**September 26, 2007 Hearing before Subcommittee on Health,
House Committee on Energy and Commerce**

Submitted by: The Honorable John D. Dingell

**Responses by: Cal Dooley, President and CEO
Grocery Manufacturers / Food Products Association**

Question # 1: I applaud your efforts to help ensure the safety of the Nation's food supply. However, I fail to see how this deviates dramatically from our current voluntary system. Under your proposal, the Food and Drug Administration (FDA) would be given only one new authority—to review the effectiveness of foreign supplier quality assurance programs adopted by all imports of record. Is the correct?

Answer: To the contrary, we believe our proposal offers a comprehensive approach to ensuring the safety of imported food, which focuses on prevention rather than on finding problems only after they are ready to enter our country. We believe our proposals, if supported by adequate appropriated resources, would make a dramatic improvement in the safety of imported food products. You are correct that, under Pillar 1 of our proposal, FDA would be given the authority to review the effectiveness of foreign supplier quality of assurance programs adopted by importers of record, but this also means that such importers of record, for the first time, would have an express legal obligation to establish such programs, and FDA would be able to enforce that new requirement. So we believe that, by itself, is quite significant.

But our proposals are more far reaching than this one new requirement. Under Pillar 2, FDA would be given the authority to establish a voluntary qualified importer program that would help redirect FDA's border surveillance to products from other importers that present a higher risk. Under Pillar 3, FDA would be given the legal mandate to build the capacity of foreign governments and thereby help to build safety and quality into food products from the source. And finally, under Pillar 4, FDA would be given the legal mandate to do its job at the border in a risk-based, science-based manner. So taken together, we believe our proposals are quite significant and would lead to dramatic improvements in imported food safety.

Question # 2: In the third prong of your proposal, you mention that FDA should help build the capacity of foreign governments. How does FDA help build the capacities of other governments when it has yet to build its own capacity? Should we not first ensure that FDA has adequately built its own capacity before extending its already stretched resources to others?

Answer: We believe that both are needed, and that, in fact, building the capacity of foreign governments will greatly reduce the burden on what FDA has to accomplish at the U.S. border. So it is an investment worth making. The fundamental premise of our proposal is that the way to best improve food safety is to take a preventive approach and seek to build food safety into the products from the very source of production. The more that foreign governments can instill the need for and oversee the safety of foods produced in their countries (that are intended for export to the United States), the better our system for food protection will be at the U.S. border. The FDA has a full and complete understanding of food safety laws and expectations for foods sold in this country, and, if given adequate appropriated resources the agency could effectively use that understanding to build foreign capacity in those very same food safety requirements.

November 6, 2007

Randall L. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Lutter:

Thank you for appearing before the Subcommittee on Health on Wednesday, September 26, 2007, at the hearing entitled "H.R. 3610, The Food and Drug Import Safety Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the question and include the text of the Member's question along with your response. Because you are being asked questions from more than one Member of the Committee, please begin the responses to each Member on a new page.

To facilitate the printing of the hearing record, your response to these questions should be received no later than the close of business **Tuesday, November 20, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your responses should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Janice D. Schakowsky, Member
Subcommittee on Health

The Honorable Anna G. Eshoo, Member
Subcommittee on Health

The Honorable Mike Ross, Member
Subcommittee on Health

The Honorable Mike Rogers, Member
Subcommittee on Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

FEB 0 1 2008

Dear Mr. Chairman:

Thank you for providing the Food and Drug Administration (FDA or the Agency) the opportunity to testify at the September 26, 2007, hearing entitled, "H.R. 3610, The Food and Drug Import Safety Act," before the Subcommittee on Health, Committee on Energy and Commerce. Randall Lutter, Ph.D., FDA's Deputy Commissioner for Policy, testified on behalf of the Agency.

We are responding to the letter of November 6, 2007, you sent in follow-up to the hearing. As instructed in your letter, we have included FDA's responses to the questions from each Member on the following, separate pages. Each question is restated in bold, followed by our response.

Thank you again for the opportunity to testify. Please let us know if there are further questions.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

Questions from the Honorable John D. Dingell

1. As part of this investigation, Committee staff has been working with various offices in your Agency to ascertain the workload of the Food and Drug Administration (FDA). FDA staff has indicated to Committee staff that there are between 2,000 and 3,000 foreign pharmaceutical product manufacturing firms registered with the U.S. that may be shipping drug products to the United States, and, as such, should be subject to periodic surveillance inspections. Is that correct?

FDA's Drug Registration and Listing System (DRLS) provides information regarding the number of establishments registered with FDA and that number is likely closer to 3,000 establishments when the query is "human drug foreign *manufacturing* sites." However, FDA only inspects those establishments that actually export drug products and active pharmaceutical ingredients (APIs) to the U.S. FDA believes that many establishments register with FDA because drug establishment registration is free and this is often misinterpreted as a sign of FDA approval in some countries. As part of our "Foreign Establishment Inventory Assessment," we intend to compare our foreign establishment inventory against import data in the Operational and Administrative System for Import Support (OASIS) to determine which establishments are shipping to the U.S. and which are not.

In the future, we hope to be able to provide more concise information about these firms with the implementation of the new electronic Drug Registration and Listing System (e-DRLS) and the Program Quality System, which is an Agency-wide initiative to provide for an electronic mechanism for manufacturers' registration and product listings, as well as for capturing inspection data from compliance reviews. The result will be a reliable, up-to-date, master inventory of FDA-regulated firms, facilities, establishments, and products, and their associated information. Initial planning for the Program Quality System initiative should be completed by the end of calendar year 2008.

2. How many foreign inspections of drug manufacturers are conducted by FDA in a year? Please provide for the record this annual number from the last 10 years.

FDA has conducted an average of 237 inspections per fiscal year (FY) in the last ten years. We report below the number of inspections each year for the last ten fiscal years.

FY97	274	FY02	211
FY98	259	FY03	189
FY99	214	FY04	257
FY00	247	FY05	255
FY01	249	FY06	212

3. During an FDA staff briefing, it was noted that FDA can only undertake about 25 of these foreign surveillance inspections per year due to resource constraints. Is this correct?

The majority of FDA foreign drug inspections are initiated as pre-approval inspections and stand-alone surveillance inspections are assigned as remaining resources permit. FDA conducted 30 stand-alone surveillance inspections in FY07. Additional Good Manufacturing Practice (GMP) surveillance inspections are conducted along with those initiated for pre-approval. Including these, FDA conducted 225 surveillance inspections in FY07.

4. Committee staff recently accompanied FDA inspectors to India and China to observe several of their inspections of firms exporting drug products to the United States. These inspectors and others told Committee staff that if an inspection is not conducted every 2 or 3 years, it is very difficult to accurately know what is taking place inside a typical foreign overseas firm. Would you agree with this statement?

We must carefully balance the use of our current resources in the most efficient manner. FDA has a program to assure the safety and quality of products coming into this country through:

- initial inspection of any sites that are included in an application, through its current Good Manufacturing Practice (cGMP). The cGMP regulation (Title 21, *Code of Federal Regulations* (CFR) 210 and 211)) requires examination and testing of ingredients prior to use in finished products by the manufacturer; and

- import programs that electronically screen 100 percent of import entries for the various requirements to market drugs and their ingredients in the U.S.

FDA's monitoring of foreign-manufactured drugs is based on more than foreign inspections. The Federal Food, Drug, and Cosmetic (FD&C or the Act) Act limits the drugs and biologics that may be imported into the U.S. Congress enacted these provisions to create a relatively "closed" distribution system for such products, which helps ensure that the domestic supply is safe and effective.

New drugs must be pre-approved by FDA as safe and effective for their intended use. Prescription drugs that were originally manufactured in the U.S. and then sent abroad may only be re-imported into the U.S. by their manufacturer. FDA approvals are manufacturer-specific and product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, manufacturing controls, labeling, and the container/closure system. Drugs manufactured for the U.S. market must be manufactured in facilities meeting the requirements of FDA's cGMP.

When an FDA-regulated product is offered for import into the U.S., U.S. Customs and Border Protection (CBP) notifies FDA. FDA performs 100 percent electronic screening of APIs and drug products entering into the U.S. to establish whether, if required, the drug product has been approved by FDA or the API is consigned to a plant that corresponds with its designated approval in the drug product application. FDA also screens to determine if the manufacturing plant is registered and the drug is listed. FDA performs surveillance examinations of imported

goods to check for compliance with U.S. requirements. In addition, the burden of proof to prohibit an FDA-regulated product from U.S. commerce is different (and considerably less) for products coming from foreign sources. Foreign-manufactured products may not be allowed into the U.S. if FDA concludes there is an appearance of a violation of the FD&C Act.

Another key tool, the Import Alert for Detention Without Physical Examination (DWPE), allows FDA field personnel to detain the product without physical examination based on the appearance of a violation as documented in the Import Alert. FDA personnel also perform periodic filer evaluations to ensure that import data being provided to the Agency is accurate.

U.S. manufacturers also have a responsibility to ensure the safety of foreign-manufactured ingredients used for their finished dosage forms. Thus, U.S. manufacturers of finished dosage drugs who import APIs from abroad have an obligation to examine and test ingredients before using them in their drug products under cGMP. FDA conducts inspections of firms' foreign as well as domestic manufacturing facilities to determine if the manufacturing facilities meet the quality standards for products for U.S. consumers. In addition, FDA inspections routinely evaluate the manufacturers' testing and controls of ingredients and supplies. If FDA determines that an imported API fails to meet specifications or is manufactured using unsafe practices, an assignment to field personnel or surveillance import alert can be used to trigger testing of future shipments, or the drug may be subject to DWPE at the U.S. border.

5. Please confirm that, by law, FDA is required to inspect domestic drug manufacturing facilities every two years.

Section 510(h) of the FD&C Act requires FDA to inspect registered domestic drug manufacturing facilities at least once every two years (Title 21, *United States Code* (USC) 360(h)), and we strive to meet that obligation.

6. When the Committee investigated this subject in the late 1990s, we found that there were firms importing drug products into the United States that had not been inspected for nearly a decade or longer. Drug firms exporting to the U.S. have increased dramatically since then. Would you agree that this situation has become much worse, with even greater lapses of time between inspections?

We are aware of the expanding global market of pharmaceutical products (and other products regulated by FDA) and the continuing outsourcing of pharmaceutical manufacturing abroad, and we are working to address the challenges these present. We continue to evaluate this dynamic, ever-changing marketplace, and improve our import operations and foreign inspection programs to meet new challenges.

Some of the progress we have made to address this expanding global market includes our efforts to improve FDA's information technology (IT) systems by using a methodical, systematic, Agency-wide (and inter-agency) approach. This effort includes the formation of the Bioinformatics Board (BiB) in 2006, which provides an important means of ensuring that IT services equally meet business needs and public safety endeavors. Currently, plans are underway to upgrade and integrate many essential IT systems related to FDA's foreign

inspection program. FDA envisions the BiB will serve the Agency's IT needs in the future and will be adaptable as the global marketplace poses new challenges over time.

In addition, FDA is beginning to develop an increased Agency presence abroad to further understand conditions in other countries and to be able to more easily exercise oversight and obtain information critical to keeping pharmaceutical products safe for United States citizens. FDA is in the early stages of negotiating with other countries to establish cooperative agreements. For example, on December 11, 2007, the U.S. Department of Health and Human Services and the State Food and Drug Administration (SFDA) of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of drugs, excipients, and medical devices exported to the U.S. from China. Among other things, SFDA will require firms that manufacture certain products intended for export to the U.S. to register with SFDA. SFDA will also assist and facilitate FDA access to relevant manufacturing sites in China.

Aside from these negotiations, the Office of Compliance within FDA's Center for Drug Evaluation and Research (CDER) conducted a series of educational workshops in China in December 2005 and April 2006 on cGMP, in collaboration with the International Society for Pharmaceutical Engineering (ISPE) and Peking University. The workshops were intended to educate participants on current methods for compliance with cGMP, to ensure effective cGMP programs, and to further the common goals of FDA and providers of quality pharmaceutical products. The workshops were open to any professionals involved in the manufacture, control, and regulation of pharmaceutical products, including process/production engineers, manufacturing personnel, quality assurance/quality control and regulatory affairs professionals, consultants, regulatory investigators and cGMP compliance officials. The workshops were designed to educate and guide participants on the methodologies and implementation of cGMP as applied to quality drug manufacturing. Presentations by both FDA and industry provided a regulatory and practical perspective on the current relevant critical topics. FDA hopes that such workshops will improve compliance with cGMP, now and in the future.

7. If the FDA regularly inspects domestic firms every 2 years in a fairly well-regulated environment, how can it justify 8 to 10 year intervals for inspections of foreign firms in parts of the world that have very rudimentary regulatory environments? Does the law require the same inspection schedule for foreign drug manufacturing firms as it does for domestic firms?

There are no statutory or regulatory requirements that direct FDA to inspect foreign drug manufacturing firms at a particular frequency. Our inspection program overseas is primarily driven by pre-approval inspections. This type of inspection brings us to sites that consistently file applications or that we have never inspected because they are new sites. In addition, we use a risk-based approach to determine which additional surveillance inspections to conduct.

8. In your testimony, you mentioned that FDA currently reviews approximately 33,400 prior notice submissions per business day. How many FDA staff review these prior notice submissions? How many prior notice submissions are received on the weekends? How many employees review those submissions?

FDA's Prior Notice Center (PNC) receives and electronically screens approximately 33,400 prior notice submissions per business day. On a typical weekend, PNC receives and electronically screens approximately 10,300 prior notice submissions. PNC performs intensive manual reviews on a targeted portion of those prior notice submissions received each and every day. PNC is staffed and fully operational on an around-the-clock basis. Each day, PNC has three 8 hour shifts to cover the 24 hour period. The number of staff on shift at any one time depends upon a variety of factors such as the time of day, the day of the week, whether it is a holiday, national threat levels, contemporary intelligence, and current food defense considerations. For example, during peak business hours when the highest volume of food is imported or offered for import into the U.S., PNC may have as many as seventeen (17) employees present to manage operations. On the other hand, when the volume of imported food shipments is at its lowest (typically weekends, holidays, and during the 11:00 p.m. to 7:00 a.m. EST timeframe), PNC may function with as few as three (3) employees on a given shift. For weekdays, the day shift may include up to seventeen (17) employees, the afternoon shift up to thirteen (13) employees and the midnight shift may include up to six (6) employees to manage operations. On weekends, PNC maintains the same three 8 hour shifts, however typically manages coverage with three (3) employees per shift.

9. You testified that FDA performs routine surveillance inspections. Can you tell the Committee what is the frequency of those inspections? What would be an ideal rate of frequency that would provide you with a high degree of confidence that these inspections were providing a full and accurate picture of the quality of food products coming into this country?

Routine surveillance examinations of imported goods represent one method by which FDA checks for compliance with U.S. admissibility requirements. Initially, all import shipments are screened through OASIS for a variety of risk factors.

FDA's screening and targeting of imported foods in OASIS is based on shipment entry information submitted as part of the entry process, along with other information, to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel. Once a shipment has been designated for further manual review, a number of possible actions can be taken including recommending examination based on compliance programs or specific surveillance assignments.

FDA also uses information submitted under the Prior Notice requirements to target food that may be intentionally contaminated or otherwise pose a significant health risk. This advance notice of imported food enables FDA to determine which shipments pose such a significant risk that they should be inspected at the border.

To manage the increasing volume of imports, FDA is refining its targeting ability to utilize data from a much wider range of sources to better inform entry decisions. By improving its use of IT systems in FDA and other systems, FDA can better identify products on which to perform additional sampling for likely contaminants. FDA also conducts foreign inspections and works with its counterparts in other countries to identify potential problems and solutions at the source.

The recent report of the Import Safety Working Group concluded that the U.S. must transition from an outdated "snapshot" approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused "video" model. Such a model identifies and targets critical points in the import life cycle where the risk to the product is greatest, and then verifies the safety of products at those important points. By refining targeting criteria in a life cycle approach, FDA will be able to conduct more rigorous and meaningful reviews of potentially high-risk food entries and inspections of manufacturing practices overseas.

Additionally, FDA plans to augment its work with food producers as well as foreign governments and Federal partners to ensure that foods produced in foreign facilities meet U.S. safety requirements, with risk-based targeted inspections at the border serving as a second layer of protection, rather than the principal one.

FDA is also considering a number of other measures to improve import safety including a voluntary certification program whereby products could be certified as meeting U.S. safety standards. This may involve verification, e.g., testing or inspection by third parties or by domestic or foreign regulatory bodies.

10. Your testimony states that FDA expects to have recommendations for a strategy to enhance FDA's food safety programs. When will these recommendations be final and publicly available?

On November 6, 2007, Secretary of Health and Human Services Michael O. Leavitt released the Food Protection Plan. Also on that day, FDA provided a briefing on the Plan for staff of the Committee on Energy and Commerce. The report is available on FDA's website at: *http://www.fda.gov/oc/initiatives/advance/food.html.*

11. You testified that FDA has the authority to commission other Federal officers and employees to conduct examinations and investigations. You note that FDA has commissioned over 9,900 Customs and Border Patrol (CBP) officers. When CBP officers are commissioned, do they work solely upon FDA examinations and investigations? How difficult is it for commissioned CBP officers to be reassigned from their FDA duties?

FDA and CBP signed a Memorandum of Understanding (MOU) on December 3, 2003. The MOU is on FDA's website at: *http://www.fda.gov/oc/bioterrorism/moucustoms.html.* It allows FDA to commission CBP officers to assist FDA in the implementation of the Prior Notice provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). This assistance includes coordinating examination and sampling operations with local FDA personnel. At ports that are not staffed by FDA personnel, this assistance could include responding to requests from PNC to examine and sample suspect shipments arriving at such ports.

Under the MOU, the commissioned CBP officers conduct their routine work for CBP and provide assistance to FDA on an as-needed basis when FDA makes a specific request. The act of commissioning them does not reassign them to FDA.

12. You noted that FDA is working to improve its information technology systems. Please describe what FDA is doing and the amount of funds FDA is investing in making this improvement. Is there a timeframe as to when these improvements will be installed and in place?

FDA is working on a number of projects that will improve import safety in the next two to three years. These include:

- Working closely with CBP to ensure that its planned Automated Commercial Environment, a component of International Trade Data System, will provide the functionality long sought by FDA.
- Developing firms' management services to provide a standard way of finding, creating, and updating the information about facilities/enterprises FDA regulates.
- Enhancements to FDA's Decision Support System to boost performance and expand its ability to rapidly access information.
- Ongoing data cleanup and upgrade of internal system interfaces to synchronize and validate data across centers and ensure rapid access to correct information.
- Substantial improvements in the IT infrastructure that helps staff exchange data among field offices and between the field and Headquarters.
- Expansion of the Electronic Exchange Network that facilitates data sharing among public health partners and collaboration among food safety experts.
- FDA's Unified Registration and Listing System (FURLS) integration of the registration and listing systems currently maintained in the individual Centers.
- Developing a Product Quality System to encompass an electronic mechanism for manufacturers' registration and product listings, and capture inspection data from compliance reviews.
- Implementation of FDA's Information and Computer Technologies plan for the 21st (ICT21) century to ensure that FDA has the infrastructure needed to support these IT initiatives and move towards the Bioinformatics era.

In addition to the improvements listed above; a few will extend beyond 2010: The Mission Accomplishment and Regulatory Compliance Services (MARCS) program manages the integration, reengineering, and enhancement of the legacy systems that support Field activities. These systems include OASIS and other components which support import processing. Improvements range from replacing the current process that screens import entries; giving investigators faster access to product information via views of Center databases; improving sample collection/tracking on both desktop and mobile platforms; to developing a broker information center to allow Customs Brokers to quickly exchange information with import reviewers.

The table below shows the total amount, in thousands of dollars, that FDA is currently investing in these improvements:

Initiative	2008
Import related enhancements in MARCS	8.259
ITDS related changes/enhancements	8.4
Standardized FIRMS data management services	0.75
Cleanup/synchronization of firms/establishment data	1
Enhanced Decision Support and reporting	3
Improvements to IT infrastructure in field offices (LABSAN)	.450
Expanded data sharing with food safety partners (eLEXNET)	.65
Improved quality of product information (PQS)	3.8
Unified Center Registration and Listing systems (FURLS)	5.126
Information and Computer Technologies for 21st Century	20.48
Total	**51.915**

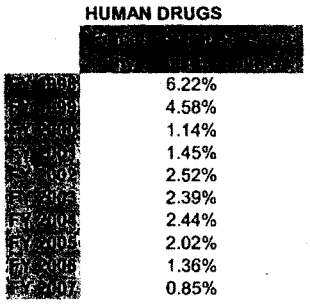
13. You noted in your testimony that FDA electronically screens all import entries through the Operational and Administrative System for Import Support (OASIS). In the melamine-tainted wheat gluten case, did the OASIS review system screen these particular import entries? Did the system detect the melamine content in the wheat gluten?

The OASIS system electronically screened information about the entries of melamine-tainted wheat gluten against existing criteria. At that time there were no screening criteria, import alerts, or import bulletins related to adulteration of foods with melamine. The OASIS system consequently did not flag these entries for attention in that regard. Once the FDA investigation connected the pet illnesses to imported plant proteins from China, screening criteria were established in OASIS to assure that each subsequent shipment of wheat gluten and other plant proteins were scrutinized manually as a part of entry review.

14. What percentage of imported pharmaceuticals is currently examined by FDA inspectors? Please provide the annual percentage of such inspections for each of the last 10 years?

As discussed in response to question 9, all import shipments are electronically screened for a variety of risk factors. This screening helps FDA personnel identify which shipments meet identified criteria for physical examination, sampling and analysis, or other review.

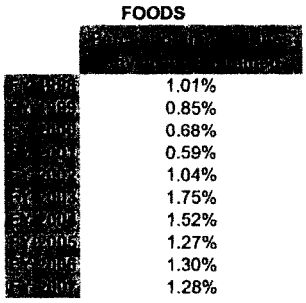
The following table represents the annual percent of human drug import lines physically examined for the last 10 years. Physically examined means that FDA either conducted an import field exam or a laboratory analysis on an import sample of an individual import line count.



15. What percentage of imported food shipments is currently investigated by FDA inspectors? What has been the annual percentage rate of such inspection for each of the last 10 years?

As discussed in response to question 9, all import shipments are electronically screened for a variety of risk factors. This screening helps FDA personnel identify which shipments meet identified criteria for physical examination, sampling and analysis, or other review. FDA also uses information submitted under the Prior Notice requirements to target food that may be intentionally contaminated or otherwise pose a significant health risk. This advance notice of imported food enables FDA to determine which shipments pose such a significant risk that they should be inspected at the border.

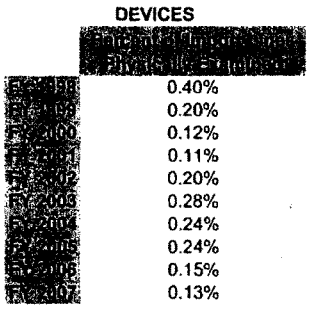
The following table represents the annual percent of food import lines physically examined for the last 10 years. Physically examined means that FDA either conducted an import field exam or a laboratory analysis on an import sample of an individual import line count.



16. What percentage of imported medical devices is currently investigated by FDA inspectors? What has been the annual percentage rate of such inspection for each of the last 10 years?

As discussed in response to question 9, all import shipments are electronically screened for a variety of risk factors. This screening helps FDA personnel identify which shipments meet identified criteria for physical examination, sampling and analysis, or other review.

The following table represents the annual percent of medical device and radiological health import lines physically examined for the last 10 years. Physically examined means that FDA either conducted an import field exam or a laboratory analysis on an import sample of an individual import line count.



17. How many inspections of foreign food-manufacturing firms does FDA conduct per year? Please provide for the record that information from the last 10 years.

The following table reflects the number of foreign food manufacturing inspections conducted over the past 10 years. Since these inspections represent only a subset of the total number of foreign food inspections conducted each year, we have also provided a column that reflects the total number of foreign food inspections for each of those years.

Foreign Food Inspections 10 years (FY 1998 – FY 2007)		
Fiscal Year	Manufacturers Only	Total Food
FY 1998	43	43
FY 1999	93	93
FY 2000	162	177
FY 2001	197	211
FY 2002	157	169
FY 2003	139	148
FY 2004	143	153

FY 2005	130	132
FY 2006	109	125
FY 2007	79	95

18. I am pleased that we agree on the premise that the FDA's imported food safety system needs reform and that the President announced a program, though one that is not funded. Will you commit to work with me to develop legislation that will achieve our common goal of increasing the safety of America's food supply?

We share a common goal of enhancing the safety of the food supply. FDA would like to work with you on the legislative ideas outlined in our Food Protection Plan as well as your legislative ideas to achieve meaningful and workable authorities that will improve FDA's ability to protect American consumers.

Questions from the Honorable Frank Pallone, Jr.

1. Please provide further detail about the financial resources FDA has to perform its safety responsibilities.

Following is a table which details FDA spending on Food Protection, including both Food Safety and Food Defense activities.

Food and Drug Administration
Total FDA Resources for Food Safety and Food Defense, Program Level
(Dollars in Thousands)

PROGRAM	FY 2001 $000	FY 2002 $000	FY 2003 $000	FY 2004 $000	FY 2005 $000	FY 2006 $000
TOTAL FOOD DEFENSE/SAFETY	354,297	480,006	495,936	483,428	530,374	535,586
Total Food Safety	353,472	382,081	393,799	377,768	380,422	377,233
Total Food Defense	825	97,925	102,137	115,660	149,952	158,353

2. How much has FDA budget increased recently, if at all? Please provide the percentage increases for the past 5 fiscal years.

Overall spending on food protection activities has increased by approximately $181.3 million, or 51% over the previous five fiscal years. The most significant yearly increase in spending was 35.5% in FY 2002.

a) Do you view these increases, particularly when accounting for inflation, as adequate?

b) If you do view them as adequate, why? If you do not view them as adequate, do you think that an importation fee, such as the one Mr. Dingell is proposing in H.R. 3610, will fill in funding gaps?

We certainly believe the increases requested by the Administration and provided by the Congress have allowed the Agency to respond to its most urgent food safety and defense needs and priorities over this period. However, we face significant challenges, such as the increasing volume of food imports.

To address these challenges, on November 6, 2007, FDA released a comprehensive Food Protection Plan to bolster efforts to protect the nation's food supply. Building upon and improving an already sound food safety protection capability, the new plan presents a robust strategy to protect the nation's food supply from both unintentional contamination and deliberate attack. The Food Protection Plan, which focuses on both domestic and imported food, complements the Import Safety Action Plan which Secretary of Health and Human Services Michael O. Leavitt presented to the President on November 6, 2007. The Import Safety Action Plan lays out a road map with short- and long-term recommendations to enhance product safety at every step of the import life cycle. Taken together, the two plans will improve efforts by the

public and private sector to enhance the safety of a wide array of products used by American consumers.

The Food Protection Plan is premised on preventing harm before it can occur, intervening at key points in the food production system, and responding immediately when problems are identified. Within these three components of protection, the plan contains a number of action steps as well as legislative proposals. We look forward to working with Congress on the necessary legislative authorities identified in the plan. Secretary Leavitt is working with the Administration to obtain the resources necessary to implement the Plan.

Ensuring that FDA-regulated products are safe and secure is a vital part of FDA's mission – to protect and promote public health. The Food Protection Plan and the Import Safety Action Plan provide an updated approach to ensure that the U.S. food supply remains one of the safest in the world.

Regarding the user fee provisions in H.R. 3610, the Administration has not taken a position on this bill. However, we have raised a few workability issues in technical assistance we have provided to the committee.

3. How much would it cost FDA to conduct quarterly inspections of food processing facilities and importers, both domestically and abroad?

FDA has not made an estimate of these costs. As of December 6, 2007, there were 140,401 domestic facilities and 197,255 foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. which registered with FDA pursuant to the Public Health Security and Bioterrorism Preparedness Act of 2002 and FDA's implementing regulation at 21 CFR Part 1, Subpart H.

Therefore, if we were to inspect the domestic facilities four times a year, this would equate to approximately 562,000 inspections a year. FDA performs approximately 10,000 – 12,000 domestic food facility inspections a year with the current resources.

Similarly, if we were to inspect foreign facilities four times a year, this would equate to approximately 789,000 inspections a year. FDA performs approximately 100 – 150 foreign food facility inspections each year with the current resources.

FDA bases inspection frequency on risk. For example, the Agency attempts to inspect high-risk establishments on an annual basis. As a part of the Food Protection Plan, FDA will look to leverage the resources of outside parties to accomplish more in-depth review of food products. By improving product knowledge and communication with all of our partners, including foreign authorities and the import community, we also can identify lower-risk products requiring less FDA scrutiny at U.S. facilities and at the border. This would enable FDA to shift more resources to evaluating more closely products that are more risky, less well known, or from unknown manufacturers.

a) How much additional staffing would be needed for FDA to conduct these inspections?

FDA has not made an estimate of the additional staff needed to conduct quarterly inspections of domestic and foreign food facilities. In an effort to maximize the public health benefit, we prioritize the use of resources to identify and mitigate the most significant risks.

Questions from the Honorable Janice D. Schakowsky

1. Under the bill, what is your understanding of how imports would be handled in cities like Chicago, which is not one of the 13 cities with an FDA lab?

a) Specifically, what would happen when fresh produce lands at O'Hare airport or arrives at the Chicago maritime port under this bill? Would it have to be sent to the FDA office in Michigan or Arkansas for it to be inspected?

2. How would this restriction affect port-related jobs in Chicago and other large port cities?

The Agency has not yet had an opportunity to determine how the bill will affect operational procedures and therefore can not provide a response to this question at this time. FDA believes restricting food imports to ports of entry located in a metropolitan area with an FDA laboratory would be impractical and problematic. FDA's existing laboratory capacity provides nationwide coverage; therefore, there is no advantage to tying ports of entry to cities with laboratories.

Questions from the Honorable Anna G. Eshoo

1. With only one percent of imported food shipments being physically inspected, can FDA demonstrate that the current screening and inspection regime is adequate? What percentage of food imports should be physically inspected?

While FDA is not able to physically inspect a large percentage of import entries, all import entries are screened through OASIS for a variety of risk factors. OASIS is an automated system for processing, and helping FDA make admissibility determinations for, FDA-regulated products offered for import.

FDA's screening and targeting of imported foods in OASIS is based on shipment entry information submitted as part of the entry process, along with other information, to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel. Once a shipment has been designated for further manual review, a number of possible actions can be taken including recommending examination based on compliance programs or specific surveillance assignments.

FDA also uses information submitted under the Prior Notice requirements to target food that may be intentionally contaminated or otherwise pose a significant health risk. This advance notice of imported food enables FDA to determine which shipments pose such a significant risk that they should be inspected at the border.

To manage the increasing volume of imports, FDA is refining its targeting ability to utilize data from a much wider range of sources to better inform entry decisions. By improving its use of IT systems in FDA and other systems, FDA can better identify products on which to perform additional sampling for likely contaminants. FDA also conducts foreign inspections and works with its counterparts in other countries to identify potential problems and solutions at the source. FDA also performs routine surveillance inspections of imported goods to check for compliance with U.S. requirements.

Within the context of the immense volume of imported food products, and based on the Centers for Disease Control and Prevention (CDC) outbreak data, imported products are generally safe. FDA is, however, currently refining its work-planning strategies to better use the data available in FDA and other systems to identify products on which to perform additional sampling for likely contaminants. FDA also conducts foreign inspections and works with its counterparts in other countries to identify potential problems and solutions at the source.

The recent report of the Import Safety Working Group concluded that the U.S. must transition from an outdated "snapshot" approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused "video" model. Such a model identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important points. By refining targeting criteria in a life cycle approach, FDA will be able to conduct more rigorous and meaningful reviews of potentially high-risk food entries and inspections of manufacturing practices overseas.

Additionally, FDA will augment its work with food producers as well as foreign governments and Federal partners to ensure that foods produced in foreign facilities meet U.S. safety requirements with risk-based targeted inspections at the border serving as a second layer of protection, rather than the principal one.

FDA is considering a number of other measures to improve import safety including a voluntary certification program whereby products could be certified as meeting U.S. safety standards. This may involve verification, e.g., testing or inspection by third parties or by domestic or foreign regulatory bodies.

a) In practice, does FDA refuse entry to food products based solely on screening or is a physical examination always required before a shipment is refused?

Physical examination is not required before a shipment is refused admission into the U.S. Under Section 801(a) of the FD&C Act, articles which appear to be adulterated, misbranded, or otherwise in violation of the Act are subject to being refused admission. The appearance of a violation can be based upon an examination of samples or "otherwise." The "otherwise" language in section 801(a) allows FDA to refuse admission based on prior experience with the same or similar products, and/or on receipt of credible information from foreign or domestic health authorities that a violation exists. Under 21 CFR Part 1.94, the owner or consignee may provide testimony in an attempt to overcome the apparent violation. If this is successful, the article is released from detention and admitted into the U.S. Otherwise, the article is refused admission.

Importers must provide FDA with advance notice of imported food shipments, which enables the Agency to more effectively target food that may be intentionally contaminated or otherwise pose a significant health risk. Food imported or offered for import without this prior notice is subject to refusal and, if refused, must be held until such notice is submitted, reviewed, and determined to be sufficient. Until the prior notice requirements are satisfied, FDA does not determine admissibility of food under section 801(a) of the FD&C Act.

b) Of the total number of shipments refused entry in the last year, how many shipments were refused entry as the result of screening alone and how many were the result of physical inspections?

The total number of refusals (all commodities, not just foods) for FY 2007 was 16,174 individual product entry lines. During FY 2007, approximately 9,814 entry lines were refused admission without a physical inspection and without FDA sample analysis. This total includes all commodities subject to FDA jurisdiction (foods, drugs, cosmetics, medical devices, biologics, etc.). The total is approximate because it does not allow for certain uncommon circumstances; for example, the collection of an audit sample after detention of a shipment without physical examination.

By way of background, shipments offered for importation into U.S. commerce (entries) often include a combination of foods, drugs, cosmetics, devices and other FDA-regulated products, as well as products not regulated by FDA, and they can include products from a number of different

countries of origin. An entry line refers to each portion of an import entry that is listed as a separate item on entry documents such as an invoice or other shipping papers. Line entries are product- and size-specific. FDA may authorize specific lines to enter the U.S. unimpeded, while others in the same entry are to be held pending further FDA review/action.

2. In a July 2007 report for Congress (*Food and Agricultural Imports from China*), the Congressional Research Service (CRS) noted that technical problems with the Operational and Administrative System for Import Support (OASIS) database as well as limitations within the system prevented CRS from securing data about food imports.

a) Is the OASIS database a robust tool for examining risk? Are there technical problems with the OASIS database? If there are, what steps can and are being taken to improve it?

OASIS handles much more than just electronic screening. It is the enterprise system through which FDA manages the entire admissibility life cycle of an imported product.

Entry reviewers utilize OASIS to display screening results; to request (when necessary) additional documentation from entry filers; to admit some shipments to the U.S. through issuance of "may proceed" notices, assign field examinations and/or sample collections for other shipments, and refer still others to compliance officers for Detention Without Physical Examination (DWPE). FDA inspectors utilize OASIS to receive and execute assignments, report the results of field examinations and reconditioning operations, and document the collection of samples. FDA compliance officers utilize OASIS to review the results of field exams and laboratory analyses; process applications for reconditioning of detained goods; review shipments referred for DWPE; review and process submissions of private laboratory analytical results; and to release, detain, and/or refuse shipments as appropriate.

OASIS was designed in the mid-1990s when the volume of FDA-regulated imports was much lower. OASIS has had a few technical problems of the sort one might expect to find in a decade-old system which is operating far beyond its original design limits. Nonetheless, OASIS runs 24 hours a day, seven days a week, and is generally quite reliable.

FDA is in the process of modernizing and upgrading OASIS in several respects. Foremost among these is the development of a more sophisticated electronic screening module. The module includes extensive, automated mining and evaluation of FDA data; input of open-source intelligence; and a system for assigning numerical risk scores to individual entry lines. Currently the module includes nine major categories of risk-based rules, of which the legacy screening rules from OASIS constitute only one. An initial version was pilot tested during the 4th quarter of FY 2007 using seafood entries at certain ports in metropolitan Los Angeles. Development is continuing during FY 2008.

The technical platform on which OASIS operates is being substantially upgraded. Major portions of OASIS are being re-engineered as the system is more fully integrated into other FDA systems. FDA has recently built a data warehouse to facilitate access to information contained in OASIS and several related systems.

3. Can you provide for the Subcommittee the overall number of food shipments that came into the U.S. in each of the last 12 months?

a) Can you tell the Subcommittee the percentage of overall food shipments that were refused entry to the U.S. in each of the last 12 months?

Shipments, refusals, and refusal rates for human food (including infant formula) by month from November 2006 through October 2007

November 2006	687,898	600	0.0872%
December 2006	643,258	791	0.1230%
January 2007	665,507	734	0.1103%
February 2007	641,186	593	0.0925%
March 2007	723,821	874	0.1207%
April 2007	670,123	695	0.1037%
May 2007	708,001	1,071	0.1513%
June 2007	669,713	771	0.1151%
July 2007	648,289	709	0.1094%
August 2007	672,193	714	0.1062%
September 2007	620,887	573	0.0923%
October 2007	725,300	781	0.1077%
Overall	8,076,176	8,906	0.1103%

* As used in this table, "shipments" are lines offered for entry in a given month, and "refusals" are lines refused during that month. Because of the life cycle of an import shipment, the lines refused in a given month typically were offered for entry during previous months. The refusal rate for a given month is thus an approximation.

Please note that the above table does not include shipments of dietary supplements, food colors, food additives, or other food-related products such as tableware.

4. Can you calculate the volume of food products that were rejected as an absolute quantity and as a proportion of total imports over the last 12 months?

FDA calculates the volume of imports in terms of the number of entry lines. Although it is not required as part of the general import entry submission, estimated quantity is received as a mandatory data element under the prior notice requirements in 21 CFR § 1.281(a)(5)(iii). However, for a number of reasons it has not proven to be a reliable indicator of overall quantity due to differences and reporting errors reflected in the standard units of measurements, such as

mass, fluid volume, the use of U.S. customary units versus International system units, disproportionate associations between product quantity and mass, differences in packaging and input errors. In addition, the relationship between an entry line and a prior notice is not necessarily one-to-one due to different submission requirements. As such, the estimated quantity may not accurately reflect the volume of the entry line that undergoes evaluation for admissibility. Given this, we refer to the monthly refusal totals and refusal rates for the past 12 months that appear above in the response to question 3.

Questions from the Honorable Mike Ross

1. It appears that assessing user fees based on line items rather than weight of the shipment cannot possibly account for the comparative costs of testing these products for consumer safety. Is this correct?

FDA calculates the volume of imports in terms of entry lines rather than weight since attempts at standardizing the self-reported quantity and associating the data to entry lines have proven to be unreliable. It should be noted that the comparative costs of testing are related more directly to characterizing specific products and the analytical tests most likely to be conducted on those products.

a) From your experience dealing with FDA inspections and food protection, can you explain what or who exactly determines what is considered a line item? Also, in regards to the $50 fee that will be charged, has FDA ever considered charging a fee for import inspections that are determined by the weight of each line item? If not, would you consider this to be a more reasonable and balanced option?

An import entry filed with CBP may contain one or more types of products. Each of these is listed by the entry filer (typically, a licensed Customs broker) as one line of the entry. For example, an entry might consist of one line of frozen whole shrimp, one line of frozen haddock fillets, and one line of canned crab meat packaged in 6 ounce cans, and one line of canned crab meat packaged in 12 ounce cans. Each product is a different line entry – either because they could have a different manufacturer, or even if from the same manufacturer, because they are packaged in different size cans (and thus, underwent different manufacturing/packaging processes). As such, each product would pose its own set of risks. FDA would evaluate the lines on their individual merits, and make a separate admissibility decision for each line.

As noted above, FDA calculates the volume of imports in terms of entry lines rather than weight since attempts at standardizing the self-reported quantity and associating the data to entry lines have proven to be unreliable. Thus, FDA would not have considered charging a fee based on weight.

2. Could you explain the process of how a particular product is eventually recommended to be placed on the FDA import alert listing, and how it is determined when that product can be removed? In addition, how does FDA currently handle repeat offenders who consistently import tainted goods after being placed on the import alert listing? Has FDA considered charging a possible fee for repeat offenders?

The placement of a product or products on import alert occurs when there is information available to FDA that would cause future shipments to appear to be adulterated, misbranded, or otherwise in violation of the FD&C Act. The recommendation for an import alert can be initiated by an FDA district office or by an FDA Center. It typically is based upon a history of violative samples. It may also be based upon other information; for example, that a food was harvested from polluted waters, that a product was manufactured or held under unsanitary conditions, or that a product was manufactured in non-compliance with good manufacturing

practices (usually as determined by a facility inspection). Detention Without Physical Examination (DWPE) may be recommended for an article with no prior history of violations, if the recommendation is adequately supported by information that future shipments would appear to be violative.

Removal of a product or products from DWPE is based upon evidence establishing that the conditions which gave rise to the appearance of a violation have been resolved. The process of removal from DWPE is typically initiated by a request from the affected party.

FDA has specific policies on recidivist firms in certain situations. Examples can be found in Import Alerts #80-04, "Surveillance and detention without physical examination of surgeon's and or patient examination gloves," and #85-02, "Surveillance (100% sampling) and detention without physical examination of condoms." Under these policies, if a firm that is listed on either of these import alerts continues to ship violative products, then FDA would typically apply increasingly more strict criteria for removal from DWPE.

The import admissibility process is governed by section 801 of the FD&C Act, but other sections of the Act also apply. Depending on the severity of the violations and/or the extent of recidivism, FDA may initiate or recommend, among other actions, seizure, injunction, and/or criminal prosecution. CBP has additional enforcement tools. In certain situations, FDA will request that CBP initiate enforcement action under its authorities for repeat offenders.

To deal with recidivists, the President's Action Plan for Import Safety proposes amending the Act to include asset forfeiture remedies for criminal offenses. FDA's Food Protection Plan proposes a new user fee which would require manufacturers and laboratories to pay the full costs of re-inspections and associated follow-up work after a failure to meet good manufacturing practices or other FDA requirements.

Questions from the Honorable Mike Rogers

1. As this sector of the biopharmaceutical industry continues to grow, can FDA ensure that imported biopharmaceutical products that are, bear, or contain a SELECT AGENT have been manufactured in a way that does not threaten our national security?

The possession, use, and transfer of select biological agents and toxins (Select Agents) is under the oversight of CDC. CDC has issued regulations governing the possession, use and transfer of such agents and administers the National Select Agent Registry Program to oversee the activities of possession of Select Agents. While FDA is not responsible for the Select Agent Registry Program and implementing regulations, FDA does provide technical assistance to inform CDC decision-making and supports compliance with the Select Agent regulations.

a) Can the chain of custody surrounding the agents be assured?

As per the response to question 1, FDA defers to CDC.

b) Can FDA ensure that these products will not contribute to the proliferation of SELECT AGENTS, compromising our Nation's security?

As per the response to question 1, FDA defers to CDC.

February 14, 2008

Randall L. Lutter, Ph.D.
Deputy Commissioner for Policy
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Lutter:

Thank you for appearing before the Subcommittee on Health on Wednesday, September 26, 2007, at the hearing entitled "H.R. 3610, The Food and Drug Import Safety Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. We appreciate your responses on February 1, 2008, to our questions, but one Member's questions were inadvertently left off. Attached are those questions. In preparing your answers to these questions, please address your response to the Member who has submitted the question and include the text of the Member's question along with your response.

To facilitate the printing of the hearing record, your response to these questions should be received no later than the close of business **Friday, February 29, 2008**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your responses should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Jim Matheson, Member
Subcommittee on Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

APR 11 2008

Dear Mr. Chairman:

Thank you for your letter of February 14, 2008, containing questions posed by Representative Jim Matheson for the record of the hearing held September 26, 2007, before the Subcommittee on Health entitled, "H.R. 3610, The Food and Drug Import Safety Act." The Food and Drug Administration (FDA or the Agency) appreciated the opportunity to present testimony at that hearing.

Representative Matheson's questions are re-stated below, followed by FDA's responses.

1. **Dr. Lutter, my colleague from New Jersey, Mr. Ferguson, and I intend to introduce a bill that would have as part of its goal to provide the Agency with more tools to better assess and address the growing problem of antibiotic resistance we are facing in this country. As you know, the possibility of antimicrobial resistance has been a concern of imported food due to antibiotic residue. However, it is a far reaching problem that has many components from all sectors - medicine, food, household goods and cleaning agents.**

   a) **How would the Agency benefit from having access to more comprehensive data collection like this at its disposal?**

Response: The Administration has not taken a position on H.R. 3697, the "Strategies to Address Antimicrobial Resistance Act." The following comments focus on the issue of antimicrobial resistance (AR) as it relates to FDA's responsibility for food and drugs. Our comments do not apply to household goods and cleaning agents.

AR is a complex phenomenon. Antimicrobial resistant bacterial populations emerge because of the combined impact of the various uses of antimicrobial drugs including their use in humans and animals. All of these pathways are not clearly defined or understood. FDA believes that human exposure through the ingestion of antimicrobial resistant bacteria from animal-derived foods represents the most significant pathway for human exposure to bacteria that have emerged or been selected as a consequence of antimicrobial drug use in animals.

FDA is proactively addressing potential human health risks associated with the use of antimicrobial drugs in food-producing animals. This approach uses risk assessment methodologies to quantify the human health impact from antimicrobial use in animals, in conjunction with robust monitoring, research, and risk management. In addition, the Agency participates in public meetings with various stakeholders to strengthen and promote science-based approaches for managing the potential human health risks associated with the use of antimicrobial drugs in food-producing animals. These include international meetings to address approaches to combat and prevent resistant pathogens.

Minimizing the emergence of antimicrobial resistant bacteria in animals and the potential spread to humans via the food supply is a complex problem requiring a coordinated, multifaceted approach. More than a dozen Federal agencies have an interest in the AR problem and several of these agencies have responsibilities related to the use of antimicrobials in agriculture. The strategy developed by FDA to address AR is one component of more broad-reaching strategies being developed by an inter-agency task force at the national level in the Public Health Action Plan to Combat Antimicrobial Resistance (Public Health Action Plan or PHAP).

FDA, along with Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), co-chairs the Inter-Agency Task Force on Antimicrobial Resistance (or the Task Force) that was created in 1999. Numerous other agencies participate in the Task Force, as do the Department of Agriculture, the Department of Defense, the Department of Veterans Affairs, and the Environmental Protection Agency. The Task Force is in the process of updating the PHAP based on input from participating agencies as well as external expert consultants. The Task Force will develop and implement plans to monitor patterns of antimicrobial drug use in both animal and human populations. This information is an important component of the national AR surveillance plan and is essential to interpret trends and variations in rates of AR, improve our understanding of the relationship between drug use and resistance, identify and anticipate gaps in availability of existing drugs, and identify interventions to prevent and control AR.

Improved surveillance for AR in agricultural settings will allow early detection of resistance trends in pathogens that pose a risk to animal and plant health, as well as in bacteria that enter the food supply. Agricultural surveillance data will also help improve understanding of the relationship between antimicrobial drug and pesticide use and the emergence of drug resistance. FDA uses all available scientific information related to AR in approving antimicrobial drugs for use in food-producing animals.

FDA is continually monitoring the literature and scientific presentations related to AR and assessing proprietary data from studies to evaluate emerging resistance. In addition, FDA solicits input from the public and interested parties on developments and research related to AR. FDA has scheduled a public hearing to provide the infectious disease community, sponsors, and other interested parties an opportunity to discuss their experience with and concerns about the emerging threat of AR, possible strategies fostering prudent use to prevent the development of AR, and the potential for the provisions of FDA's Orphan Drug Act or other incentives to facilitate antimicrobial drug development. The meeting will be held April 28, 2008, in Rockville, Maryland. FDA will accept comments to the docket (Docket No. FDA-2008-N-

0225) through May 26, 2008. Additional details of this public hearing and request for comments are scheduled to be published in the *Federal Register* on April 15, 2008.

2. **I appreciate that FDA is demonstrating concern of possible antibiotic resistance and is acting on imported food contaminants, such as antibiotic residues, to detain products until shipments are proven to be free of such residues. As I mentioned, our bill encourages implementation of many of the 13 items identified by the Task Force as "top priorities," updates to the Public Health Action Plan to Combat Antimicrobial Resistance, as well as encourages that antimicrobial resistance be regarded as an international issue.**

   a) **Has the issue of antibiotic residue on food been discussed with the Task Force?**

Response: First, we must take care to make the proper distinction between antibiotic residues and antibiotic resistance. Antibiotic residues are those products remaining in the tissue of an animal after it has been treated with antibiotics. AR is the result of microbes changing in ways that reduce or eliminate the effectiveness of drugs, chemicals, or other agents to cure or prevent infections.

The Task Force has discussed the issue of antibiotic residue on food. As part of its goal to monitor AR in animal and plant pathogens and in bacteria that can be transmitted to humans through the food supply, the Task Force has recommended that pilot studies be initiated to assess the extent of environmental contamination by antimicrobial drug residues and drug-resistant organisms that enter the soil or water from human and animal waste. If contamination is detected, the pilot studies will conduct appropriate surveillance in waste, surface and ground water, and soil from agricultural areas in which waste is used for fertilizer, and conduct further studies to determine potential impact on human and animal health.

Further, as part of its goal to identify gaps and address existing research needs and identify new ones, the Task Force has identified the need for additional research, including high risk and high payoff research in nontraditional fields, to enhance the understanding and assess the impact of the effects of preventive, therapeutic, growth-promoting agents and residues of agents in the environment on the microbiota of animals, plants, soil, and aquatic environments.

   b) **With the global nature of our food supply today, do you think this international issue should be discussed in regard to the Public Health Action Plan?**

Response: Because the food supply network is increasingly international in scope, it is appropriate that the important and complex issue of AR related to international issues be considered in discussions addressing the Public Health Action Plan. The agencies involved in the revision of the PHAP therefore have agreed to incorporate international activities in each relevant action item of the plan.

   c) **It is my understanding that the Task Force published Part I: Domestic Issues in 2001, and has yet to come out with Part II, which was intended to address global issues. Is that correct?**

Page 4 – The Honorable John D. Dingell

Response: The Task Force has decided to not produce Part II of the plan, devoted to international issues. Instead, the plan is being revised and will incorporate international aspects within each relevant action item. The Task Force will hold its annual public meeting to update progress on revising and implementation of the PHAP the week of June 23, 2008, in Bethesda, Maryland. Details will be announced in the *Federal Register* prior to the meeting.

Thank you again for the opportunity to provide testimony at the hearing. We look forward to continuing to work with you and your staff on these important public health issues.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health
Committee on Energy and Commerce

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

The Honorable Jim Matheson, Member
Subcommittee on Health
Committee on Energy and Commerce

October 31, 2007

Mr. Hallock Northcott
President and CEO
American Association of Exporters and Importers
Suite 810
1050 17th Street, N.W.
Washington, DC 20036

Dear Mr. Northcott:

Thank you for appearing before the Subcommittee on Health on Wednesday, September 26, 2007, at the hearing entitled "H.R. 3610, The Food and Drug Import Safety Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached is a question directed to you from a certain Member of the Committee. In preparing your answer to this question, please address your response to the Member who has submitted the question and include the text of the Member's question along with your response.

To facilitate the printing of the hearing record, your response to this question should be received no later than the close of business **Monday, November 8, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your responses should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

❖AAEI AMERICAN ASSOCIATION OF EXPORTERS AND IMPORTERS
The Voice of the International Trade Community Since 1921

February 7, 2008

Via E-Mail: Melissa.sidman@mail.house.gov
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

ATTN: Melissa Sidman, Legislative Clerk/Public Health

Re: Additional Questions to AAEI on H.R. 3610, "The Food and Drug Safety Import Act"

Dear Mr. Chairman:

We greatly appreciated the opportunity to testify on behalf of the American Association of Exporters and Importers (AAEI) before the Health Subcommittee on September 26, 2007 concerning H.R. 3610. We respectfully submit additional comments below for submission into the record on specific provisions of the bill in response to your questions transmitted to us by cover letter dated October 31, 2007. Our answer follows each question as reproduced below in bold typeface.

1.) In your written testimony, you state, "We believe that, with the tremendous growth in multiple overseas marketplaces which may not yet or ever choose to impose similar certification regimes upon these very same exporters, American retailers and the consumer could suffer a significant diminution in quality and variety." Doesn't this argue for a stronger inspection regime to be put in place by the United States in order to protect its consumers?

A stronger inspection regime only for U.S. imports which is not required for imports to other countries will make certain manufacturers avoid the U.S. market altogether, and thus, limit the number of suppliers that U.S. importers may purchase goods for the U.S. market. Any legislative or regulatory action by the U.S. on imported products could cause serious and unnecessary damage to our huge export economy because U.S. interests must be understood in today's complex WTO environment and our growing framework of trade agreements. With the enormous degree of international competition in food commodity production already facing our companies and industries, we are extremely concerned that reciprocal actions could prove very difficult trade barriers to overcome.

Again, we recommend that the Committee explore taking advantage of the strength of ongoing U.S. efforts to concentrate on development of international harmonization standards. Such efforts could provide a model that the Committee could use to assist the promotion of U.S. foods and FDA regulated products.

2.) In your written testimony, you note that your organization's analysis has shown that user fees can unfairly burden certain industries. Could you provide the Committee with evidence to support this claim?

1050 17th Street, NW, Suite 810; Washington, DC 20036; Telephone 202/857-8009; Fax; 202/857-7843; Email: HQ@AAEI.org

As we noted in our written testimony, our views on user fees was based on conversations with our retailer members that fees assessed per line item will disproportionately impact small and medium enterprises (SME's), particularly those that import a wide variety of products currently regulated under the Food Drug and Cosmetics Act. The example that we cited, specifically specialty food retailers who may cater to traditional "geographically" based consumers, was based on anecdotes from food industry members. However, we believe that such data is not yet available and anecdotal evidence is all that we can rely upon at this point.

3.) Section 3 of H.R. 3610 permits the Secretary of Health and Human Services to waive or reduce user fees in the event that the Secretary finds such fees to be paid will exceed the anticipated present and future costs of inspections. In your opinion, will this provision reduce import costs for small- and medium-sized enterprises, which you claim will be disproportionately affected by the implementation of user fees?

Unless the provision directs HHS and CBP to program an override into the ACS or ACE systems to ensure that the fee does not exceed the declared value on the customs entry, SME's will have to monitor the imposition of such fees and seek relief on a transaction basis. AAEI continues to believe that a fundamental element in the design of such systems must be the economic impact upon small and medium size enterprises. Again, as we suggest in our written testimony, the Committee may wish to explore the use of an incremental approach.

4.) In the case of an agency with limited resources, such as the FDA, doesn't it make sense to restrict ports of entry in order to concentrate those resources, make the best use of them, and mitigate the entry of risk of unsafe foods and drugs into U.S. commerce?

AAEI opposes restricting the number of ports through which food and drugs may be imported into the United States because the U.S. cannot inspect its way out of the product safety problem – regardless of the number of ports handling FDA-regulated products. Concentrating FDA resources at a few ports will make it difficult for our industries trade and logistics providers to adjust to the dynamic economic environment. Such restrictive ports will serve as a bottleneck to our interstate distribution system which allows most major corporations with flexibility in its supply chain and multiple alternate methods and location of delivery with minimal product cost or availability implications.

As we suggested in our written testimony, because imports will continue to grow, we urge the Committee to authorize FDA to treat importers as an "account" by reviewing the companies' record of compliance for all their importations, rather than individual transactions. By treating importers as an account, CBP is currently able to quickly determine a company's compliance profile and work with the company to remedy any deficiencies. CBP can then concentrate its resources on companies which do not demonstrate a high level of compliance and present the great risk for violations. In these efforts, CBP serves as an excellent model.

Instead, we strongly urge Congress to provide federal agencies with support to implement "One Face at the Border." The effort has been designed to eliminate lack of coordination and even agency cross purposes, at our land, air and sea

ports. Achievement of this goal was initiated in the creation of the Department of Homeland Security. Over the past several years, AAEI has testified to the importance of both preventing restoration of and further eliminating the extraordinarily burdensome and inefficient processes which have been suggested by a variety of special interests. Increasing the government-wide focus on product safety, including CPSC leadership and multiple agency participation in the enforcement of Intellectual Property Rights protection, along with tracking financial transactions that may be financing terrorism are extremely worthy goals. Unprecedented cooperation and formal coordination of efforts, whether legislative or Administration driven, would make all the difference. In this, AAEI and the trade community have long supported the government's multi-agency automation efforts and the use of data to provide more transparency to the supply chain and import clearance process.

5.) Your opposition to restricting the ports of entry for foods and drugs is premised upon the notion that such restriction would impose logistical burdens on importers and impede the distribution of such products. Can you cite similar difficulties that have arisen from USDA's policy of restricting ports of entry?

It is our understanding that CBP estimates that nearly 36% of products imported to the U.S. are regulated by the FDA – a far higher percentage than imported goods regulated by USDA.

Again, we believe that application of the USDA restricted port model for individual product imports would have a negative impact upon the 50 states and literally hundreds of ports can only be calculated with full understanding of the consequences of economic dislocation in Congressional districts nationwide as well as the anticipatable impact upon land ports along either border. We are reluctant to support such a policy without studying the economic impact for multiple product and industry imports in favor of ease and simplicity of government processing.

6.) Is it your opinion that the threat of civil penalties would serve as an incentive to importers to secure their supply chains in order to prevent the introduction of unsafe articles of food into commerce in the United States?

AAEI believes that good corporate citizens will continue to act in a responsible and honorable way. Bad actors will not be deterred from choosing to take shortcuts in security or otherwise engage in behavior that may end up endangering the American consumer, and the mere addition of civil penalties will do nothing but put an undue burden on companies that are already struggling under a crushing weight and a tremendously confusing maze of fees, restrictions, and penalties. Threat or actual loss of any "trusted trader" status is a far more effective threat than the mere addition of more penalties.

Again this is not an area where AAEI has specific expertise, but we comment based upon the strong belief of our members that significantly increased and burdensome monetary penalties levied against manufacturers and importers will do little in today's international marketplace to affect change and enhance product safety without implementation of a system in which penalties are correlated to the level of culpability found during an investigation.

7.) Many countries, including Canada and Mexico, in addition to the European Union, already require country-of-origin labeling for the articles of food that they import. Shouldn't U.S consumers be entitled to this same information?

AAEI is concerned with development of multiple agency Country of Origin rules which may be more confusing U.S. consumers than the current regime. CBP's rules are harmonized internationally through the WTO and multiple Free Trade Agreements whereas FDA has an independently developed and implemented system that lacks even a nexus of compatibility or overlap with CBP's regulatory regime. Companies find it difficult to comply with multiple country of origin labeling designed for different purposes (e.g., duty preference under FTA, safety, security). Such labeling requirements should be harmonized with our trading partners, principally Canada, Mexico and the EU.

We hope that you and the other Members of the Committee on Energy and Commerce find our answers to your questions helpful and clarify any of our written testimony.

AAEI, therefore, respectfully requests that the Committee include these comments in its record on H.R. 3610. AAEI and its members are available to discuss our comments with you and to assist the Committee staff regarding this important legislation.

Respectfully submitted,

Hall Northcott

Hallock Northcott
President & CEO

October 30, 2007

Caroline Smith DeWaal, J.D.
Food Safety Director
Center for Science in the Public Interest
Suite 300
1875 Connecticut Ave, N.W.
Washington, D.C. 20009

Dear Ms. DeWaal:

Thank you for appearing before the Subcommittee on Health on Wednesday, September 26, 2007, at the hearing entitled "H.R. 3610, The Food and Drug Import Safety Act." We appreciate the time and effort you gave as a witness before the Subcommittee on Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached is a question directed to you from a certain Member of the Committee. In preparing your answer to this question, please address your response to the Member who has submitted the question and include the text of the Member's question along with your response.

To facilitate the printing of the hearing record, your response to this question should be received no later than the close of business **Friday, November 9, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your responses should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Janice D. Schakowsky, Member
Subcommittee on Health

CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of
Nutrition Action Healthletter

November 9, 2007

The Honorable John D. Dingell
Chairman
House Committee on Energy and Commerce
ATTEN: Melissa Sidman
2125 Rayburn House Office Building
Washington, DC 20515

RE: Response to the Question for the Record from Rep. Janice D. Schakowsky

Dear Mr. Chairman,

Thank you for the opportunity to testify Wednesday, September 26, 2007, before the Subcommittee on Health regarding H.R. 3610, the Food and Drug Import Safety Act. I am pleased to provide a response to the question for the record submitted by Rep. Janice D. Schakowsky.

Rep. Schakowsky asked what a recall notification process for food would look like. The Center for Science in the Public Interest (CSPI) believes providing mandatory recall authority at the agencies that oversee the safety of our food supply is an essential element of any reform.

In the current system, recalls of contaminated food are voluntary. The Federal Food, Drug, and Cosmetic Act does not give the Food and Drug Administration (FDA) the power to order a producer to recall a food product, with the exception of infant formula. If a firm does not recall a product, the FDA can go to court to seek an injunction or seizure of the product. But these legal actions waste precious time and if a food company or importer fails to recall a contaminated product, it could continue to reach consumers. Mandatory recall authority would ensure that recalled foods are removed from the market more quickly and effectively. Therefore, CSPI applauds inclusion of mandatory recall in section 10 of H.R. 3610.

However, section 10 stops short of requiring adequate notice to consumers, a defect that could be remedied by adopting the mandatory recall framework included in H.R. 1148, the Safe Food Act; H.R. 3624, the Consumer Food Safety Act; or H.R. 3484, the SAFER Meat, Poultry and Food Act. The approach taken in these bills, in addition to providing for mandatory recalls, would explicitly require FDA to notify state and local health authorities and consumers who have or may have purchased the recalled product. I have attached a proposed amendment to Section 10 based on the recall authorities provided by the above bills. CSPI appreciates the committee's efforts to protect the public from preventable foodborne illnesses and looks forward to working with the committee to see that effective food safety legislation is enacted in this Congress.

1875 Connecticut Avenue, NW, Suite 300 • Washington, DC 20009-5728 • tel 202 332 9110 • fax 202 265 4954 • www.cspinet.org

The Center for Science in the Public Interest is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 900,000 subscribers to its *Nutrition Action HealthLetter* and by foundation grants. We accept no government or industry funding.

Sincerely,

Caroline Smith DeWaal

Caroline Smith DeWaal
Director of Food Safety

CSD/dwp

Enclosure

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Janice D. Schakowsky, Member
Subcommittee on Health

Attachment
CSPI proposed amendment to section 10 of H.R. 3610

SEC. 10. RECALL AUTHORITY.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by section 6 of this Act, is amended by adding at the end the following:

''SEC. 418. RECALL AUTHORITY.

"(a) NOTICE 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 (whether or not 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.—If 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 (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 to—

Attachment
CSPI proposed amendment to section 10 of H.R. 3610

"(A) cease distribution of the food;

"(B) notify all persons—

"(i) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

"(ii) to which the food has been distributed, transported, or sold, to immediately cease distribution of the food;

"(C) recall the food;

"(D) in conjunction with the Secretary, provide notice of the finding of the Secretary—

"(i) to consumers to whom the food was, or may have been, distributed; and

"(ii) to State and local public health officials; or

"(E) take any combination of the measures described in this paragraph, as determined by the Secretary to be appropriate in the circumstances.

"(2) MANDATORY ACTIONS.—If a person referred to in paragraph (1) refuses to or does not adequately carry out the actions described in that paragraph within the time period and in the manner prescribed by the Secretary, the Secretary shall—

"(A) have authority to control and possess the food, including ordering the shipment of the food from the food establishment to the Secretary—

"(i) at the expense of the food establishment; or

"(ii) in an emergency (as determined by the Secretary), at the expense of the Administration; and

"(B) by order, require, as the Secretary determines to be necessary, the

Attachment
CSPI proposed amendment to section 10 of H.R. 3610

person to immediately—

"(i) cease distribution of the food; and

"(ii) notify all persons—

"(I) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

"(II) if the food has been distributed, transported, or sold, to immediately cease distribution of the food.

"(3) NOTIFICATION TO CONSUMERS BY SECRETARY.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1)—

"(A) to consumers to whom the food was, or may have been, distributed; and

"(B) to State and local public health officials.

"(4) NONDISTRIBUTION BY NOTIFIED PERSONS.—A person that processes, distributes, or otherwise handles the food, or to which the food has been distributed, transported, or sold, and that is notified under paragraph (1)(B) or (2)(B) shall immediately cease distribution of the food.

"(5) AVAILABILITY OF RECORDS TO SECRETARY.—Each person referred to in paragraph (1) that processed, distributed, or otherwise handled food shall make available to the Secretary information necessary to carry out this subsection, as determined by the Secretary, regarding—

"(A) persons that processed, distributed, or otherwise handled the food;

Attachment
CSPI proposed amendment to section 10 of H.R. 3610

and

"(B) persons to which the food has been transported, sold, distributed, or otherwise handled.

"(c) INFORMAL HEARINGS ON ORDERS.—

"(1) IN GENERAL.—The Secretary shall provide any person subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as practicable but not later than 2 business days after the issuance of the order.

"(2) SCOPE OF THE HEARING.—In a hearing under paragraph (1), the Secretary shall consider the actions required by the order and any reasons why the food that is the subject of the order should not be recalled.

"(d) POST-HEARING RECALL ORDERS.—

"(1) AMENDMENT OF ORDER.—If, after providing an opportunity for an informal hearing under subsection (c), the Secretary determines that there is a reasonable probability that the food that is the subject of an order under subsection (b), if consumed, would present a threat to the public health, the Secretary, as the Secretary determines to be necessary, may—

"(A) amend the order to require recall of the food or other appropriate action;

"(B) specify a timetable in which the recall shall occur;

"(C) require periodic reports to the Secretary describing the progress of the recall; and

"(D) provide notice of the recall to consumers to whom the food was, or may have been, distributed.

Attachment
CSPI proposed amendment to section 10 of H.R. 3610

"(2) VACATION OF ORDERS.—If, after providing an opportunity for an informal hearing 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 provided in this section shall be in addition to, and not exclusive of, other remedies that may be available."

STATEMENT OF AMERICAN FREE TRADE ASSOCIATION

The American Free Trade Association (AFTA) is a trade association of importers, distributors and wholesalers providing American consumers throughout the country with alternative sources of brand name, genuine and unadulterated food products. AFTA appreciates the opportunity to provide the Health Subcommittee with its comments and testimony in response to Congressman Dingell's introduction of H.R. 3610, the Food and Drug Import Safety Act of 2007.

Members of the American Free Trade Association applaud all efforts to ensure the safety and integrity of the domestic supply of foods and drugs. AFTA believes (i) that American consumers must know that the products entering this country are safe for their children, safe for their pets and safe to enter the commercial marketplace; (ii) that American consumers must be able to continue enjoying the benefits of a competitive global marketplace—one that thrives because of the successful relationship forged between product safety, trade facilitation and supply chain integrity; and (iii) that any legislative initiative intended to ensure the health and safety of American consumers do so in a manner encouraging continued viability of lawful small and medium sized importers and distributors. H.R. 3610 is an important step forward in our country's efforts to protect its citizens from harmful food and drug imports. AFTA looks forward to working with the bill's sponsors to ensure that the legislation is made even stronger and is even better able to reflect the symbiotic needs of consumers, the industry and the government.

In light of the foregoing, AFTA is pleased to offer the following specific comments to the proposed legislation included within the Food and Drug Import Safety Act of 2007.

SECTION 2: RESEARCH ON TESTING TECHNIQUES

Testing food imports at ports of entry to determine product safety and ensure no adulteration of food products within 60 minutes of arrival is a laudable goal. However, this idealistic objective must be tempered with the practical realization that not all food shipments will be able to undergo such testing without risking loss of product integrity and without the creation of substantial, additional and very expensive infrastructure capabilities that do not presently exist. As Congress is already aware, earlier this year, the FDA had announced its intention to close at least half of its existing laboratories due to lack of use and deterioration. Although that decision has since been suspended, the reasons for the initial announcement cannot be forgotten. FDA lacks the resources, human and financial, to carry out the functions and operations even of its existing laboratory facilities. To undertake research hoping to develop additional and more stringent testing protocols than currently exist before "fixing" the Agency's current problems may be, respectively, premature and not the best utilization of current and anticipated agency resources.

Even in today's commercial environment in which sampling of less than 1 percent of food shipments occurs, more and more importers—large and small—complain loudly of unnecessary entry delays and port congestion. Even if user fees were to be assessed (which we do not believe should occur), even if the FDA was required to maintain its current roster of laboratories, even if Congress appropriated substantial additional resources to facilitate such port level testing, the port congestion and entry delays resulting from required port of entry testing of all food shipments would measurably and painfully disrupt the distribution of critical food supplies into the American marketplace.

In light of the foregoing, AFTA urges the Secretary to consult comprehensively and often with affected industry and trade associations such as the American Free Trade Association as it researches and develops appropriate testing methods to prevent entry of intentionally adulterated imported food product. This type of industry-based consultation and collaborative effort is the only means for the Agency to ensure that its research consider both the needs and mandates of the government agencies, as well as the practical business realities of the importing trade community.

SECTIONS 3 AND 4: USER FEES FOR FOOD AND DRUGS

The FDA is charged with protecting the American consumers from unsafe products. The funding required for the agency to carry out its mission should be legislatively appropriated and not passed onto American importing companies and traders, the majority of whom are small and medium sized businesses already suffering from the decreased value of the American dollar and increased global competition. Food

safety efforts are intended to benefit all residents and visitors in the United States, and the costs to assure food safety is most appropriately born by that broad class and not the import community. Moreover, it is not reasonable to pass along the costs of increased product testing and border enforcement responsibilities solely to importers of commodities required and needed by American consumers, especially when the problems leading to the proposed assessment were primarily caused by parties other than domestic importers!

Summarily and admittedly painting a picture with broad strokes, the tainted food products giving rise to legislation such as H.R. 3610 became adulterated at the place of manufacture, not because of any action or inaction taken by the importer or lawful product distributor. While it may be reasonable to hold product manufacturers responsible for ensuring product safety and mandating that manufacturers commit the investment necessary to so protect American consumers from any threats to health or safety, there is no justification to switch this burden onto the backs of small and medium sized importers and global traders.

H.R. 3610 proposes a $50 per line item user fee on all shipments of food products and $1000 per line item on all shipments of drug products. Oftentimes, this exceeds the domestic value of that line item and collectively may easily surpass any revenue hoped to be realized by the importer. Importers into the United States provide American consumers with the benefits of being a participant in the global marketplace. It is not appropriate to tax these traders for the privilege of doing business in their own country. To do so would be to discourage an entire industry; to do so would be to limit domestic supply of critical food and drug products; to do so would be to say to the American consuming marketplace that the only way our government can afford to protect you is to charge you more money for your basic and critical consumer commodities.

It is, respectfully, inappropriate and inaccurate to represent that the only source of funding sufficient to enable the FDA to carry out its mission of ensuring the safety of imported food products is to assess user fees against lawful small and medium sized importers such as those represented by the American Free Trade Association. These traders do not dictate product specifications nor do they contract with overseas suppliers for processing of manufactured product. Third party importers supply branded merchandise to American consumers believing in the reputation and quality control mechanisms instituted by the product manufacturer itself—- the same beliefs held by American consumers, who have come to depend upon AFTA's members' businesses to provide cost effective and alternative sources of these brand name and allegedly reputable foodstuffs.

Food and drug manufacturers and not importers should be held responsible for any funds not legislatively allocated to the FDA to ensure product safety. AFTA's members provide American consumers with food products at competitive prices and at more outlets throughout the country than those products would otherwise be made available. If these importers and distributors are required to add user fees to the costs of entering these products into the country, the United States would certainly have less and more expensive food for its consumers. This cannot be the goal of any legislation intending to make our country's marketplace safer or of any legislation intended to meet the consumers' needs for safe and accessible food products.

SECTION 5: RESTRICTING THE NUMBER OF PORTS FOR FOOD SHIPMENTS

Imported food products serve critical needs of American consumers throughout the country. It is impractical to limit these imports to selective ports in metropolitan areas surrounding existing FDA laboratories that the FDA itself concedes are underutilized and in poor physical condition. Moreover, the increased costs of in land transit from those ports to ultimate customers are costs that are bound to be passed on to consumers.

The myriad and volume of food shipments into the United States demands that importers be provided with more than merely a few ports in which to enter their products. The port congestion and delays that will inevitably occur if over 10 million annual food shipments were entered through only several U.S. ports of entry is too vast to even estimate or reasonably contemplate.

Importantly, there are currently no FDA laboratories at either the northern or southern border crossings. Does this mean that all food shipments will necessarily and only be able to enter on the east or west coasts? The United States has major food distributors and wholesalers located on both the Northern and Southern borders, all of whom could very well be forced to close their doors if required to bear the increased costs of transporting perishable foodstuffs over land from ports hundreds of miles away. The resulting economic catastrophe will be astronomical and will quickly surpass the product safety crisis currently facing our country.

SECTION 805: SAFE AND SECURE FOOD IMPORTATION PROGRAM

AFTA supports any program facilitating the identification of low risk importers. To this end, it is critical that FDA consult closely with industry and trade associations to make sure that the programs instituted are practical and reflect industry realities, bearing in mind the variety of distribution systems supplying the domestic marketplace with safe food products and the need to protect proprietary business information. AFTA looks forward to being a part of this constructive and collaborative effort.

SECTION 8. CIVIL PENALTIES

Intentionally introducing unsafe and adulterated food product into U.S. commerce should be severely punished in any legislative solution intended to ensure entry of only safe foodstuffs into the U.S. Accordingly, AFTA believes that H.R. 3610 must be appropriately amended to so reflect such a knowledge and intent standard, as a predicate to penalties sufficient to immediately close the doors of any small or medium sized innocent importer or manufacturer.

The existing language in H.R. 3610 assesses penalties of up to $1,000,000 against importers and/or manufacturers introducing adulterated food product into interstate commerce. Without a doubt, intentionally introducing adulterated food into interstate commerce must be prohibited and severely punished. However, global market realities include the possibility that certain perishable products may become adulterated without the importer or manufacturer's knowledge during transit; products may contain pesticides or other contaminants not known by the processor or the importer at the time of product purchase. It is imperative that any provision for civil penalties be based on the knowledge of the importer or manufacturer that the product at issue was knowingly adulterated with the intention to cause harm to the health or safety of the American consumer.

As currently drafted, the contemplated civil penalties may be assessed against "any person who introduced into interstate commerce" an adulterated food article. HR. 3610 must clarify who is actually potentially liable for these contemplated civil penalties or the legislation will merely serve as a means for increased litigation. For example, is it possible that a customs broker or freight forwarder could be personally liable for "introducing" adulterated food into interstate commerce about which he or she had no direct knowledge? Does this mean that a third party importer who purchases product from a food wholesaler, which lawfully transacts business perhaps even in a country "certified" as contemplated by this legislation, is nevertheless personally liable if without his knowledge that product enters U.S. commerce with a contaminant or ingredient not known to the importer or identified to the importer at the time of purchase? Without clarification as to financial liability, it is reasonable to assume that no party within the supply or distribution chain will knowingly assume any such risk and distribution of food products within the U.S. marketplace will literally come to a standstill. AFTA does not believe that this is the intent of H.R. 3610 and looks forward to working with the bill's sponsors to clarify this provision.

SECTION 9. CONTINUED OPERATION OF FIELD LABORATORIES

While certainly the FDA should be required to maintain its current laboratory facilities and operations, even with its existing laboratory infrastructure the Agency has not met its burden of ensuring entry of only safe products. Accordingly, while without a doubt the FDA should not be permitted to lessen its current capabilities, Congress should require the Agency to create additional laboratory facilities to expedite sampling and laboratory analysis in order to improve the Agency's capacity to ensure the safety of imported foods and drugs.

SECTION 419. INSPECTION AND OTHER STANDARDS; APPLICABILITY; ENFORCEMENT; CERTIFICATIONS

The Bioterrorism Act of 2002 purported to create a system for foreign food facility registration sufficient to ensure the safety of the domestic food supply. To now require certification of these same foreign food facilities because the existing system did not, in hindsight, provide enough assurances of product safety to the U.S. government will certainly infuriate many U.S. trading partners and put U.S. importers in the unenviable position of having to convince their suppliers once again to comply with yet another new, unique and burdensome U.S. law as a condition of market access.

Moreover, to require certification of foreign food facilities or, in lieu thereof, to require certification of foreign governments, while not requiring the same certification of domestic factories or distributors is to invite unnecessary and undesirable, WTO scrutiny into what may certainly be perceived as a discriminatory and clearly discriminatory trade practice. If Congress and/or the FDA encourages importer verification of supply chain security and product safety, as it should, and works with the industry to develop the appropriate program guidelines and protocols, there is no basis to also require certification of foreign shippers, which, as already stated, will necessarily create havoc for the United States as it seeks to act within the parameters of the global marketplace.

The American Free Trade Association appreciates the need to expeditiously pass Federal legislation or implement similar regulatory initiatives satisfactorily ensuring the safety of imported foods and drugs. AFTA also appreciates, however, the importance of crafting legislation that not only protects consumers' health and safety, but also guarantees consumers' continued access to safe, unadulterated and competitively priced food products.

AFTA looks forward to working with Congress to craft legislation ensuring entry of unadulterated food products into the United States and appreciates the opportunity to submit this testimony to the esteemed subcommittee members.